DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2013

Food and Drug Administration

Justification of Estimates for Appropriations Committees

Message from the FDA Commissioner

I am pleased to present the Administration's FY 2013 budget request for the Food and Drug Administration (FDA).

The FY 2013 budget will allow FDA to sustain its record of accomplishment in an era when FDA mandates and responsibilities continue to grow. Our work during FY 2011 serves as a good example of FDA's strong performance: FDA approved 35 novel medicines, including many groundbreaking therapies that offer important medical advances for patients. Not only are we bringing new drugs to market, we are doing so quickly and efficiently – acting as fast as or faster than other countries – while still maintaining the gold standard for drug safety and effectiveness. Our performance in other program areas is equally strong.

The FY 2013 budget supports core FDA responsibilities and advances the following key priorities:

Safety of Imports from China: During the past decade, the global production of goods that FDA regulates has exploded in volume. In addition to importing more finished products, manufacturers increasingly rely on imported materials and ingredients in their U.S. production facilities. Nowhere is this trend more obvious than in our trade with China. To address these challenges, the budget contains new resources to increase FDA's capacity to detect and address risks in products and ingredients manufactured in China before they result in harm to Americans.

Medical Countermeasures (MCM): In FDA's FY 2012 budget, Congress funded the FDA initiative to develop MCMs to respond to chemical, biological, radiologic and nuclear threats, and to naturally emerging diseases such as pandemic influenza. Additional funding in FY 2013 will allow FDA to support partnerships with industry, academia, and with our government partners designed to shorten MCM development timelines and improve the success rate for MCMs. FDA will also expand technical assistance to developers for the highest priority MCMs.

Life Sciences-Biodefense Laboratory Complex: The FY 2013 budget includes resources to equip state-of-the-art laboratory facilities on FDA's White Oak, Maryland, campus that support essential research to protect patients and consumers. As the General Services Administration completes construction of the lab complex, FDA's FY 2013 budget contains resources to equip the facilities and make the complex operational. These facilities will allow FDA to support more efficient development of new, innovative medical products and to assess product safety and effectiveness.

Food Safety: For FY 2013, FDA is requesting new user fees to implement the landmark Food Safety Modernization Act. With these resources, FDA will advance a prevention-focused food safety system that supports industry efforts to deliver safe food and protect American consumers from harm. The proposed fees will also allow FDA to improve import safety, leverage the valuable work of FDA's state and local food safety partners, and strengthen FDA's ability to identify and assess food safety risks in domestic and imported food.

Prescription Drug, Medical Device, Generic Drug, Biosimilar and Other Fee Programs: For FY 2013, FDA is requesting that Congress reauthorize existing user fee programs for drugs and devices. FDA is also proposing new user fee programs to support generic drug review, biosimilar review and other priorities, such FDA's cosmetic and food contact substance programs.

The resources in this budget will allow FDA to perform its fundamental public health responsibilities in new and more efficient ways. Our budget also supports industry efforts to innovate and bring new products to market that will benefit American patients and consumers and strengthen our economy.

Margaret A. Hamburg

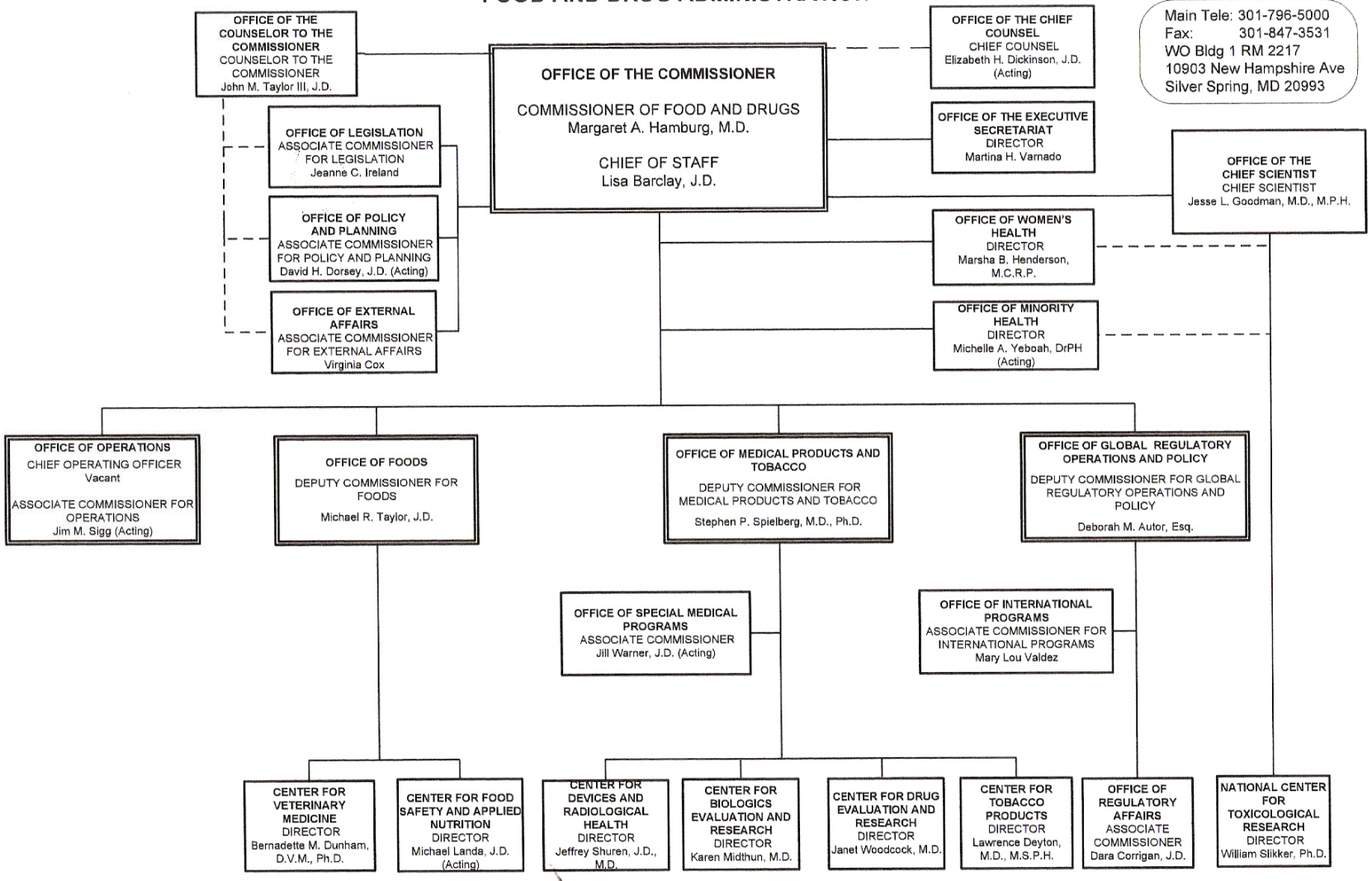
Margaret A. Hamburg, M.D.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

FOOD AND DRUG ADMINISTRATION



Approved by the FDA Reorganization Coordinator and Principal Delegation Control Officer

1/10/12

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

Executive Summary

Statement of FDA Mission

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

FY 2013 Budget Overview

The fiscal year (FY) 2013 President's Budget request for FDA is $4,486,368,000. This amount is the FDA total program level, which includes all budget authority, current law user fees, and new proposed user fees.

The FY 2013 budget requests a total program level increase of $654,164,000 above the amount enacted into law for FY 2012. The FY 2013 total for user fees is $1,969,057,000, which includes $583,367,000 in proposed new user fees. The FY 2013 increase in budget authority is $11,502,000.

The following information summarizes the FDA budgets for fiscal years 2011, 2012 and 2013.

FY 2013 Overview Table Food and Drug Administration (Dollars in Thousands)					
	FY 2011 Enacted [2]	**2011 Actuals[3]**	**2012 Enacted**	**FY 2013 Request**	**+/- FY 2012 Enacted**
Total Program [1]	**$3,690,481**	**$3,339,281**	**$3,832,204**	**$4,486,368**	**$654,164**
User Fees	**$1,233,480**	**$879,434**	**$1,326,395**	**$1,969,057**	**$642,662**
Budget Authority	**$2,457,001**	**$2,459,847**	**$2,505,809**	**$2,517,311**	**$11,502**
FTE	**12,950**	**13,151**	**13,496**	**14,648**	**1,151**

[1] FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, 44 IDDA FTE and the associated funds.

[2] FY 2011 Enacted reflects the -0.2% rescission pursuant to P.L. 112-10.

[3] FY 2011 Actuals include $88,000 in funds from the $2,000,000 Gulf Oil Spill supplemental appropriation.

FDA FY 2013 Budget Request

The initiatives and resources for FY 2013 will allow FDA to achieve fundamental public health priorities in the following areas:

A. Protecting Patients
+$363,669,000 / 593 FTE

This initiative proposes new user fees to support FDA generic drug activities and to improve generic drug review performance. FDA is also proposing new user fees to support the development and review of biosimilar products, which are structurally and therapeutically similar to biological products manufactured by an innovator.

FDA is also proposing to increase its capacity to detect and address the risks of drugs and drug ingredients manufactured in China to assure that they do not result in harm to Americans. Finally, the FDA budget also contains new resources to equip state-of-the-art laboratory facilities on the FDA White Oak, Maryland, campus that will support essential research to protect patients and consumers.

B. Transforming Food Safety
+$253,359,000 / 355 FTE

The Transforming Food Safety Initiative will bolster FDA efforts to build a strong, reliable food safety system to protect American consumers, as envisioned in the landmark FDA Food Safety Modernization Act of 2011 (FSMA). Supported by

food safety investments commenced during FY 2011 and FY 2012, the user fee resources in this FY 2013 initiative will allow FDA to continue to establish a prevention-focused domestic and import food safety system.

FDA is also requesting budget authority to increase its capacity to detect and address the risks of foods and food ingredients manufactured in China and to assure that they do not result in harm to Americans. In this initiative, FDA is also proposing new user fee programs to support the cosmetic and food contact substance programs.

C. Advancing Medical Countermeasures +$3,510,000 / 7 FTE

The FDA Medical Countermeasures Initiative (MCMi) is designed to meet America's national security and public health requirements for MCM readiness. In advance of Congress' FY 2012 appropriation for the MCMi, FDA received an allocation of one-time funding at the close of FY 2010 to immediately commence MCMi activities. With these funds, FDA established a base program at its current operating level of 77 FTE.

The FY 2013 budget will allow FDA to sustain the current level of staffing and activities for the MCMi. With these FY 2013 resources, FDA will support partnerships with industry, academia, and with government partners to shorten MCM development timelines and improve the success rate for MCMs. FDA will also expand technical assistance to developers, focusing on the highest priority MCMs.

D. Data Consolidation and IT Savings - $19,706,000 / - 0 FTE

FDA made significant progress in recent years to consolidate into two modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an FDA computing environment that reduces FDA costs for environment setup and support and provides agility not previously possible. The result has been savings in power consumption and the ability to use FDA equipment and IT support resources more efficiently.

Under this FY 2013 initiative, FDA will realize savings that flow from the consolidation effort. These savings also meet the requirements of Executive Orders 13589 (Promoting Efficient Spending) and 13514 (Federal Leadership in Environmental, Energy, and Economic Performance).

E. FDA Current Law User Fees
+$59,295,000 / +196 FTE

FDA user fee programs support safe and effective review for human and animal drugs, biological products, medical devices and the review of other FDA-regulated products. User fees also allow FDA programs to achieve enhanced premarket review performance. Other FDA user fees support the regulation of tobacco products, the inspection of mammography facilities, the certification of color additives, and the certification of FDA-regulated products exported from the United States. Finally, new user fees enacted by the FDA Food Safety Modernization Act support essential food safety activities. The budget request includes inflationary increases for FDA user fee programs, as authorized by law.

Details of the FDA FY 2013 Initiatives

The FDA Congressional Budget Justification contains business case papers justifying the funding increases described above. Within each business case paper, FDA identifies the need for the FY 2013 funding, the activities that FDA will conduct, and the performance that FDA will achieve.

OVERVIEW OF PERFORMANCE

Background

This Performance Budget details the resources FDA needs and the performance commitments FDA is making to address public health challenges in FY 2013. In an increasingly global economy, and facing revolutionary advances in science and technology, FDA recognizes the need to modernize and transform operations to address the emerging needs of the 21st century. For more than a century, FDA demonstrated a dedication to principles that have made it the world's gold standard for regulating food and medical products. These principles are:

- dedication to assuring the safety of the products that FDA regulates
- dedication to protecting Americans against persistent and emerging public health threats
- commitment to advancing the public health by empowering consumers to make safe and healthy choices about medicine and nutrition
- commitment to accelerating the development and availability of promising new medical therapies and technologies that will extend and improve lives
- commitment to transparency and accountability by sharing information about how we make decisions and how well we are performing our critical mission activities.

The format of this Performance Budget is designed to make it easier to understand FDA programs and performance and to communicate FDA's commitment to achieving improved public health outcomes and performance results at the FDA subprogram level. This format mirrors how FDA will be measuring and reporting on its performance in the future, moving beyond measures of activities and outputs, to focus greater attention on the key program results and public health outcomes valued by the American public. Developing the right measures for each subprogram is an important and challenging endeavor requiring continual improvement over time.

FDA Strategic Priorities

In April 2011, FDA released the final version of a strategic priorities document outlining the goals that will guide the agency and its 12,000 employees through 2015. The document, entitled "Strategic Priorities 2011 – 2015: Responding to the Public Health Challenges of the 21st Century," outlines FDA's strategic intentions and plans for the next five years. The document communicates the Commissioner's key priorities, including cross-cutting strategic priorities, program-specific strategic goals, and long-term objectives. These goals and objectives provide the vehicle for focusing efforts to achieve FDA's public health mission and to fulfill FDA's role in supporting the larger mission and strategic goals of HHS.

The FDA Strategic Plan describes some of the new critical public challenges FDA faces. Science and technology are changing our world in dramatic ways. We are seeing an explosion of knowledge and capabilities emerging from many domains of research and from around the globe. In addition, we live in an increasingly globalized world, which has made ensuring the safety of food, drugs, and devices for the American people a global endeavor that integrates products and people across borders.

FDA will address these challenges and aims to fulfill its mission by embracing innovation and actively pursuing partnerships with federal, state, and local agencies, international authorities, academia, non-government organizations, and the private sector.

The document outlines a path to achieve FDA's vision for the next five years. We envision a transformed and integrated global food safety system, focused on prevention and improved nutrition. We envision patients and families benefiting from decades of investment in medical science and technology. We envision a strong foundation of regulatory science to support FDA efforts to ensure the safety and effectiveness of new medical products throughout their life cycles.

Performance Management Overview

FDA-TRACK is the agency-wide performance management system that FDA launched in April 2010. FDA-TRACK monitors, analyzes and reports monthly performance on all 114 FDA program offices and on eight key cross-cutting initiatives. Each quarter, the FDA-TRACK team uses statistical models to analyze monthly performance data collected from each office and initiative. Face-to-face briefings are then conducted with each program office whereby the responsible office directors present their performance data and results to the FDA executive leadership. These briefings stimulate discussion and facilitate better communication, decision-making, plan of action and ultimately, performance. Briefing summaries and performance results are then posted to the FDA-TRACK website, allowing FDA's stakeholders to monitor progress on more than 600 performance measures and 100 key projects.

FDA-TRACK is also used for the reporting of our most high priority cross-cutting initiatives. Interested parties will be able to see FDA's performance measures and see FDA's progress in critical public health programs such as expediting egg farm inspections and the implementation of our Biosimiliars Program, as well as operational support initiatives such as improving the time to hire new employees and response time to emergency calls into our call center network.

The objectives of FDA-TRACK can be explained through its name:

- **T**ransparency – provides interested parties an unprecedented look into how FDA performs its work.
- **R**esults – highlights performance measures and results with relevance to the agency's public health mission.
- **A**ccountability – requires senior managers to develop, track, and report performance measures that will improve the agency's accountability to the public; holds the program offices accountable for their priorities, plans and results.
- **C**redibility – encourages sharing of information about FDA performance which is essential for the agency's credibility; provides the opportunity to submit suggestions which will be considered as part of the continuous improvement efforts.
- **K**nowledge-sharing – enables the identification of common issues and interdependencies among program offices to improve FDA's operational effectiveness through better collaboration and sharing of ideas.

The performance measures in FDA-TRACK represent the foundational activities and outputs produced by our employees. To better express how these activities and outputs contribute to our overall public health mission, an effort is in place to align each FDA-TRACK measure to one or more of FDA's performance outcome

goals. This alignment will provide even greater opportunities for FDA's leadership to make clear and data-driven decisions based on performance.

In the first year of FDA-TRACK, FDA has seen significant performance improvement in many of our programs, including the elimination of the backlog of generic new animal drug applications and increases in hospital participation in the MedSun Program. From the operational-side, FDA has dramatically improved its advisory committee vacancy rate and progressed to dramatically reduce its Freedom of Information Act (FOIA) backlog. FDA-TRACK has enabled better performance by providing a medium to track progress, monitor results, discuss concerns and communicate achievement.

To date, the FDA-TRACK website has attracted over 400,000 visitors and 14,000 monthly subscribers and was recently awarded the HHS Innovation Award.

FDA Budget by Strategic Goal

The table below shows the alignment of FDA's budget with HHS Strategic Plan goals.

FDA FY 2013 Budget by HHS Strategic Goal

(Dollars in Millions)

HHS Strategic Goals and Objectives	FY 2011	FY 2012	FY 2013
1 Strengthen Health Care	**$1,914**	**$2,010**	**$2,380**
1.A Make coverage more secure for those who have insurance and extend affordable coverage to the uninsured			
1.B Improve health care quality and patient safety	$1,914	$2,010	$2,380
1.C Emphasize primary and preventative care linked with community prevention			
1.D Reduce growth of health care costs while promoting high-value, effective care			
1.E Ensure access to quality, culturally competent care for vulnerable populations			
1.F Promote the adoption and meaningful use of health information technology			
2. Advance Scientific Knowledge and Innovation	**$115**	**$116**	**$126**
2.A Accelerate the process of scientific discovery to improve patient care			
2.B Foster innovation at HHS to create shared solutions			
2.C Invest in the regulatory sciences to improve food & medical product safety	$115	$116	$126
2.D Increase our understanding of what works in public health and human services			
3. Advance the Health, Safety and Well-Being of the American People	**$1,220**	**$1,613**	**$1,879**
3.A Promote the safety, well-being, resilience and healthy development of children and youth			
3.B Promote economic and social well-being for individuals, families and communities			
3.C Improve the accessibility and quality of supportive services for people with disabilities and older adults			

HHS Strategic Goals and Objectives	FY 2011	FY 2012	FY 2013
3.D Promote prevention and wellness	$1,015	$1,396	$1,637
3.E Reduce the occurrence of infectious diseases	$144	$153	$179
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies	$62	$64	$63
4. Increase Efficiency, Transparency and Accountability of HHS Programs	**$19**	**$16**	**$25**
4.A Ensure program integrity and responsible stewardship of resources			
4.B Fight fraud and work to eliminate improper payments			
4.C Use HHS data to improve American health and well-being of the American people			
4.D Improve HHS environmental, energy, and economic performance to promote sustainability	**$19**	**$16**	**$25**
5. Strengthen the Nation's Health and Human Service Infrastructure and Workforce	**$2**	**$3**	**$3**
5.A Invest in HHS workforce to meet America's health and human service needs today and tomorrow			
5. B Ensure that the Nation's healthcare workforce meets increased demands			
5.C Enhance the ability of the public health workforce to improve health at home and abroad			
5.D Strengthen the Nation's human service workforce			
5.E Improve national, State and local surveillance and epidemiology capacity	$2	$3	$3
Total	**$3,271**	**$3,759**	**$4,413**

Note: These resource totals are estimates that account for over 90 percent of FDA's program costs.

FDA FY 2013 Budget
Protecting Patients
Budget Authority: +$25,148,000 / -3FTE
Proposed User Fees: +$338,521,000,000 / 596 FTE

The following table displays the FDA budget for the Protecting Patients initiative in the FY 2013 Congressional budget justification.

Protecting Patients

(Dollars in Millions) [1]

Program	FY 2011 Enacted	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
Budget Authority:				
Human Drugs	**$474.889**	**$473.054**	**$471.309**	**-$1.745**
Center	344.076	343.061	341.977	-1.084
Field Activities	130.813	129.993	129.332	-0.661
Biologics	**$210.593**	**$210.250**	**$209.476**	**-$0.774**
Center	169.735	169.737	169.172	-0.565
Field Activities	40.857	40.513	40.303	-0.210
Animal Drugs and Feeds	**$28.738**	**$28.923**	**$28.796**	**-$0.127**
Center	25.917	26.257	26.142	-0.114
Field Activities	2.821	2.666	2.653	-0.013
Devices and Radiological Health	**$318.369**	**$319.675**	**$318.258**	**-$1.417**
Center	236.761	238.478	237.485	-0.993
Field Activities	81.609	81.197	80.773	-0.424
National Center for Toxicological Research	**$48.077**	**$49.832**	**49.602**	**-$0.230**
FDA Headquarters	**$93.564**	**$89.358**	**$94.59**	**$5.231**
White Oak Consolidation	**$38.459**	**$40.386**	**$58.044**	**$17.658**
Other Rent and Rent Related	**$29.161**	**$34.951**	**$36.851**	**$1.900**
GSA Rental Payments	**$80.366**	**$85.847**	**$90.500**	**$4.653**
Total, Budget Authority, Salaries and Expenses	**$1,283.757**	**$1,332.276**	**$1,357.424**	**$25.148**
Biosimilars User Fee [2]	**$0.000**	**$0.000**	**$20.242**	**$20.242**
Generic Drug User Fee [2]	**$0.000**	**$0.000**	**$299.000**	**$299.000**
Medical Products Reinspection Fee [2]	**$0.000**	**$0.000**	**$14.746**	**$14.746**
International Courier User Fee [2]	**$0.000**	**$0.000**	**$4.533**	**$4.533**
Total, Program Level	**$1,283.757**	**$1,332.276**	**$1,695.945**	**$363.669**

[1] The FY 2013 request displayed in this table reflects increases for commissioned corps pay and increases and absorptions for FY 2013 rent activities. In addition to the amounts displayed in this table, the amounts shown in other FDA FY 2013 business case papers also contribute to the total resources available to FDA programs. The FY 2013 column does not include the Administrative savings proposed in the FY 2013 Budget.

[2] FDA proposes these user fees in the FY 2013 President's Budget. The amounts in this table include program support and associated rent activities.

1. Initiative Summary

In this initiative, FDA proposes new user fees to support:

- the activities of the Generic Drug Program
- the development and review of biosimilar products[1]
- surveillance of FDA-regulated commodities at express courier hubs
- expansion of the current Reinspection Fee authority for food and feed establishments
- reinspections of medical product establishments.

In this initiative, FDA also requests new budget authority to increase its capacity to detect and address the risks of products and ingredients manufactured in China and to assure that these produces do not result in harm to Americans.

This initiative also contains new budget authority to equip state-of-the-art laboratory facilities on FDA's White Oak, Maryland, campus that will support essential research to protect patients and consumers.

Finally, this initiative also provides new budget authority to support the pay increase for Commissioned Corps personnel that serve at FDA.

2. Why is this funding necessary?

A. Generic Drug User Fee: The growth in generic drug applications has outpaced FDA resources, resulting in an application backlog and an increase in time to approval. Generic drugs are now increasingly complex, and product testing and manufacturing often occurs in overseas facilities.

To keep pace with the increase in applications and to respond to changes in the industry, FDA is proposing increased resources in the form of user fees. These fees will:

- strengthen the FDA generic drugs program
- enhance the application review process
- allow FDA to increase post-market safety and overseas inspection activities.

[1] Biosimilar products are structurally and therapeutically similar to biological products manufactured by an innovator company.

Without these fee resources, FDA cannot respond to the growing demand from patients, payers, and the generic drug industry. The generic industry supports this user fee proposal.

Generic drugs are widely known to provide cost-effective treatment. According to industry estimates, generic drugs saved consumers approximately $931 billion between 2001 and 2010. In 2010, generic drugs generated savings of $158 billion, or an average of $3 billion per week.

With each new generic version of a brand-name drug that FDA approves, consumers have an additional option to save money on their prescription needs. The proposed user fee investments in FDA's generic drug program will generate additional savings by bringing more generics to market sooner, which will benefit more American patients.

Health care payers and plans, including Medicare, Medicaid, the Department of Veterans Affairs and the Department of Defense, as well as private health care plans will experience savings from greater availability of generic drugs. A greater availability of generic drugs will also mitigate some risks associated with drug shortages, thereby ensuring that patients have access to the drugs they need.

B. Biosimilars User Fee: Biosimilars offer the potential to reduce the costs of and promote greater patient access to biological products. With this proposed user fee, FDA will establish efficient pathways for approving biosimilars, which will encourage development of important therapies that will benefit patients and allow industry sponsors to bring new products to market more quickly and efficiently.

Savings will also accrue to Federal health programs such as Health care payers and plans, including Medicare, Medicaid, the Department of Veterans Affairs and the Department of Defense. Private sector health plans, upon which millions of Americans depend, will also experience savings from the availability of biosimilars, while providing important patient access to a wider range of therapeutic alternatives.

Biological products cost $15,000 to $150,000 or more per patient per year. These high costs represent a disproportionately large share of Federal government and private sector pharmaceutical costs. In light of these high costs, the Congressional Budget Office (CBO) has estimated that federal savings associated with biosimilars could equal $7 billion during the next decade. However, these savings will only materialize if FDA has the resources to conduct a biosimilar and interchangeable biological product review program and the resources to support the innovation required to spur biosimilar development.

C. Drug Manufacturing Inspections in China: Global production of goods that FDA regulates has increased dramatically during the past decade. In addition to

importing more finished products, manufacturers increasingly use imported materials and ingredients in their U.S. production facilities. This trend makes the distinction between domestic and imported products obsolete.

This trend is increasingly evident in trade between the U.S. and China. China is the source of a large and growing volume of imported drugs and drug ingredients.

This FDA initiative supports a prevention-focused import safety program in China. With this FY 2013 initiative, FDA will increase its capacity to detect and address risks of drugs and drug ingredients manufactured in China and to assure that these products do not result in harm to Americans. The initiative will place greater responsibility on Chinese manufacturers to institute measures to assure that drugs and drug ingredients imported to the United States are safe and meet FDA standards. There is a parallel component to this initiative related to foods in the FDA Transforming Food Safety business case paper.

D. Life Sciences – Biodefense Laboratory Complex: During the past two decades, an unprecedented level of investment has led to revolutionary advances in the biomedical sciences. To fulfill its mission to protect patients and consumers, FDA's scientific infrastructure must keep pace with these advances.

The 2007 report on *FDA Science and Mission at Risk* concluded that FDA is unable fulfill its mission, in part because it lacks modern science facilities. Funding the CBER-CDER Life Sciences-Biodefense Laboratory will provide safe, certified laboratory capacity for FDA to perform its medical product safety and review responsibilities.

On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction is underway. With the resources requested in this initiative, FDA will outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex. FDA must make this investment now to ensure that the laboratory is operational and ready for occupancy in FY 2014.

E. International Courier User Fee: For FY 2013, FDA is proposing a new International Courier User Fee. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities, predominantly medical products, at express courier hubs.

Current FDA staffing does not match the current workload and expected growth in import volume arriving through international express courier facilities. Express couriers and other couriers have indicated that they expect dramatic growth in shipments, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of its international courier activities through user fees.

F. Reinspection User Fee: The FDA Food Safety Modernization Act, which Congress enacted in December 2010, authorized Reinspection Fees for reinspections of food and feed establishments. FDA is proposing to expand this authority to medical product establishments. With this change, medical product establishments will pay the full cost of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements.

G. Pay Costs (Commissioned Corps): FDA can only fulfill its public health responsibilities if it has sufficient resources to pay the workforce that conducts FDA medical product safety programs. To maintain its Commissioned Corps workforce, who provide scientific, professional, and technical expertise to all programs, FDA must continue to meet the full cost of the workforce payroll, including the proposed pay increase.

3. What activities will the funds support?

The following information displays estimates for the activities funded with the FY 2013 increases for Protecting Patients. In the case of the new user fee programs to support generic drug and biosimilar review, as FDA continues to plan for and implement these programs and as the fee programs mature, FDA will adjust the allocation of funds to support generic drug and biosimilar program activities based on the anticipated workload and the fee revenue that FDA receives.

A. Generic Drug User Fee (+ $268,218,000 / 410 FTE)[2] (All UF)

With the proposed user fee resources, FDA will enhance the generic drug review process and increase FDA's capacity to conduct reviews of Abbreviated New Drug Applications (ANDA) with greater efficiency and transparency. FDA will conduct additional pre-approval and bioequivalence inspections to verify manufacturing compliance with Current Good Manufacturing Practices (CGMP) for generic drug products.

CDER: $166,938,000 / 200 FTE
ORA: $ 16,311,000 / 46 FTE
FDA HQ: $ 13,676,000 / 10 FTE

FDA will increase inspections of foreign facilities involved in manufacturing generic drug products.

CDER $13,757,000 / 19 FTE
ORA: $35,500,000 / 104 FTE

[2] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities section of this document.

FDA will also increase post-market safety and surveillance activities related to generic drug products.

CDER: $22,036,000 / 31 FTE

B. Biosimilars User Fee (+$17,626,000 / 68 FTE)[3] (All UF)

In FY 2011, FDA's Center for Drug Evaluation and Research (CDER) received an appropriation of $1,852,000 from Congress to begin to develop and implement its biosimilars program. With these funds, FDA purchased equipment to support biosimilar characterization and funded contracts to support biosimilars program activities.

With the proposed user fee resources in FY 2013, FDA will review biosimilar biological product applications, supplements, and other submissions related to biosimilar products. This work will include biosimilar product development meetings and activities related to investigational new drug applications (INDs). FDA will issue action letters that communicate decisions on biosimilar product applications and hire investigators to conduct 30 domestic biosimilars pre-approval inspections in FY 2015 and 12 foreign biosimilars pre-approval inspections in FY 2016. Full performance will not be reached until the out-years, since investigators need intensive training before conducting inspections.

CDER: $9,886,000 / 38 FTE
CBER: $ 516,000 / 2 FTE
ORA: $1,290,000 / 5 FTE
FDA HQ: $ 129,000 / 0.5 FTE

FDA will also develop regulations and guidance documents to foster the development of biosimilars.

CDER: $5,418,000 / 21 FTE
CBER: $ 258,000 / 1 FTE
FDA HQ: $ 129,000 / 0.5 FTE

C. Drug Manufacturing Inspections in China (+$5,287,500 / 11 FTE)[4] (All BA)

With the resources requested in this initiative, FDA will perform additional foreign inspections in China, focusing on facilities that produce drugs and drug ingredients that potentially pose the greatest risks to patients in the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA manufacturing quality and good manufacturing practices.

FDA HQ: $4,725,000 / 9 FTE

[3] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities section of this document.
[4] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support section of this document.

FDA will expand risk modeling and risk analysis to improve FDA's ability to better target inspection resources to high-risk drugs and drug ingredients manufactured in China.

FDA HQ: $562,500 / 2 FTE

D. Life Sciences-Biodefense Laboratory Complex (+$17,658,000 / 0 FTE) (All BA)

As the General Services Administration completes construction of the Life Sciences-Biodefense Laboratory complex, FDA's FY 2013 budget request contains resources to make the facilities operational and to properly certify the new laboratory. The new laboratory will allow FDA to support more efficient development of new and innovative medical products and to better assess product safety and effectiveness. With these resources, FDA can operate in modern laboratory facilities that are essential to protect patients and consumers and to accomplishing FDA's public health mission.

E. International Courier User Fee: +$4,087,000 / 17 FTE[5,6] (All UF)

The user fee will address the growing volume of imports that enter the United States through international couriers. The fee revenue will support the cost of FDA import operations to conduct FDA work at international courier facilities. Funding generated from this user fee program will allow FDA to:

- conduct import entry reviews
- collect samples and conduct physical exams to determine whether a product can be admitted into the United States
- initiate compliance actions to prevent the release of unsafe products
- establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

F. Reinspection User Fee: +$12,277,000 / 53 FTE[7] (All UF)

When FDA identifies violations during an inspection or issues a warning letter following an inspection, FDA conducts follow-up inspections to verify that the problem was corrected. FDA procedures usually require that FDA conduct a follow-up inspection of the firm within six months of issuing a warning letter.

[5] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

[6] The food safety portion of this user fee, totaling $1,047,000, is found in the Transforming Food Safety business case paper.

[7] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

Of the total FTE increase for this activity, FDA will hire 21 new investigators. When the new investigators are fully trained, FDA will have the capacity to conduct an estimated 329 domestic medical product reinspections.

G. Pay Costs (Commissioned Corps): (+$799,000) (All BA)

For medical product safety programs, the FY 2013 budget authority amount for higher Commissioned Corps pay costs is $799,000. For all FDA programs, pay cost will increase by $1,502,000.

H. Program Support for the FY 2013 Protecting Patients Initiative
+12,995,500 / 55 FTE ($337,500 / 0 FTE BA; $12,658,000 / 48 FTE UF)

The FY 2013 Protecting Patients Initiative includes resources to ensure that FDA medical product programs that participate in this initiative receive the support necessary to achieve their public health outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communication, ethics, headquarters coordination and related support functions.

Biosimilars User Fee:	*+$ 1,032,000 / 4 FTE*
Generic Drug User Fee:	*+$10,520,000 / 40 FTE*
Drug Manufacturing Inspections—China: (BA):	*+$ 337,500 / 0 FTE*
International Courier User Fee (Medical Products):	*+$ 185,000 / 1 FTE*
Reinspection User Fee	*+$ 921,000 / 3 FTE*

I. Rent Activities for FDA Medical Product Programs
(+24,722,000 / -14 FTE) ($1,067,000 BA; $23,655,000 UF)

The FY 2013 Protecting Patients Initiative includes resources to pay the GSA Rent and the Other Rent and Rent-Related costs for the new employees hired under the FY 2013 Protecting Patients Initiative.

These funds will also allow FDA to pay a portion of the increased cost of GSA Rent and Other Rent and Rent-Related activities for the facilities that support FDA's base program. To fully meet its rent obligations, FDA must also redirect program resources to cover its rent costs.

The GSA Rent account includes funds for FDA payments to GSA for FDA's office and laboratory facilities. GSA rent also includes funds for payments to the Department of Homeland Security for guard services and the operation of security systems at FDA facilities. The Other Rent and Rent-Related account includes funds for commercial rent and other payments related to leased facilities that are not part of the GSA building inventory.

Inflationary Rent (BA):	*+$ 1,067,000 / 0 FTE*
Biosimilars User Fee Initiative Rent:	*+$ 1,584,000 / 0 FTE*
Generic Drugs User Fee Initiative Rent:	*+$20,262,000 / 0 FTE*
International Courier User Fee (Medical Products) Initiative Rent:	*+$ 261,000 / 0 FTE*
Reinspection User Fee Initiative Rent:	*+$ 1,548,000 / 0 FTE*

In addition to the amounts displayed above, FDA will also redirect the following amount from medical product programs to pay the remaining FY 2013 costs for rent activities.

Inflationary Rent Absorption (BA): *-$5,486,000 (non-add) / -14 FTE*

4. How does this initiative support important public health priorities?

The Generic Drug and Biosimilar User Fees support the FDA mission of promoting and protecting the public health by supporting the review of product applications for safety and efficacy, and by making affordable treatments available to patients. The generic drug user fee and the biosimilars user fee will also foster innovation and improve health care quality.

Funding for drug manufacturing inspections in China will enable FDA to strengthen the supply chain for drugs and drug ingredients manufactured in China. This initiative has the potential to reduce import safety emergencies, reduce the number of adverse events and allow FDA to identify safety problems associated with drugs and ingredients manufactured in China earlier in the supply chain.

The funding request for the Life Sciences-Biodefense Laboratory Complex will allow FDA to harness the power of science to improve the health of Americans. The new laboratory complex will also have an essential role in fulfilling FDA responsibilities for drug and biologic safety. The Life Sciences-Biodefense Laboratory Complex supports important priorities such as:

- protecting American's health and safety during public health emergencies
- transforming health care
- implementing personalized medicine
- using scientific discovery to improve patient care.

The International Courier and the Reinspection user fee programs proposed in this initiative support the core public health priority of improving health care quality and patient safety.

The increases for Commissioned Corps pay costs, Program Support and Rent Activities proposed in this initiative support FDA mission critical activities within FDA medical product programs.

5. What are the risks of not proceeding with this initiative?

A. Generic Drug User Fee: Without additional resources from the proposed Generic Drug User Fee, FDA will not be able to address the growing number of pending generic drug applications and ensure more timely availability of generic drugs. Without these improvements, patients may continue to struggle to afford medical treatments that they need and health care payers will face increased drug costs.

Delays in the availability of less-expensive generic drugs will result in higher costs for patients – some of whom may forego critical medicines if their drugs are unaffordable – leading to poorer health outcomes. Without the user fees, FDA will not be able to respond to important changes in generic manufacturing, including the increasing complexity of some products and the shift to overseas manufacturing.

B. Biosimilars User Fee: Failure to establish a user fee program for biosimilar biological products will significantly delay patient access to new, affordable medical products. Failure to establish this new fee program will limit the opportunities for an important new industry and limit the availability of the products that provide affordable alternatives for patients. This will adversely affect health care and limit opportunities for new, high-quality U.S. jobs associated with this new biotechnology industry. Finally, the Federal government will miss the opportunity to generate significant savings, estimated by CBO at $7 billion by the end of the decade.

C. Drug Manufacturing Inspections in China: Without this initiative, FDA will not have the resources to adequately identify and address risks associated with drugs and drug ingredients imported from China. Not funding the initiative could result in preventable harm to patients in America.

D. Life Sciences-Biodefense Laboratory Complex: Without this investment, FDA pay double rent for the new lab it cannot occupy and for the old lab it cannot vacate. FDA also will not have the needed infrastructure to enable sound, science-based regulatory decisions that support new markets for new medical products and that protect the health of patients.

E. International Courier User Fee: Without the resources for the proposed International Courier User Fee, FDA cannot adequately protect the health of Americans. Without this user fee, FDA cannot:

- reduce the risk of unsafe or contaminated imports from reaching U.S. consumers
- prevent harm from counterfeit and unsafe products
- reduce the time between detection and appropriate risk management response.

F. Reinspection User Fee: The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of the reinspection. If facilities that fail to comply with FDA regulations do not pay for reinspections, FDA must shift resources from priority public health activities to conduct facility reinspections. The proposed Reinspection User Fee will also make this activity consistent with the Reinspection User Fee for food and feed.

G. Pay Increase (Commissioned Corps), Rent Activities and Program Support for Medical Product Programs: Pay, rent, utilities and other costs to support the FDA workforce are fixed costs that FDA does not control. If FDA does not receive the increases for Commissioned Corps pay and for rent costs, FDA will fail to maintain its staff of investigators, epidemiologists, safety experts and other professionals that are the backbone of FDA's medical product safety workforce. The FY 2013 Protecting Patients Initiative includes resources for Program Support to ensure that FDA medical product initiatives for FY 2013 receive the support necessary to achieve their public health outcomes.

6. What will FDA accomplish with the initiative?

A. Generic Drug User Fee: This initiative will enable FDA to address the increased number of generic drug applications, as well as the increasing complexity of generic drug products. Moreover, FDA will have limited ability to respond to changes in the generic drug industry, particularly the dramatic growth of foreign manufacturing.

The proposed fee resources will result in more timely availability of generic drugs. The user fee program will supplement the existing generic drug program and will result in measurable improvements in FDA performance. The user fee agreement includes several performance targets that FDA expects to achieve by the end of FY 2017:

- Review and act on 90 percent of all ANDAs, ANDA amendments, and ANDA prior approval supplements regardless of current review status, pending on October 1, 2012
- Review and act on 90 percent of complete electronic ANDAs within 10 months after the date of submission
- Conduct inspections of foreign facilities on a risk-adjusted biennial basis, on parity with inspections at domestic facilities.

B. Biosimilars User Fee: This initiative will enable FDA to continue to reduce the scientific, legal and regulatory uncertainty surrounding the development of biosimilars. Reducing this uncertainty will increase investments in this promising area and lead to quicker development and launch of biosimilars, resulting in lower costs for life-saving treatments for many Americans.

The biosimilars user fee will supplement base spending from appropriations and enable FDA's biosimilar program to support this emerging industry. FDA will use these resources to continue to identify scientific, regulatory, and policy issues surrounding biosimilar biological product development.

The user fee agreement with industry included the following performance targets for FY 2013:

- Review and act on 70 percent of original biosimilar biological product application submissions within 10 months of receipt
- Review and act on 70 percent of resubmitted original biosimilar biological product application submissions within 6 months of receipt.

By September 30, 2013, FDA's Office of Regulatory Affairs will complete the hiring of five additional employees and will begin to train these employees. By September 30, 2015, once the new employees are fully trained, ORA will conduct an additional 30 domestic biosimilars pre-approval inspections, and by September 30, 2016, ORA will conduct 12 additional foreign biosimilars pre-approval inspections.

C. Drug Manufacturing Inspections in China: The investment will allow FDA to hire the staff needed to support additional foreign inspections in China.

D. Life Sciences-Biodefense Laboratory Complex: This investment is critical for FDA to be an active participant in 21st century medical product development and to fulfill its mission to patients and consumers. The investment supports FDA efforts to develop and maintain a world-class science workforce and brings much needed core scientific capacities to FDA.

This initiative will benefit every American by increasing access to new medical technologies that treat serious illnesses and improve quality of life. It will increase the accuracy and efficiency of FDA review, thereby reducing adverse health events, regulatory costs, and the time-to-market for new medical technologies.

E. International Courier User Fee: Express couriers have indicated that they expect significant growth in shipments during the next year, further taxing FDA resources. These fees will help FDA increase staffing levels to

protect public health and meet the expected increase. This increase will support import controls to prevent unsafe products from entering the United States.

F. Reinspection User Fee: The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of the reinspection.

FY 2013 Protecting Patients Performance Tables:

FDA is using FDA-TRACK, our agency-wide performance management system, to track, analyze, and report monthly and quarterly performance measures, progress and accomplishments for FDA's most important initiatives. These initiatives include ongoing efforts as well as new efforts as showcased in the following FY 2013 performance tables. Upon finalization and receipt of the FY 2013 request, FDA will be developing performance measures and/or key project milestones for the funded initiatives. You will find these measures, milestones, and progress on the FDA-TRACK website - www.fda.gov/fdatrack.

The following tables contain performance items associated with this initiative.

Performance Measures	FY 2012 Enacted Performance Level	FY 2013 Performance Level +/- FY 2011 Enacted	Most Recent Actual
Begin to establish an abbreviated regulatory review pathway for biosimilar and interchangeable biological products.	Identify scientific, legal, and policy issues related to biosimilar and interchangeable biological products, and establish the regulatory review pathway for biosimilar and interchangeable biological products.	+2 guidance documents	N/A
Percentage of original biosimilar biological product application submissions reviewed and acted on within 10 months	N/A	70 percent	N/A
Percentage of resubmitted original biosimilar biological product applications reviewed and acted on within 6 months	N/A	70 percent	N/A

Performance Measures	FY 2012 Enacted Performance Level	FY 2013 Performance Level +/- FY 2011 Enacted	Most Recent Actual
Domestic and Foreign Biosimilar Inspections	0	Hire and train 5 FTE in 2013. (+30 domestic inspections in FY 2015; +12 foreign inspections in FY 2016)	N/A
Foreign In-Country Human Drug Inspections	0	Hire and train 9 FTE in 2013. (+120 in-country inspections in FY 2015)	N/A
Enhance the safety or efficacy of drugs and biologics by conducting state-of-art laboratory tests	N/A	When fully constructed and operational, the CDER/CBER Life Science Lab will allow FDA to: • Develop improved assays, standards and tests for medical products • Use state-of-the-art technologies to aid in medical product evaluation.	N/A

FDA FY 2013 Budget
Transforming Food Safety
Budget Authority + $6,018,000 / 8 FTE
User Fees + $247,341,000 / 347 FTE

The following table displays the budget authority and user fees for the Transforming Food Safety Initiative in the FY 2013 Congressional Budget Justification.

Transforming Food Safety and Nutrition

(Dollars in Millions) [1]

Program[2]	FY 2011 Enacted	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
Budget Authority:				
Foods	**$835.682**	**$866.061**	**$862.890**	**-$3.171**
Center	252.322	264.296	263.524	-0.772
Field Activities	583.360	601.765	599.366	-2.399
Animal Drugs and Feeds	**$125.495**	**$109.098**	**$108.599**	**-$0.500**
Center	73.998	58.442	58.188	-0.254
Field Activities	51.497	50.656	50.411	-0.245
National Center for Toxicological Research	**$10.292**	**$10.207**	**$10.159**	**-0.047**
FDA Headquarters	**$76.529**	**$55.333**	**$59.487**	**4.154**
Other Rent and Rent Related	**$43.316**	**$30.175**	**$31.79**	**1.619**
GSA Rental Payments	**$84.063**	**$73.833**	**$77.80**	**3.963**
Total, Budget Authority, Salaries and Expenses	**$1,175.377**	**$1,144.707**	**$1,150.725**	**$6.018**
Food Export Certification User Fee	**$0.000**	**$0.000**	**$1.267**	**$1.267**
Food Reinspection User Fee	**$0.000**	**$14.700**	**$15.367**	**$0.667**
Food Recall User Fee	**$0.000**	**$12.364**	**$12.925**	**$0.561**
International Courier User Fee[3]	**$0.000**	**$0.000**	**$1.047**	**$1.047**
Food Establishment Registration Fee[3]	**$0.000**	**$0.000**	**$220.200**	**$220.200**
Cosmetics User Fee[3]	**$0.000**	**$0.000**	**$18.698**	**$18.698**
Food Contact Notification User Fee[3]	**$0.000**	**$0.000**	**$4.901**	**$4.901**
Total, Program Level	**$1,175.377**	**$1,171.771**	**$1,425.130**	**$253.359**

[1] The FY 2013 request displayed in this table reflects increases for commissioned corps pay and increases and absorptions for FY 2013 rent activities. In addition to the amounts displayed in this table, the amounts shown in other FDA FY 2013 business case papers also contribute to the total resources available to FDA programs. The FY 2013 column does not include the Administrative savings proposed in the FY 2013 Budget.

[2] Includes funds for Cosmetics, Dietary Supplements and Nutrition/Food Labeling activities.

[3] FDA proposes these user fees in the FY 2013 President's Budget. The amounts also include associated rent activity.

1. Initiative Summary

The Transforming Food Safety Initiative reflects the vision of a strong, reliable food safety system for American consumers, as established by the landmark

FDA Food Safety Modernization Act of 2011 (FSMA). Supported by food safety investments during FY 2011 and FY 2012, the user fee resources in this FY 2013 initiative will allow FDA to continue to establish a prevention-focused domestic and import food safety system. Under this initiative, FDA will leverage the valuable food safety work of state, local, tribal, and territorial food safety partners. FDA also proposes user fees to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs.

FDA is requesting budget authority to increase its capacity to detect and address the risks of products and ingredients manufactured in China and to assure that they do not result in harm to Americans. In this initiative, FDA is also proposing new user fee programs to support the cosmetic and food contact substance programs.

Finally, this initiative also contains the resources to support the pay increase for Commissioned Corps personnel that serve at FDA and the inflationary rent costs for FDA food safety and nutrition programs. Funding this pay increase and rent cost will help ensure that FDA retains the professional staff that performs essential food safety and nutrition functions to protect American consumers and improve public health.

2. Why is this funding necessary?

A. Transforming Food Safety

The Economic and Public Health Cost of Foodborne Illness: The Centers for Disease Control and Prevention (CDC) estimates that each year nearly 48 million Americans (1 in 6) become sick, 128,000 are hospitalized, and 3,000 die due to foodborne diseases.[1] Reducing foodborne illness by just 10 percent would keep 5 million Americans from getting sick each year. Preventing a single fatal case of *E. coli* O157 infection would save an estimated $7 million.[2]

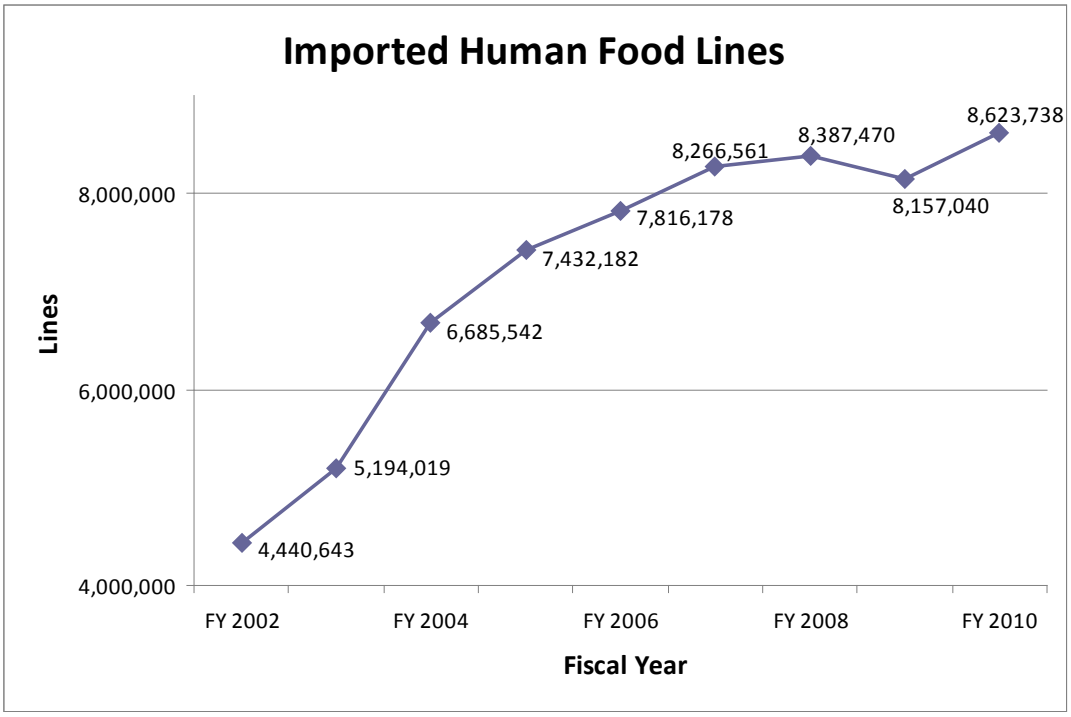
The passage of the Food Safety Modernization Act of 2011 provided FDA with the authority to address significant and longstanding gaps that have hindered FDA's ability to protect the U.S. food and feed supplies. FSMA allows FDA to ensure that industry achieves high rates of compliance with prevention-oriented food and feed safety standards, to better respond to and contain problems when they occur, and to meet the food safety challenges of the rapidly globalizing food supply.

[1] http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.
[2] http://www.cdc.gov/foodsafety/cdc-and-food-safety.html . Based on Frenzen, et al., Journal of Food Protection, Vol. 68, No. 12, 2005, Pages 2623 – 30, the cost (measured by medical costs, lost work and other factors) associated with the death of a patient due to *E. coli* O157 infection is $7 million. CDC updated the Frenzen estimate using the Consumer Price Index.

FDA must implement a sustainable, multi-year, multi-pronged approach to fulfill the requirements of FSMA. FDA is organizing its FY 2013 budget request to support and expand the activities that FDA began in FY 2011 and continued during FY 2012 to implement and enforce FSMA. These investments are modest compared to the economic value of the nation's food and feed supplies and the costs that industry, government, and the health care system experience during an outbreak.

The complexity and diversity of the American food supply has grown dramatically during the past generation. As FSMA recognizes, the food safety issues that the nation faces are complex and diverse.

The Rising Volume of Food Imports: FDA regulates more than $450 billion of domestic and imported foods. An estimated 15 percent of the U.S. food supply is imported, including 50 percent of fresh fruits, 20 percent of fresh vegetables, and 80 percent of seafood.[3] These imports originate from more than 250,000 foreign establishments in 200 countries each year. The graph below illustrates the dramatic growth in food imports since FY 2002.



The Cost of Foodborne Illness: Outbreaks caused by contamination in the food and feed supply are costly to all – to consumers, to the food and feed industries, and to the health care industry. A 2007 study estimated the average hospital stay at 5.8 days for each case of foodborne illness requiring

[3] http://www.foodsafety.gov/news/fsma.html

hospitalization. The same study estimated the average cost per case of foodborne illness at between $16,100 (for an adult) and $26,700 (for a child).[4] In the aggregate, the costs of foodborne illnesses and outbreaks are in the billions of dollars. A 2012 study using an enhanced cost-of-illness model estimated that the aggregated cost of foodborne illness is $77.7 billion per year.[5] In June 2011, the U.S. Department of Agriculture (USDA) Economic Research Service (ERS) estimated that the annual economic cost of foodborne illness and premature death caused by *Salmonella* is $2.7 billion. The annual estimated cost of illness caused by *E. coli* O157 is $489 million. These estimates include medical costs due to illness, the cost (value) of time lost from work due to nonfatal illness, and the cost (value) of premature death.[6]

Major Pathogens Responsible for Foodborne Illness: The exhibit below identifies the annual number of foodborne illnesses caused by major pathogens that FDA is addressing with the resources in the Transforming Food Safety Initiative. The exhibit also lists several foods commonly responsible for most foodborne illnesses, by pathogen type.

Annual Cases of Domestically Acquired Foodborne Illness per Pathogen[7]

Pathogen	CDC Estimate of Annual Cases
Norovirus	5,461,731
Salmonella (nontyphoidal)	1,027,561
Campylobacter spp.	845,024
E. coli (STEC) O157 and non-O157	175,905
Vibrio spp., other	17,564
Listeria *monocytogenes*	1,591
Hepatitis A virus	1,566
TOTAL	**2,067,645**

[4] Roberts, American Journal of Agricultural Economics
[5] Economic Burden from Health Losses Due to Foodborne Illness in the United States, Journal of Food Protection, January 2012.
[6] http://www.ers.usda.gov/data/foodborneillness
[7] http://www.cdc.gov/foodborneburden/PDFs/11_228412_Pitts_factsheet_tables_remediated.pdf

Foods Commonly Responsible for Most Foodborne Illness per Pathogen[2]:

- Norovirus: produce, oysters and other shellfish
- *Salmonella*: eggs, poultry, meat, produce
- *Campylobacter*: poultry, raw milk
- *E. coli* O157: ground beef, leafy greens, raw milk
- *Vibrio*: raw oysters
- *Listeria*: deli meats, unpasteurized soft cheeses, produce
- Hepatitis A virus: produce, shellfish.

FDA Food Safety Strategy: FDA is organizing its FY 2013 budget request to support and expand on the activities that FDA commenced in FY 2011 and FY 2012 to implement FSMA. These strategies are also consistent with FDA's longstanding goal of reducing foodborne illness.

In enacting FSMA, Congress envisioned that FDA would implement a broad preventive controls framework for domestic and imported food and feed across the food distribution chain. Implementing FDA's new FSMA authorities is fully consistent with FDA efforts to strengthen preventive controls for food safety and to enhance FDA capacity to conduct data-driven risk-based priority setting to achieve FDA food safety responsibilities.

Strategic Plan for Food Safety: In September 2011, FDA released the *Food and Veterinary Medicine Strategic Plan.* This plan contains FDA's strategy for food safety and preventing foodborne illness of unknown origins and illness that can be specifically attributed to known sources.[8]. The FDA strategic plan includes the following goals:

- Improve effectiveness and efficiency across all levels of the program. This goal includes establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and building a model for evidence-based resource planning.

- Establish science-based preventive control standards across the farm-to-table continuum. This goal includes adopting science-based regulations that protect the food and feed supply from contamination, including the identifying the most significant foodborne contaminants and evaluating the effectiveness of our controls for those contaminants.

- Achieve high rates of compliance with preventive controls standards domestically and internationally. This goal includes conducting domestic and foreign inspections, implementing new enforcement tools, and

[8] The strategic plan can be found on the FDA web site at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

improving mechanisms for assuring that imported foods and feeds meet preventive controls standards.

- Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making. This goal includes maintaining and strengthening mission-critical science capabilities, improving centralized food safety planning and performance measurement, and improving information sharing internally and externally, including effective communication of research plans and knowledge gaps.

Food Establishment Registration Fee

To meet the goals of the *Food and Veterinary Medicine Strategic Plan* and to implement FSMA, FDA is proposing $220,200,000 in a new food facility registration user fee. The fee will support the following food safety activities:

- establishing new, effective, and comprehensive food safety standards
- establishing a new program for import safety
- increasing the number and efficiency of inspections
- launching an integrated national food safety system with states and localities
- expanding research activities, which will include improved data collection and risk analysis
- maintaining a current facilities registration database and supporting other information technologies to improve FDA's risk-based decision capabilities.

These improvements are designed to:

- reduce the risk of illness associated with food and feed
- decrease the frequency and severity of food- and feed-borne illness outbreaks
- reduce instances of contamination
- greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events.

B. Food Manufacturing Inspections in China

Global production of goods that FDA regulates increased dramatically during the past decade. In addition to importing more finished products, manufacturers increasingly use imported materials and ingredients in their U.S. production facilities. This trend makes the distinction between domestic and imported products obsolete.

This trend is increasingly evident in trade with China. China is the source of a large and growing volume of imported food and food ingredients.

This FDA initiative supports a prevention-focused import safety program in China. With this FY 2013 initiative, FDA will increase its capacity to detect and address risks of foods and food ingredients manufactured in China and to assure that these products do not result in harm to Americans. This initiative will place greater responsibility on Chinese manufacturers, processors, packers, and distributors to institute measures to assure that foods and food ingredients imported to the United States are safe and meet FDA standards. A parallel element of this initiative appears in the Protecting Patients business case paper.

C. Cosmetics User Fee

Every day, Americans use a wide variety of cosmetic products, including skin moisturizers, perfumes, lipsticks, nail polishes, eye and face make-up, shampoos, hair straighteners, hair colors, mouthwashes, and deodorants. Consumers expect their cosmetics – and the ingredients in cosmetics – to be safe. FDA plays a critical role in ensuring that the nation's cosmetics are among the safest in the world.

FDA is proposing new legislative authority to require domestic and foreign cosmetic manufacturers to pay an annual registration fee to support FDA cosmetic safety and other FDA cosmetic responsibilities. The user fees will improve FDA capacity to promote greater safety and understanding of cosmetic products.

During the past decade, Americans have seen an explosion in the numbers and types of cosmetic products sold annually. From FY 2004 to FY 2010, the number of cosmetics imports has nearly doubled, growing from less than 1 million import lines in FY 2004 to more than 1.9 million import lines in FY 2010. In the face of this growth, FDA has inadequate, incomplete, and often outdated data on cosmetic products and ingredients.

The cosmetic industry is also undergoing rapid and significant change. Manufacturing has become more global, cosmetics technology has become increasingly sophisticated, and cosmetics ingredients have become more complex. For example, the use of nanotechnology in cosmetics can result in products with different chemical or physical properties, which may pose different safety challenges.

Based on these challenges, FDA proposes to strengthen the FDA Cosmetics Program by relying on user fees to supplement appropriations of budget authority. With these resources, FDA will conduct priority Cosmetics Program activities that meet public health and industry goals.

D. Food Contact Notification User Fee

FDA has statutory responsibility for the safety of all food contact substances in the United States. The food packaging industry that develops food contact substances has annual sales of more than $60 billion. To ensure the safety of these products, the Food and Drug Administration Modernization Act (FDAMA) of 1997 established a premarket notification process for food contact substances, known as the Food Contact (FCN) Notification Program.

Food contact substances include components of food packaging and food processing equipment that come in contact with food. The FCN program, which has been operational since 2000, is the preferred process for obtaining authorized uses of food contact substances. Under the FCN program, food contact substances may be marketed 120 days after submitting a notification to FDA, unless FDA raises an objection. As this process does not require rulemaking, it is simpler, more efficient, and requires fewer resources than the food additive petition process used for food additives that are not food contact substances.

Because of its greater efficiency and predictability, FDA and industry have hailed the FCN Program as a significant regulatory success and an example of sensible regulation. The FCN program supports applications for innovative food contact substances that help mitigate microbial food contamination and provide consumers with more healthful and safe food choices.

However, section 409(h)(5) of the FD&C Act specifies that the FCN program can operate only if adequately funded. The requirement for adequate funding protects public health by ensuring that FDA has sufficient resources to prevent the marketing of unsafe food contact substances.

The user fees proposed in this initiative will assure that the FCN program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations.

The addition of user fees will add predictability for FDA, the regulated industry, and consumers. The proposed user fees investment in the FCN program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used in contact with food.

E. International Courier User Fee

For FY 2013, FDA is proposing a new International Courier User Fee. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities, including food products, at express courier hubs.

Current FDA staffing does not match the current workload and expected growth in import volume arriving through international express courier facilities. Express couriers and other couriers have indicated that they expect dramatic growth in shipments, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of its international courier activities through user fees.

F. Pay Costs (Commissioned Corps)

FDA can only fulfill its public health responsibilities if it has sufficient resources to pay the workforce that conducts FDA food safety programs. To maintain its Commissioned Corps workforce, who provide scientific, professional, and technical expertise to all programs, FDA must continue to meet the full cost of the workforce payroll, including the proposed pay increase.

3. What has this program accomplished?

Implementing FSMA – Recent Accomplishments: With the passage of FSMA in January of 2011, Congress gave FDA new authorities and new responsibilities to protect the safety of America's food and feed supplies. FDA immediately began to implement key FSMA priorities. In addition to FSMA, FDA continues to rely on its core authorities in the Food, Drug and Cosmetic Act and other statutes to improve the safety of food and feed.

The following are highlights of FDA's recent food and feed safety accomplishments:

- In March 2011, FDA published a draft guidance for industry on *Salmonella* testing for firms that manufacture, process, pack, or hold human foods or direct-human-contact animal foods (such as pet food or animal feeds).

- In March 2011, FDA established Vet-LRN, the Veterinary-Laboratory Response Network. Vet-LRN integrates state and federal laboratories resources and expertise to achieve timely and accurate reporting, identifying, and analyzing of chemical and microbiological contamination events related to animal feed.

- In April 2011, FDA issued updated guidance related to seafood hazards and controls. The guidance contains FDA's latest recommendations to the seafood industry to reduce or eliminate food safety hazards in fish and fishery products.

- In May 2011, FDA announced the first two regulations issued under new FSMA authority. These regulations on detention of foods and refused

entry reporting for imports will help ensure the safety and security of the U.S. food supply. The regulation on detaining imports strengthens FDA's ability to prevent potentially unsafe, adulterated or misbranded food from entering commerce. The regulation on refusing entry requires anyone importing food or feed to inform FDA if any country has refused entry to the same product.

- In July 2011, FDA issued a draft guidance for the dietary supplement industry on ensuring the safety of new dietary ingredients. The draft guidance advises manufacturers and distributors when a premarket safety notification for a dietary supplement containing a new dietary ingredient is necessary. The guidance also assists industry in preparing premarket safety notifications.

- In August 2011, in collaboration with the Partnership for Food Protection, FDA launched PETNet, the Pet Event Tracking Network. PETNet is a voluntary, secure, web-based information exchange, surveillance and alert system. PETNet allows Federal and State agencies to share information about emerging pet-food incidents, including illness linked to consuming pet food or defects in pet food products.

- In October 2011, FDA issued the first integrated Foods and Veterinary Medicine Program Strategic Plan for public comment. The plan contains FDA's strategy for food safety and preventing foodborne illness.

FSMA Activities Funded with the FY 2012 Budget Increase: For FY 2012, Congress appropriated $39,000,000 to FDA to implement additional FSMA responsibilities. With FY 2012 funding approved by Congress, FDA plans to conduct the following specific activities to implement the FSMA:

- Establish protective and practical standards for key risk factors to enhance produce safety and protect the health of consumers

- Develop and issue guidance and standards necessary for a prevention-oriented food safety system designed to protect consumers

- Develop performance standards for food hazards

- Engage in extensive outreach, dialogue, and other efforts with the food industry to ensure that FDA standards and guidance are protective and practical

- In support of the Integrated Food Safety System, provide funding to our regulatory and public health partners in the form of state grants, cooperative agreements or inter-agency agreements

- Upgrade IT systems to allow for the acceptance of FDA, state, and foreign data to support the move towards a national workplan

- Hire new employees, so that by FY 2014, once the employees are fully trained, FDA can conduct 731 import verification inspections for the Foreign Supplier Verification Program

- Hire new employees, so that by FY 2015, once the employees are fully trained, FDA can conduct 127 foreign assessments or audits.

4. What activities will the funds support?

FSMA Activities Funded with the FY 2013 Increase: With the resources in this FY 2013 initiative, FDA will commence additional high priority food and feed safety activities. The primary focus of FY 2013 funding will be establishing the new food safety system that Congress mandated in FSMA.

The FY 2013 activities described below build on investments funded by Congress in FDA's FY 2011 and FY 2012 appropriations.

A. Transforming Food Safety[9]
+$199,254,000 / 241 FTE (All UF)

The user fee increases in the Transforming Food Safety initiative will support efforts to reduce a broad range of foodborne illnesses caused by bacterial, viral, and parasitic pathogens. Examples of specific pathogens that this initiative will address include:

- *Salmonella*
- *E. coli*
- Hepatitis A
- *Vibrio*
- *Shigella*
- *Listeria monocytogenes*
- Norovirus
- *Cyclospora*.

In the summer of 2011 alone, there were outbreaks of foodborne illness associated with *E. coli* in strawberries, *Salmonella* in imported papayas, and *Salmonella* in domestic sprouts. These outbreaks, as well as the European outbreak in the spring associated with *E coli* O104:H4 in which at least 40 people died and more

[9] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

than 3,200 became sick, are recent examples of the far-reaching effects that foodborne illness can have.

Regulations & Guidances - FSMA Sections 101, 103, 104, 105, 106, 110, 204, 209, 210, 405
+$55,525,000 / 42 FTE (All UF)

Foodborne illnesses linked to known causes are largely preventable if the parties involved in today's global food chain implement appropriate preventive measures at each step of the process where control of hazards is necessary.

Regulations and guidances are important prevention-focused tools that guide food industry efforts and provide the framework for accountability and meeting appropriate standards under FSMA. The more successful the food system is at each stage – producing, processing, transporting, and preparing foods – the safer America's food supply will be.

User fee funding in this initiative will enable FDA to work closely with food industry experts to gain the detailed knowledge of specific sectors and operations needed to develop sound guidance. FDA will develop science-based guidances that support industry efforts to adopt preventive controls. FDA will hold public meetings and engage in outreach and dialogue with the food industry to ensure that FDA standards and guidance are practical and protective. FDA will also implement a preventive, risk-based system to fully address all aspects of the manufacturing, packing, and storage of animal feed to ensure that hazards are properly identified and controls are in place. This system will also help to:

- eliminate or control risks from feed hazards
- establish regulatory limits for feed hazards
- develop guidance and provide training and outreach to regulatory partners and industry.

FDA will also rely on user fee funding to continue to develop regulations, guidances, and standards in the following priority areas:

- safe production of food and animal feed
- uniform hazard analysis standards
- scientifically sound, risk-based controls for food, feed and dietary ingredients
- food safety plans for food and feed facilities.

To implement and enforce preventive controls in food and feed processing facilities, FDA will train more than 1,600 FDA inspection personnel. FDA will also train some of FDA's 21,000 state, tribal, and territorial food safety partners. The training will include preventive control inspection and enforcement methods to

ensure that inspection personnel are prepared to conduct sound, effective inspections under the new preventive controls framework.

Finally, FDA will provide extensive outreach, education and technical assistance to growers, industry and consumers to promote compliance with the new standards.

CFSAN UF $26,846,000 / 35 FTE
CVM UF $3,679,000 / 7 FTE
ORA UF $25,000,000 / 0 FTE

Domestic Inspections - FSMA Section 201
+$20,143,000 / 19 FTE (All UF)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable to produce safe products.

The user fee resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs. Fee resources will also allow FDA to improve its food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. These improvements are essential to achieve the greatest public health value from FDA inspection and compliance programs and to successfully manage the growth in safety-related compliance cases that FDA anticipates due to the increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote access devices will allow field staff to examine shipments and complete all required electronic submissions for data entry on site. With this investment, field staff can also print labels for samples they collect and complete collection reports and all necessary documents.

In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. This technology will provide opportunities to enhance targeting of shipments, resulting in greater assurance of the safety of commodities that FDA physically examines.

CFSAN UF $6,498,000 / 16 FTE
ORA UF $13,645,000 / 3 FTE

Import Safety - FSMA Sections 201, 211, 301-308[10]
+$52,357,000 / 94 FTE (All UF)

This investment will support comprehensive, prevention-focused import food and feed safety programs that will place greater responsibility on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, transporters, and importers – to assure that imported food and feed are safe and meet regulatory requirements.

Prior to the enactment of FSMA, there was no statutory requirement for importers to proactively ensure that the foods they import are manufactured in compliance with FDA regulations or that imported food is not adulterated or misbranded.

The existing system places the primary responsibility of supply chain verification for imported food products on FDA and the FDA resources located at the U.S. border. In a globalized and increasingly complex world, it is not feasible to rely on a regulatory body to perform thorough supply chain verification by examining and sampling commodities when they are offered for import. Such an approach cannot provide adequate assurance of food and feed safety.

To ensure that imported foods are as safe as those produced domestically, FDA will develop and implement a variety of approaches to assure the safety of imported foods. These approaches include:

- foreign supplier verification (FSMA section 301)
- accredited third party certification (FSMA section 307)
- comparability assessments (related to FSMA sections 301, 302, 303, 305) improved foreign inspections (FSMA section 201)
- foreign audits of other foreign regulatory systems and training of regulatory partners (FSMA sections 305, 306, 307, 308)
- improved foreign inspections (FSMA section 201).

Through these approaches, FDA will leverage the work of foreign regulators and harness private sector supply chain management efforts to expand overall coverage and safety of the supply chain for imported foods and feeds.

New FY 2013 user fee funds in this initiative will allow FDA to further expand accredited third party certifications, foreign inspections, and foreign food safety system comparability assessments. FDA will periodically audit these programs and program participants using fee resources. FDA will also expand integrated food safety training programs to include foreign regulatory partners, third party, and industry representatives to better support global implementation of improved

[10] Some of the activities covered in other sections of this document also contribute to import safety.

importer accountability and the preventive controls framework mandated by FSMA. With fee resources, FDA will obtain greater assurance of the safety of imported foods. FDA will also periodically audit these programs using fee resources and will audit program participants.

FDA will continue to administer the Foreign Supplier Verification Program (FSVP) and conduct import verification inspections using risk-based strategies to target inspections and rapid field tests to better target sampling at the border. FDA will establish and implement procedures for electronic verification of importers compliance status with FSVP. This electronic verification will allow FDA to make appropriate admissibility determinations for foods offered for import. FDA will develop and implement training programs to ensure that FDA staff has the education and competencies to conduct import verification inspections.

FDA will continue to conduct initial assessments and periodic audits of comparable countries, export programs, and recognized third party certification programs to ensure that they meet U.S. food and feed safety standards. FDA will also continue to conduct capacity building with foreign partners. FDA will expand partnerships with other public health agencies to conduct international outreach, training, and technical support for food safety and develop materials and information packets to support foreign inspections. Additionally, the FDA will work with foreign regulatory counterparts on a country and multilateral basis to:

- improve information sharing
- conduct outreach to the private sector
- collaborate to facilitate implementation of the FSMA import safety provisions.

FDA will use information supplied through these programs to make risk-based decisions for import entry. FDA will also use this information to make decisions on where FDA will conduct border exams, which foods to target, and where FDA will target import sampling. User fee funds will also allow FDA to continue to develop the infrastructure and processes to enable timely enforcement action. FDA will continue to implement the new enforcement authorities provided by FSMA, including:

- suspension of registrations
- administrative detention
- the refusal of goods from foreign firms that refuse inspection.

Concurrently, FDA will use user fee funds to expand critical enforcement and compliance support for foreign food facility inspections. These activities include:

- planning inspections
- notifying foreign firms to request permission to conduct inspections

- reviewing inspection reports
- developing decision support systems
- managing follow-up on compliance actions.

CFSAN UF $14,873,000 / 20 FTE
ORA UF $37,484,000 / 74 FTE

Integrated Food Safety System - FSMA Sections 201, 202, 203, 204, 205, 209, 210
+$39,128,000 / 67 FTE (All UF)

With these user fee resources, FDA will continue to develop and implement an integrated national food safety system built on:

- uniform regulatory program standards
- strong oversight of the food supply
- sustainable multi-year infrastructure investments in state, local, tribal and territorial regulatory and public health partners.

These investments will provide more uniform coverage and safety oversight of the food and feed supply.

As part of establishing a national integrated food safety system, FDA will provide funding to regulatory and public health partners in the form of state grants, contracts or cooperative agreements to improve, strengthen and standardize regulatory activities among all partners. The result will be more consistent oversight, application and enforcement of food and feed safety laws and regulations.

FDA will develop and administer food safety certification programs for FDA inspectors, investigators, and analysts, and for FDA's regulatory partners. FDA will also provide field liaisons to assist the states with implementing the Manufactured Food Regulatory Program Standards. This investment will improve food and feed safety by facilitating communication and ensuring that all parties are performing to a national standard. In addition, FDA will conduct audits of regulatory and public health partners to measure their performance against FDA food and feed safety program standards.

In addition, FDA will expand the current FDA proficiency testing program to better target food safety and food defense concerns in support of the FSMA mandate for laboratory accreditation. FDA will develop and validate certification testing instruments and provide scientific coordinators to serve as resources to support the states as FDA moves to national standards for laboratories. State laboratory accreditation will support the development of the infrastructure to support state programs, which will advance the acceptance and use of state data. Accrediting

state laboratories will also allow FDA to integrate and use analysis conducted at the state level for microbiological, chemical and microanalytical testing. FDA will then be able to establish an integrated consortium of laboratory networks to rapidly identifying and removing contaminated products from the market.

FDA will evaluate and implement new methods to detect microbiological and chemical contaminants in food. FDA will also update Foods Program manuals that establish standards for validating analysis methods, such as the Bacteriological Analytical Manual, Pesticide Analytical Manual, and Elemental Analysis Manual. FDA will evaluate and implement fit-for-purpose method extensions and new instruments.

These actions will build lab capacity for partner labs and food safety programs, which will allow FDA to coordinate the development and validation or analytical methods and improve surveillance of foodborne illness.

CFSAN UF $11,423,000 / 15 FTE
ORA UF $27,705,000 / 52 FTE

Risk Analysis - FSMA Sections 103, 104, 105, 106, 201, 204, 301, 203, 303, 306 +$11,621,000 / 3 FTE (All UF)

These user fee resources will allow FDA to rank and prioritize food safety concerns and identify how to apply FDA resources to achieve the best possible public health outcomes. FDA will improve and implement data-driven risk ranking and prioritization tools to inform regulatory, compliance and resource allocation decision-making processes that are critical to successfully implementing and supporting FDA's FSMA responsibilities.

Currently, FDA relies on investigational or epidemiological approaches to understand and prevent foodborne outbreaks. However, new knowledge management tools, such as iRisk and iPrioritize, and investments in innovative information technology will provide a systematic and transparent approach to identify, characterize and evaluate food safety risks throughout the food supply system and to evaluate the potential impact of control measures or intervention strategies.

FDA will adapt these tools for use by the public and industry to improve their understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards. By identifying food safety risks, FDA protects consumers and supports industry efforts to produce safer foods. Through these efforts, FDA and industry also avoid the potential high costs that result from consumer illness or injury caused by contaminated or unsafe foods.

CFSAN UF $11,621,000 / 3 FTE

Planning and Response - FSMA Sections 202, 204, 205, 206
+$10,758,000 / 9 FTE (All UF)

These user fee resources will allow FDA to:

- respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public
- improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts
- support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to recall unsafe food voluntarily.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private sources. FDA will also enhance existing systems, such as the Field Accomplishments and Compliance Tracking System (FACTS), as well as expand tools for surveillance and outbreak detection. FDA will further expand tools and databases to collect information from post-response activities. This effort will allow FDA to identify trends and improve the effectiveness of future response and prevention activities. FDA will also enhance the Reportable Foods Registry to better support the food recall requirements in FSMA.

In addition, FDA will develop and implement traceback procedures for domestic and imported foods. Likewise, FDA will continue to explore and evaluate methods and novel information technologies to rapidly and effectively identify consumers who received unsafe food, and thereby prevent or better control a foodborne illness outbreak.

In the area of feed safety, FDA will develop a network of shared state and federal laboratory data. FDA will also work with regulatory partners to close current gaps in the oversight of the feed industry. FDA will determine which laboratory accreditation options will best ensure that participating laboratories perform competent testing and provide consistent and meaningful data that will enable compliance with established FDA standards and make surveillance possible in partnership with the Veterinary Laboratory Response Network (*Vet-LRN*).

The user fees in this initiative will also support efforts to respond to high priority chemical and microbial feed and drug contamination events that could signal concerns for the human food system. Current initiatives in this area include development of a database of feed toxicant events and an investigation of *Salmonella* in veterinary diagnostic samples.

CFSAN UF $9,342,000 / 6 FTE
CVM UF $1,176,000 / 2 FTE
ORA UF $240,000 / 1 FTE

Science for Food Safety – Critical Capacity for Implementation of FSMA
+$9,722,000 / 7 FTE (All UF)

Scientific research and analysis provide the basis for developing appropriate standards and guidances. This investment will allow FDA to establish food and feed safety standards that are based on the latest scientific developments and that address hazards from farm to table.

With these user fee resources, FDA will develop innovative methods and tools to validate preventive controls and to better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins. This research will allow FDA to inform food standard setting and improve the speed and effectiveness of outbreak and contamination response.

FDA will develop next generation methods to detect high priority contaminants in animal feeds and feed components. FDA will:

- evaluate and customize commercially available systems to detect illegal drug residues in animal feed and animal derived products for human consumption
- develop metabolism studies to identify marker residues used to develop and validate analytical methods to detect residues in imported and domestic animal feed
- expand the technical capacity of its laboratory surveillance networks to analyze animal feed commodities for contamination.

CFSAN UF $8,875,000 / 5 FTE
CVM UF $847,000 / 2 FTE

B. Food Manufacturing Inspections in China[11]
+4,112,500 / 8 FTE (All BA)

With the budget authority resources in this initiative, FDA will perform additional foreign inspections in China, focusing on facilities that produce higher risk foods and food ingredients destined for export to the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA food safety, quality and good manufacturing practices.

FDA HQ: $3,675,000 /7 FTE

[11] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

FDA will also expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk foods and manufacturing that originate in China.

FDA HQ: $437,500 / 1 FTE

C. Cosmetic Safety[12]
+$16,332,000 / 60 FTE (All UF)

FDA will conduct the following activities with the new user fee resources in this initiative:

- FDA will establish and maintain a Cosmetic Registration Program and issue standards to implement the program.
  CFSAN UF $5,123,000 / 9 FTE

- FDA will acquire, analyze, and apply scientific data and information to set U.S. cosmetic standards. FDA will maintain a strong U.S. presence in international standard-setting efforts. FDA will also provide education, outreach, and training to industry and consumers.
  CFSAN UF $6,889,000 / 33 FTE

- FDA will refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities.
  ORA UF $4,320,000 / 18 FTE

D. Food Contact Notification User Fee[13]
+$4,458,000 / 7 FTE (All UF)

With the user fee resources in this initiative, FDA will:

- support the efficient and timely review of food contact notifications
- update standards in and provide guidance for industry
- conduct education, outreach, and training
- participate in international harmonization and standard setting for food contact substances.

CFSAN UF 4,458,000 / 7 FTE

[12] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.
[13] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

E. International Courier User Fee[14,15]
(+$721,000 / 3 FTE) (All UF)

The user fee will address the growing volume of imports that enter the United States through international couriers. The fee revenue will support the cost of FDA import operations to conduct FDA work at international courier facilities. Funding generated from this user fee program will allow FDA to conduct the following essential import safety activities:

- conduct entry reviews
- collect samples and conduct physical exams to determine whether a product can be admitted into the United States.
- initiate compliance actions to prevent the release of unsafe products
- establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

F. Pay Costs (Commissioned Corp): (+$703,000) (All BA)

For Transforming Food Safety programs, the FY 2013 budget authority amount for higher Commissioned Corps pay costs is $703,000. For all FDA programs, pay cost will increase by $1,502,000.

G. FSMA User fees (+$2,495,000 /0 FTE) (All UF)

Please refer to the Current Law User Fee business case paper for a discussion on the Export Certification, Food Reinspection, and Food Recall user fees.

H. Program Support for the FY 2013 Transforming Food Safety Initiative
+$14,157,500 / 36 FTE ($262,500 BA, $13,895,000 UF)

The FY 2013 Transforming Food Safety Initiative includes resources to ensure that programs that participate in this initiative receive the support necessary to achieve their public health outcomes. Program support includes activities such as:

- finance and budgeting
- human resources support
- contracting, billing, and legal support
- communications, ethics, headquarters coordination and related support functions.

[14] In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.
[15] The Protecting Patients portion of this user fee, totaling $4,533,000, is found in the Protecting Patients business case paper.

Food Establishment Registration Fee UF	*+$12,544,000 / 32 FTE*
Cosmetic Safety UF	*+$ 980,000 / 3 FTE*
Food Contact Notification UF	*+$ 267,000 / 1 FTE*
International Courier UF	*+$ 104,000 / 0 FTE*
China Initiative (BA)	*+$ 262,500 / 0 FTE*

I. Rent Activities for FDA Food Safety Programs
+$11,125,000 / 0 FTE ($939,000 BA, $10,186,000 UF)

The FY 2013 Transforming Food Initiative includes resources to pay the GSA Rent and the Other Rent and Rent-Related costs for the new employees hired under the FY 2013 Protecting Patients Initiative.

These funds will also allow FDA to pay a portion of the increased cost of GSA Rent and Other Rent and Rent-Related activities for the facilities that support FDA's base program. To fully meet its rent obligations, FDA must also redirect program resources to cover its rent costs.

The GSA Rent account includes funds for FDA payments to the General Services Administration (GSA) for FDA offices and laboratory facilities. GSA rent also includes funds to pay the Department of Homeland Security for guard services and operating of security systems at FDA facilities. The Other Rent and Rent-Related account includes funds for commercial rent and other payments related to leased facilities that are not part of the GSA inventory of buildings.

Inflationary Rent (BA)	*+$ 939,000*
Transforming Food Safety Initiative User Fee Rent	*+$8,402,000*
Cosmetic Safety User Fee Initiative Rent	*+$1,386,000*
Food Contact Notification Use Fee Initiative Rent	*+$ 176,000*
International Courier User Fee Initiative Rent	*+$ 222,000*

In addition to the amounts displayed above, FDA will also redirect the following amount from FDA Food Safety programs to pay the remaining FY 2013 costs for rent activities.

Inflationary Rent Absorption (BA): -$4,643,000 (non-add) / 0 FTE

5. How does this initiative support important public health priorities?

A. Transforming Food Safety: The Transforming Food Safety Initiative, resourced through the Food Establishment Registration Fee, builds on the food safety activities approved by Congress in FDA's FY 2011 appropriation. The FY 2013 resources are part of a continued, multi-year FDA effort to implement and enforce the FDA Food Safety Modernization Act and key priorities of the President's Food Safety Working Group.

Funding this initiative will also allow FDA to achieve the Administration's vision of a strong, reliable food safety system for American consumers that also sustains the economic health of all segments of America's food industry, by

- reducing the risk of illness associated with food and feed
- decreasing the frequency and severity of food- and feed-borne illness outbreaks
- reducing instances of contamination
- greatly diminishing the burden on American businesses and the U.S. economy due to these events.

B. Food Manufacturing Inspections in China: Funding for the China inspection initiative will allow FDA to strengthen the supply chain for foods and food ingredients manufactured in China. The result will be fewer import safety emergencies, less foodborne illness and earlier identification of safety problems associated with food and food ingredients manufactured in China.

C. Cosmetics User Fee: The Cosmetic User Fee in this initiative will strengthen FDA efforts to protect public health by preventing harm to consumers, ensuring the safety of cosmetic and removing unsafe cosmetic from the market. By increasing the information that FDA obtains from the cosmetic registration system that will serve as the basis for assessing this user fee, FDA will develop necessary guidance and standards for industry. FDA will also be better able to identify research gaps, such as the safety of novel ingredients used in cosmetics.

D. Food Contact Notification User Fee: This program supports Executive Branch and public health priorities for food safety. With these resources, FDA will:

- protect consumers by allowing FDA to conduct pre-market reviews of food contact substances
- increase the availability of safe food contact substances
- prevent unsafe food contact substances from reaching the marketplace
- apply the most modern regulatory science to the review of food contact substances.

E. International Courier Use Fee: The International Courier user fee program proposed in this initiative supports the core public health priority of improving health care quality and patient safety.

F. Pay Increase (Commissioned Corps), Rent Activities and Program Support for FDA food safety programs: The increases for Commissioned

Corps pay costs, Rent Activities and Program Support proposed in this initiative support FDA mission critical activities within FDA food safety programs.

6. What are the risks of not proceeding with this initiative?

Transforming Food Safety: The resources in this initiative will promote public health in the United States by increasing the safety of America's food supply. Not funding this initiative will result in an inability of FDA to take full advantage of the new authorities it was granted under the FSMA to protect the health of Americans. Not funding this initiative will continue the pattern of recurring outbreaks and health risks from domestic and imported food, with the resulting disruptions to the food system and the economic burdens that result from foodborne outbreaks.

These resources will allow FDA to expand its implementation of the landmark new authorities in the Food Safety Modernization Act that will better protect public health by *preventing* food safety problems rather than primarily *reacting* to problems after they occur.

Funding the Food Safety elements of the initiative will allow FDA to:

- reduce the number of foodborne illnesses and deaths
- identify sources of risk in the food and feed safety systems
- reduce the number of unsafe or potentially unsafe imported foods
- strengthen oversight of imported food and feed
- improve domestic and foreign industry compliance with food and feed safety standards
- reduce the time required to detect and respond to outbreaks
- enhance food safety integration between Federal, State, local, tribal, territorial, and foreign public health partners.

Funding this initiative will benefit more than 300 million Americans, plus countless international consumers who benefit from U.S. leadership in food safety and security. This initiative also offers special benefits for the following populations and interests:

- populations susceptible to foodborne illness, such as the young and elderly
- vulnerable populations suffering disparities in health
- the $1 trillion food production, processing, manufacturing, restaurant, and retail food industries

- foreign trading partners who share economic and public health concerns and want to continue to trade in raw, processed and finished human food and animal feed with the United States.

The consequences of not making the priority investments outlined above, however, will severely limit FDA's ability to fulfill FSMA's vision of a modern new food safety system that is prevention-oriented, science- and risk-based, and efficient.

- FDA will have limited capacity to develop guidance, conduct industry outreach and provide other technical assistance to support implementation of preventive controls, which will mean inconsistency and substantial delay in implementing the new rules.

- The re-training of FDA's inspection force will be incomplete and delayed, thus undermining the effectiveness of the preventive controls framework and missing opportunities to improve the efficiency and public health value of inspection.

- FDA support for federal-state integration and state capacity building will be eroded, thus limiting FDA's ability to leverage state efforts to improve inspection efficiency and performance.

- FDA will be unable to create the new import oversight system mandated by Congress and thus will continue to be limited primarily to port of entry screening of imports rather than building a collaborative system of import oversight grounded in reliance on industry supply chain management practices.

Without the user fees to support the Cosmetics Program, FDA will continue to lack vital information necessary to maintain oversight of the domestic cosmetic industry and engage in leadership on international harmonization. Furthermore, without knowledge of the full range of cosmetic products and ingredients marketed in the United States and the domestic and foreign facilities that are involved in providing cosmetics to American consumers, FDA does not have the full capability to protect American consumers from unsafe products.

Without the user fees to support FDA's food contact substances program in this initiative, FDA faces the risk of reverting to the less efficient and less predictable process for regulating food contact substances. Such a change will cost U.S. consumers more on a product-by-product basis. Such a change will also have a significant negative impact on industry innovation, as premarket authorizations with food additive petitions require longer review timeframes, thus delaying the entry of new food contact substances into the market and delaying industry's recovery of research and development costs.

Moreover, without better knowledge of the full range of food contact products being marketed in the United States, including those from foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe packaging products.

Food Manufacturing Inspections in China: Without this initiative, FDA will not have the resources to adequately identify and address risks associated with foods imported from China. Not funding the initiative could result in preventable harm to patients in America.

International Courier User Fee: Without the resources for the proposed International Courier User Fee, FDA cannot adequately protect the health of Americans. Without this user fee, FDA cannot:

- reduce the risk of unsafe or contaminated imports from reaching U.S. consumers
- prevent harm from counterfeit and unsafe products
- reduce the time between detection and appropriate risk management response.

Pay Increase (Commissioned Corps), Rent Activities and Program Support for Food Safety Programs: Pay, rent, utilities and other costs to support the FDA workforce are fixed costs that FDA does not control. If FDA does not receive the increases for Commissioned Corps pay and for rent costs, FDA will fail to maintain its staff of investigators, epidemiologists, safety experts and other professionals that are the backbone of FDA's food safety workforce. The FY 2013 Transforming Food Safety Initiative includes resources for Program Support to ensure that FDA food safety initiatives for FY 2013 receive the support necessary to achieve their public health outcomes.

7. What will FDA accomplish with the initiative?

The Transforming Food Safety initiative will allow FDA to develop and implement an integrated prevention-focused food safety system, as envisioned by the White House Food Safety Working Group and supported by the FDA Food Safety Modernization Act. The initiative will leverage partnerships and resources with federal, state, local, tribal, and territorial regulatory partners and foreign governments to significantly improve effectiveness and efficiency in preventing and responding to food safety problems.

Accomplishing these objectives will greatly enhance domestic and global efforts to substantially reduce foodborne illnesses caused by contamination of the food supply for years to come. Resources in this initiative also offer the potential to substantially reduce chronic diseases linked to excessive sodium intake.

Specific deliverables appear in the performance table below. In summary, this investment will:

- Decrease the number of unsafe or potentially unsafe products entering the United States, reduce the risk of illnesses and injuries to consumers, and contribute to lower health care costs and reduced economic impact from foodborne outbreaks

- Enable ranking and prioritization of food safety concerns and identify how to best apply FDA and industry resources to achieve the greatest public health outcomes

- Improve enforcement methods to achieve higher rates of compliance and improve inspection efficiency to increase FDA's ability to monitor the growing food industry

- Establish an integrated consortium of accredited laboratory networks

- Streamline and strengthen efforts to prevent, detect, trace back investigate, respond to and learn from foodborne outbreaks to increase efficiency and success of incident responses

- Increase assurance that food and feed imported in the U.S. is safe through audits and verification of implementation of preventive controls in foreign facilities, thereby reducing the likelihood of injury or illness to consumers from unsafe or contaminated foods

- Increase consumer health protection through better identification and risk-based targeting of areas of concern in the food and feed supply chain through the FDA Foreign Supplier Verification Program

- Develop new tools and methods to improve FDA's ability to establish regulatory standards, conduct post-market surveillance, document risk through laboratory testing, respond to outbreaks, and produce scientific evidence to prove that a product is a threat to public health.

Performance Tables:

FDA is using FDA-TRACK, our agency-wide performance management system, to track, analyze, and report monthly and quarterly performance measures, progress and accomplishments for FDA's most important initiatives. These initiatives include ongoing efforts as well as new efforts as showcased in the following FY 2013 performance tables. Upon finalization and receipt of the FY 2013 request, FDA will be developing performance measures and/or key project milestones for the funded initiatives. You will find these measures, milestones, and progress on the FDA-TRACK website - www.fda.gov/fdatrack.

Transforming Food Safety Performance Table:

The following tables contain performance items associated with this initiative.

Performance Measures	FY 2011 Enacted Performance Level	FY 2013 Performance Level +/- FY 2011 Enacted	Most Recent Actual
Develop educational and outreach sessions for FDA personal, industry and states concerning the new preventive control regulations Preventative Controls Regulation Training	N/A	+50 sessions across the country	N/A
Develop strategic field assignments for domestic and foreign inspections of dietary ingredient manufacturers	N/A	• Reduce the number of intentionally adulterated products • Inspect 200 total, both foreign and domestic, dietary ingredient manufacturers	N/A
Prioritize and establish control points for hazards in dietary ingredients	N/A	Develop guidance	N/A
Educate field inspectors in dietary ingredient preventive control inspection protocol and technique	N/A	Conduct 4 annual training courses	N/A
Draft guidance documents for animal food preventive controls regulations	N/A	Draft 1 guidance document	N/A
Develop and deliver training on the requirements under the animal food preventive controls regulations	N/A	Develop and deliver 2 training courses	N/A
Expand foreign food safety system comparability assessments	5 comparability assessments initiated	+4	N/A

Performance Measures	FY 2011 Enacted Performance Level	FY 2013 Performance Level +/- FY 2011 Enacted	Most Recent Actual
State grants, contracts, cooperative agreements or inter-agency agreement between federal agencies *(Proposed Food Registration and Inspections UF)*	10	+10	NA
3rd Party Assessments and Performance Audits	N/A	+30 FTE – hire and train in 2013. +254 assessments/audits full performance realized in 2016	N/A
Importer Verification Inspections	N/A	+22 FTE – hire and train in 2013. +609 inspections full performance realized in 2015	N/A
Expand the capabilities of Pet Event Tracking Network (PETNet)	N/A	• Assess the initial (PETNet) launch • Expand the system to food-producing animals or medicated feed monitoring; • Develop appropriate survey questions for non-pet species; • Assess whether to include non-pet food in the same system	N/A
Ensure that participating laboratories perform testing and provide consistent and meaningful data for FDA compliance and surveillance purposes	N/A	• Develop 1 white paper describing accreditation requirements. • Develop and conduct 2 training courses and proficiency testing.	N/A
Expand the technical capacity of laboratory surveillance networks to analyze animal feed commodities for contaminants	1 project developing next generation methods for high priority contaminants in animal feeds and feed components	• +1 project developing next generation methods for high priority contaminants in animal feeds and feed components • Develop and evaluate commercially available systems for detection of illegal drug residues • Identify marker residues for detecting residues in imported and domestic animal feed products	N/A

FY 2013 China Initiative Performance Table:

The following table contains performance items associated with this initiative.

Performance Measures	FY 2012 Enacted Performance Level	FY 2013 Performance Level +/- FY 2012 Enacted	Most Recent Actual
Foreign In-Country Food Safety Inspections	0	Hire and train 7 FTE in 2013. (+135 in-country inspections in FY 2015)	N/A

FY 2013 Cosmetics User Fee Performance Table:

The following table contains performance items associated with this initiative.

Performance Measures	FY 2011 Enacted Performance Level	FY 2013 Performance Level +/- FY 2011 Enacted	Most Recent Actual
Establish a Mandatory Cosmetic Registration Program	NA	Establish a Mandatory Cosmetic Registration Program	NA
Issue guidance in essential areas to help industry comply with the new program	NA	+2 guidances	NA

FDA Medical Countermeasures Initiative
+$3,510,000 / 7 FTE

The following table displays the FDA budget authority for the Medical Countermeasures Initiative in the FY 2013 Congressional Budget Justification.

Advancing Medical Countermeasures

(Dollars in Millions)

Program	FY 2010 $170M One-Time Allocation (non-add)[1]	FY 2011 Enacted	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
Budget Authority:					
Human Drugs	**$28.017**	**$0.000**	**$4.756**	**$5.596**	**$0.840**
Center	27.144	0.000	4.756	5.596	0.840
Field Activities	0.873	0.000	0.000	0.000	0.000
Biologics	**$27.362**	**$0.000**	**$1.974**	**$2.226**	**$0.252**
Center	26.489	0.000	1.974	2.226	0.252
Field Activities	0.873	0.000	0.000	0.000	0.000
Devices and Radiological Health	**$17.099**	**$0.000**	**$2.997**	**$3.720**	**$0.723**
Center	16.661	0.000	2.997	3.720	0.723
Field Activities	0.438	0.000	0.000	0.000	0.000
FDA Headquarters	**$90.234**	**$0.000**	**$9.013**	**10.312**	**1.299**
Other Rent and Rent Related	**$2.603**	**$0.000**	**$0.472**	**0.616**	**0.144**
GSA Rental Payments	**$4.685**	**$0.000**	**$0.826**	**1.078**	**0.252**
Total Advancing Medical Countermeasures	**$170.000**	**$0.000**	**$20.038**	**$23.548**	**$3.510**

[1] Under the August 20, 2010, budget amendment and a related announcement by Secretary Sebelius, FDA received $170 million from amounts appropriated under Public Laws 111-8 and 111-117. Under the terms of Public Law 112-10 (April 15, 2011), FDA can spend the $170 million on activities related to chemical, biological, radiological and nuclear threats, in addition to the previous authority to spend these funds on emerging infectious diseases.

1. Initiative Summary:

The FDA Medical Countermeasures Initiative (MCMi) is designed to meet America's national security and public health requirements for medical countermeasure (MCM) readiness. In advance of Congress' FY 2012 appropriation for the MCMi, FDA received an allocation of one-time funding at the close of FY 2010 to immediately commence MCMi activities. With these funds, FDA established a base program at its current operating level of 77 FTEs.

The FY 2013 budget contains resources that will allow FDA to sustain the current level of staffing and activities for the MCMi. With these FY 2013 resources, FDA will support partnerships with industry, academia, and government partners to improve MCM development timelines and success rate for MCMs. FDA will also expand technical assistance to developers for the highest priority MCMs.

2. Why is this funding necessary?

The FDA plays a vital role in protecting the United States from chemical, biological, radiological, and nuclear (CBRN) threats, and from emerging infectious diseases. FDA is responsible for ensuring that MCMs – such as drugs, vaccines, and diagnostic tests – to counter these threats are safe, effective, and secure. In addition, FDA works closely with Federal partners through the Department of Health and Human Services' (HHS) Public Health Emergency Medical Countermeasures Enterprise (Enterprise) to build and sustain the MCM programs necessary to respond to public health emergencies.

The Threat: According to the U.S. intelligence community, CBRN weapons and emerging infectious diseases present real, substantial and growing threats to the national security of the United States, and will continue to do so for the foreseeable future. For example, the March 2011 unclassified annual threat assessment from the U.S. intelligence community states that:

> . . . many of the countries pursuing [weapons of mass destruction] programs will continue to try to improve their capabilities and level of self-sufficiency over the next decade. Nuclear, chemical, and/or biological weapons – or the production technologies and materials necessary to produce them – also may be acquired by states that do not now have such programs. Terrorist or insurgent organizations acting alone or through middlemen may acquire nuclear, chemical, and/or biological weapons and may seek opportunistic networks as service providers.[1]

The March 2011 threat assessment echoes a 2009 assessment. According to the U.S. intelligence community, "[o]ver the coming years, [the United States] will continue to face a substantial threat, including in the U.S. Homeland, from terrorists attempting to acquire biological, chemical, and possibly nuclear weapons and use them to conduct large-scale attacks."[2] This assessment also stressed that "[i]n particular . . . the terrorist use of biological agents represents a growing threat . . ."

In October 2011, the Honorable Tara O'Toole**,** Under Secretary for Science and Technology, U.S. Department of Homeland Security in testimony before the Committee on Homeland Security and Governmental Affairs described the growing biological weapons threat:

---

[1] Clapper, J.R. Statement for the Record on the Worldwide Threat Assessment of the U.S. Intelligence Community for the House Senate Committee on Armed Services. *Annual Hearing to Receive Testimony on the Current and Future Worldwide Threats to the National Security of the United States*, Hearing, March 10, 2011. Available at: http://www.dni.gov/testimonies/20110310_testimony_clapper.pdf. Accessed December 22, 2011.

[2] Blair, D. Testimony before the Armed Services Committee, United States Senate. *Annual Threat Assessment of the Intelligence Community*, Hearing, March 10, 2009. Available at: http://www.dni.gov/testimonies/20090310_testimony.pdf. Accessed December 22, 2011.

> We are living in the midst of a biotechnology revolution where the knowledge and tools needed to acquire and disseminate a biological weapon are increasingly accessible. It is possible today to manipulate pathogens' characteristics (e.g. virulence, antibiotic resistance), and even to synthesize viruses from scratch. These procedures will inexorably become simpler and more available across the globe as technology continues to mature . . .Even small-scale attacks could be highly lethal and disruptive, and as has been noted, there is a real possibility of a campaign of bioattacks on multiple targets (the "reload" phenomenon) – because these weapons are self-replicating organisms. Moreover, it is not necessary for a nation-state to maintain a large stockpile of bioweapons to pose a significant asymmetric threat as the development of a significant offensive bioattack capability could occur within weeks or months.[3]

Numerous U.S. governmental reports have highlighted similar concerns.[4] For example, the *National Security Strategy* of 2010 notes that "[t]he effective dissemination of a lethal biological agent within a population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, social, and political consequences."[5]

And in a November 2009 report, the National Security Council estimated that the economic cost of a well-executed bioterrorist attack on American soil could exceed one trillion dollars. Such an attack could have profound consequences for our way of life, for trust in government, and for our society and political order. [6]

Naturally occurring emerging infectious diseases also pose a growing threat and could have similar consequences.[7] For example, in 2006 the Congressional Budget

---

[3] O'Toole, TJ. Testimony before the Homeland Security and Governmental Affairs Committee, United States Senate. Ten Years after 9/11 and the Anthrax Attacks: Protecting against Biological Threats, Hearing, October 18. 2011. Available at http://hsgac.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=1b1b1599-2539-47a0-a2d7-aa9fbb966fb8. Accessed December 22, 2011.

[4] *U.S. Government Judgments on the Threat of Biological Weapons*. Baltimore, MD: Center for Biosecurity of UPMC. March 2011. Available at http://www.upmc-biosecurity.org/website/resources/publications/2010/pdf/2010-01-19-gov_judgments_BWthreat.pdf. Accessed December 22. 2011.

[5] *National Security Strategy*. Washington, DC: The White House. May 2010. Available at http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf. Accessed December 22. 2011.

[6] *National Strategy for Countering Biological Threats*. Washington, DC: White House, National Security Council. November, 2009. Available at: http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf. Accessed December 22, 2011.

[7] See for example *Strategic Implications of Global Health* (ICA 2008-10D) [Washington, DC: National Intelligence Council; December 2008. Available at: http://www.dni.gov/nic/PDF_GIF_otherprod/ICA_Global_Health_2008.pdf (accessed December 22, 2011)] which assessed that while numerous infectious and noninfectious health conditions can potentially impact U.S. strategic interests, "…for the foreseeable future [infectious diseases] will remain the top health-related threat to U.S. national security…" noting that the U.S. population "…will

Office estimated that in the year following a severe influenza pandemic, U.S. gross domestic product could decline by 4.25 percent, a loss of approximately $645 billion to the U.S. economy in current dollars.[8]

The FDA MCMi: In August 2010, HHS Secretary Sebelius released the results of year-long review of the Enterprise. This review assessed U.S. readiness to reduce the impact of a future public health emergency and improve the nation's capacity to respond quickly and effectively to CBRN and emerging infectious disease threats.[9] The *Enterprise Review* revealed that regulatory uncertainties associated with MCM development are among the most significant obstacles to successful MCM development.[10]

The *Enterprise Review* identified key steps that the Federal government must take to modernize the Enterprise. In particular, the report highlighted how critical FDA is to the success of the Enterprise. The report also called for greater investment in regulatory innovation and MCM regulatory science and for FDA to take an even more active role in fostering the development and facilitating the availability of MCMs.

In response, FDA immediately launched its MCMi to enhance FDA's regulatory processes, to foster clear regulatory pathways for MCMs and to facilitate the timely use of available MCMs. The MCMi is a comprehensive program to address key challenges in three areas:

- enhancing the regulatory review process for the highest priority MCMs and related technologies
- advancing regulatory science for MCM development
- modernizing the regulatory and legal framework.

The FY 2013 investment will contribute to sustaining the MCMi and to protecting the United States from potentially catastrophic CBRN and emerging infectious disease threats. The MCMi is essential to reduce the slow pace of development and reverse the high failure rates associated with MCM development. In addition, the MCMi is essential to helping transform the Enterprise so it can respond faster and more

---

continue to be vulnerable to emerging infectious diseases – many of which will originate overseas (e.g., HIV/AIDS, West Nile, and dengue fever) – including a potential influenza pandemic or an outbreak of a "mystery" disease (e.g., SARS.)"

[8] *A Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues.* Washington, DC, Congressional Budget Office. December 8, 2005; revised July 27, 2006. Available at: http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf. Accessed December 22, 2011.

[9] Sebelius, K., Speech before the American Medical Association Third National Congress on Health System Readiness. Washington, DC: US Department of Health and Human Services; December 1, 2009. http://www.hhs.gov/secretary/speeches/sp20091201.html. Accessed December 22, 2011.

[10] *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf. Accessed December 22, 2011.

nimbly to "…any attack or threat, known or unknown..." as envisioned in the *Enterprise Review*.

3. What has this program accomplished?

Since the announcement of the FDA MCMi in August 2010, FDA and its drug, device and biologics programs have worked aggressively to ensure that the United States has access to high-priority MCMs to respond to CBRN and emerging infectious disease threats, such as pandemic influenza.

MCMi Accomplishments: During its first year, FDA made substantial progress to implement the MCMi using the one-time funding that HHS transferred to FDA. The *MCMi Year 1 Status Report* summarizes FDA's achievements as of September 2011[11] For example, FDA:

- Established Public Health and Security Action Teams for multiplex *in vitro* diagnostic tests and for therapies and diagnostics for acute radiation syndrome
- Launched a rigorous MCM regulatory science program that identified more than 80 intramural research projects for funding
- Sponsored an Institute of Medicine workshop to obtain authoritative guidance for the MCM regulatory science program FDA's regulatory science program for MCMs
- Published a request for information to solicit science recommendations for the extramural component of the MCM regulatory science program
- Established a partnership with the Defense Advanced Research Projects Agency (DARPA) to collaborate on regulatory science research
- Issued an umbrella Emergency Use Authorization (EUA) for doxycycline post-exposure prophylaxis to support pre- and post-event activities for mass distribution and dispensing efforts to address an anthrax event
- Participated in an analysis on the feasibility of expanding the existing shelf-life extension program to include State and local MCM stockpiles
- Hosted a meeting of state and local public health leaders to share information on MCM legal issues related to emergency preparedness and response
- Launched the MCMi professional development program, which includes threat briefings by experts to ensure that FDA reviewers are fully aware of the threats – and therefore the risks – as they conduct risk-benefit analyses on MCM products.

[11] *FDA's Medical Countermeasures Initiative Year-1 Status Report*. Washington, DC: US Food and Drug Administration. September 2011. Available at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM270750.pdf. Accessed December 22, 2011.

Since the release of the *MCMi Year 1 Status Report,* FDA:

- Issued a 5-Year strategic plan for the MCMi[12]
- Launched Public Health and Security Action Teams for warfighter trauma care and to address pediatric, pregnancy, and special population issues
- Held workshops on developing and evaluating next-generation smallpox vaccines and regulating multiplex *in vitro* diagnostic tests
- Held an advisory committee meeting on smallpox drugs
- Published a concept paper on a novel regulatory approach for multiplex diagnostic tests
- Initiated a portfolio review and gap analysis of the intramural MCM regulatory science program to inform future MCM regulatory science investments
- Launched a program to qualify animal models as drug development tools
- Developed legislative proposals to enhance emergency preparedness and response that were submitted to Congress
- Issued an amendment to the EUA for doxycycline emergency kits for United States Postal Service employees who volunteer to support implementing the National Postal Model for emergency response.

MCM Activities Funded with the FY 2012 Appropriation: For FY 2012, Congress appropriated $20,038,000 to provide a base of funding for FDA's MCMi. The FY 2012 appropriation allows FDA to sustain 70 of its 77 MCMi FTE and supports an investment in MCM regulatory science ($327,000).

With FY 2012 funding approved by Congress, FDA will conduct the following MCMi activities:

- Sustain Public Health and Action Teams for warfighter trauma care, acute radiation syndrome, pediatric, pregnancy, and special population issues, and in vitro diagnostics
- Establish a Public Health and Action Team for next-generation assessment of MCM safety and efficacy during public health emergencies
- Finalize analysis of the regulatory gaps associated with the use of stockpiled MCMs to identify data needs to support the continued development of pre-EUA packages, with special focus on at-risk populations such as children
- Provide technical assistance to the developers of the highest-priority MCMs (MCMs procured by the U.S. government) to foster effective development and to support regulatory review

[12] Available at http://www.fda.gov/downloads/EmergencyPreparedness/MedicalCountermeasures/UCM286201.pdf

- Strengthen extramural MCM regulatory science partnerships with NIH and DoD, focusing on tools to assess efficacy, MCM product quality, and advanced diagnostics
- Work with Enterprise partners to fill data needs associated with the development of pre-EUA packages for stockpiled MCMs
- Implement a program to qualify animal models as drug development tools
- Issue revised guidance on *Animal Models—Essential Elements to Address Efficacy Under the Animal Rule*
- Foster MCM development through agreements with Enterprise partners that facilitate MCM collaboration, communication, and information sharing
- Identify and communicate best review practices for interfacing with and supporting MCM sponsors
- Enhance rapid deployment and pre-event planning and positioning of MCMs.

4. What activities will FY 2013 funding support?

With this FY 2013 increase, FDA will support 7 FTE that are performing MCM activities. Currently, FDA is supporting the 7 FTE with the one-time funding allocated to FDA under Public Laws 111-8 and 111-117. The FY 2013 budget increase will allow FDA to sustain its full, current MCMi operating level of 77 FTE and to conduct the following MCMi activities.

A. Medical Countermeasures (+$3,510,000 / 7 FTE)

FDA MCMi Objective 1 – Enhance the Review and Approval Processes for MCMs (+$1,081,000 / 4 FTE)

FDA will operationalize Public Health and Security Action Teams for pediatric, pregnancy, and special population issues and teams for the next-generation assessment of MCM safety and efficacy during public health emergencies.

FDA will foster the development and deployment of MCMs by strengthening its program of technical assistance – including the development of regulatory management plans – for the developers of the highest-priority MCMs. FDA will also ready MCMs for use under an EUA in advance of an emergency.

CDER + $840,000 / 3 FTE
CDRH + $241,000 / 1 FTE

FDA MCM Objective 2 – Advance Regulatory Science for MCM Development and Evaluation (+$1,792,000 / 2 FTE)

FDA will sustain its MCM regulatory science program, relying heavily on partnerships with industry, academia and U.S. government partners that enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. In particular, FDA will focus investments in regulatory science on:

- developing and qualifying tools to assess efficacy, such as animal and biomimetic models
- developing methods to assess product quality and assays to support the release of MCMs
- developing and assessing advanced diagnostic tests
- developing novel manufacturing platforms.

CBER + $252,000 / 1 FTE
CDRH + $241,000 / 1 FTE
FDA HQ +$1,299,000 / 0 FTE

FDA MCM Objective 3 – Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response (+$241,000 / 1 FTE)

FDA will continue to work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response. These efforts include strengthening FDA's program to support rapid deployment and pre-event planning and positioning of MCMs.

CDRH + $241,000 / 1 FTE

B. Rent Activities for Advancing Medical Countermeasures Initiative (+$396,000 / 0 FTE*)*

The $396,000 increase in budget authority will enable FDA to pay GSA Rent and Other Rent and Rent-Related costs for employees supported by the FY 2013 MCMi increase. Funding these rent activities will reduce the need to redirect resources from core, mission-critical public health activities to pay rent costs.

5. How does this initiative support important public health priorities?

The FDA MCMi supports important national security and public health priorities. Through the MCMi, FDA is helping to ensure that Americans have access to the medicines and vaccines they need to counter a deliberate CBRN attack or a naturally occurring epidemic.

The FY 2013 budget request for MCMi supports the need for "rapid and reliable development of medical countermeasures to respond to public health threats," as articulated in the National Security Strategy of 2010. FDA's MCMi will also protect American's health and foster resilience in response to emergencies.

The FY 2013 funding will also help implement FDA priorities articulated in the HHS *Enterprise Review*, released on August 19, 2010.[13] As recommended by the review, FDA will promote MCM development by:

- supporting robust engagement with sponsors and government partners to facilitate the development of critical MCM products
- establishing clear regulatory pathways for developing MCMs
- advancing FDA MCM regulatory science to identify and resolve gaps that prevent successful MCM development and approval
- modernizing the legal, regulatory, and policy framework to foster the application of advances in regulatory science to the regulatory review process and supporting preparedness for and response to CBRN threats and emerging infectious disease threats with through the availability of MCMs.

6. *What are the risks of not proceeding with this initiative?*

Not approving the FY 2013 MCMi budget request poses genuine risks for the health of Americans and the security of the United States:

- The Nation's ability to respond to natural or deliberate infectious disease outbreaks and CBRN threats will remain limited and insufficient.
- FDA will not be able to sustain the MCMi program at the level necessary to support the priorities in the *Enterprise Review*.
- The Federal government will not be able to fulfill its responsibility to protect the nation's health and keep Americans safe during public health emergencies.

[13] *The Public Health Emergency Medical Countermeasures Enterprise Review – Transforming the Enterprise to Meet Long-Range National Needs*. Washington, DC: US Department of Health and Human Services. August 2010. Available at: https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf. Accessed December 22, 2011.

- The United States will not be able to realize the return on the multibillion-dollar investments it has made in biodefense during the past decade.

7. *What will FDA accomplish with the initiative?*

Funding this initiative will support:

- a highly interactive review process for MCMs and related technologies
- a strong FDA workforce with enhanced expertise in CBRN issues
- active FDA engagement and collaboration with Federal MCM partners
- clear, well-defined and appropriate regulatory and scientific plans for HHS' highest priority MCMs
- an MCM regulatory science program to foster MCM development
- an improved legal framework and improved regulatory and policy approaches to MCM development and use
- faster development and availability of MCMs
- a more resilient Nation that is better able to cope with the CBRN and infectious disease threats
- job creation and economic development; every bioscience job creates 5.8 additional jobs
- stronger national security.

FY 2013 Medical Countermeasures Performance Table:

FDA is using FDA-TRACK, our agency-wide performance management system, to track, analyze, and report monthly and quarterly performance measures, progress and accomplishments for FDA's most important initiatives. These initiatives include ongoing efforts as well as new efforts as showcased in the following FY 2013 performance tables. Upon finalization and receipt of the FY 2013 request, FDA will be developing performance measures and/or key project milestones for the funded initiatives. You will find these measures, milestones, and progress on the FDA-TRACK website - www.fda.gov/fdatrack.

The following tables contain performance items associated with this initiative.

Performance Measures	FY 2012 Enacted Performance Level	FY 2013 Performance Level +/- FY 2012 Enacted	Most Recent Actual
Enhance development, evaluation, approval, and surveillance processes for high-priority MCMs and platform technologies; create Public Health and Security Action Teams to analyze processes, identify gaps and hurdles, and propose recommendations for improvement	• Establish Public Health and Action Team for next-generation assessment of MCM safety and efficacy during public health emergencies • Increase technical assistance to the developers of the highest-priority MCMs (i.e., MCMs that have been procured by the US government) to foster effective development and support regulatory review	• Operationalize Public Health and Action Teams for pediatric, pregnancy and special population issues and next-generation assessment of MCM safety and efficacy during public health emergencies • Foster the development and deployment of MCMs by: (1) strengthening its program to provide technical assistance—including the development of regulatory management plans—to the developers of the highest-priority MCMs; and (2) readying MCMs for use under an EUA in advance of an emergency	N/A
Support MCM development and evaluation by establishing regulatory science programs for MCM products based on extramural, collaborative research programs	• Strengthen extramural MCM regulatory science partnerships with NIH and DoD with a focus on tools to assess efficacy, MCM product quality, and advanced diagnostics	• Sustain MCM regulatory science program that relies heavily on partnerships with industry, academia and additional U.S. government partners with a focus on developing tools to assess efficacy, MCM product quality, advanced diagnostics, and novel manufacturing platforms	NA
Modernize the legal, regulatory, and policy framework for efficient preparedness and response by assessing current laws and regulations and proposing changes that will facilitate an efficient response to public health emergencies	• Enhance rapid deployment and pre-event planning and positioning of MCMs	• Strengthen program to support rapid deployment and pre-event planning and positioning of MCMs	NA

FDA Data Consolidation and IT Savings
- $19,706,000 / - 0 FTE

The following table displays the budget authority amounts for Data Consolidation and IT Savings in the FY 2013 President's Budget for each FDA program.

(Dollars in Millions)

Program	FY 2013 Request
Budget Authority:	
Foods	**-$7.651**
Center	-$2.335
Field Activities	-$5.316
Human Drugs	**-$4.222**
Center	-$3.073
Field Activities	-$1.149
Biologics	**-$1.875**
Center	-$1.517
Field Activities	-$0.358
Animal Drugs and Feeds	**-$1.219**
Center	-$0.748
Field Activities	-$0.471
Devices and Radiological Health	**-$2.851**
Center	-$2.133
Field Activities	-$0.718
National Center for Toxicological Research	**-$0.530**
FDA Headquarters	**-$1.358**
TOTAL Budget Authority, Salaries and Expenses	**-$19.706**

1. Initiative Summary:

FDA made significant progress in recent years consolidating into two modern data center facilities. During the consolidation, FDA modernized and standardized its hardware and software infrastructure. This effort provides an internal cloud computing environment that reduces FDA's costs for environment setup and support, and provides agility not previously possible. In addition, FDA has established new operational procedures and processes to achieve greater consistency and standardization.

Data Consolidation and IT Savings

Through virtualization, FDA achieves savings and reduces its physical server footprint. The result has been savings in power consumption costs and virtualization that allows FDA to use equipment and support resources more efficiently. FDA's new data centers already meet or exceed all 2012 and 2013 Executive Orders and HHS green computing, consolidation, cloud computing and virtualization objectives.

This modernization and consolidation was the first step to begin the information technology transformation at FDA. With these changes in FY 2013, FDA will realize data center operation management and service contract savings as well as savings through consolidating software systems with similar business processes. These changes will also expedite the retirement of legacy systems. Under this initiative, FDA will achieve savings that meet the requirements of Executive Orders 13589 (Promoting Efficient Spending) and 13514 (Federal Leadership in Environmental, Energy, and Economic Performance).

2. How will FDA achieve Data Consolidation and IT Savings?

FDA will achieve Data Consolidation and IT Savings on an enterprise-wide and center-specific basis.

A. FDA enterprise-wide savings (-$11,104,000 / 0 FTE)

Data Center Contract Support Consolidation – FDA has successfully reduced the number of data centers through years of data center consolidation. The remaining two primary consolidated data centers are currently managed by two distinct service providers. Consolidating the operations support of these two data centers will achieve operational and process efficiencies by:

- eliminating redundant contractor management teams
- standardizing the code promotion and release processes
- achieving economies of scale from the consolidation of 24/7/365 network and server operations support teams.

The data center and contract support consolidations address the findings identified in the November 2007 FDA Science Board Report “FDA Science and Mission at Risk” and the June 2009 “GAO Report on FDA Information Technology.” The consolidations also meet or exceed the goals outlined in Executive Order 13514 and the HHS Green Computing and Consolidation objectives.

Reducing Redundant IT Devices – To comply with Executive Orders 13589 and 13514, FDA will reduce the number of redundant IT devices. This initiative, with the appropriate health and safety exceptions, will achieve efficiencies by:

- reducing device costs, including hardware, software licenses, and maintenance
- reducing helpdesk and desktop support costs.

B. Center-specific savings (-$8,602,000 / 0 FTE):

The Center for Food Safety and Applied Nutrition will achieve savings by:

- delaying or forgoing planned investments related to data transmission improvement infrastructure
- maximizing the use of local storage and minimize peak hour transmission of large files across the network to reduce the data transmission volume of the existing telecommunication infrastructure.

The Center for Drug Evaluation and Research will achieve savings by:

- consolidating analysis initiatives and streamlining existing databases to improve efficiency.

The Center for Biologics Evaluation and Research will achieve savings by:

- reducing expenditures by moving to a centralized data management model
- streamlining IT implementation of similar business processes and expediting the retirement of legacy systems.

The Center for Veterinary Medicine will achieve savings by:

- reengineering business processes to maximize the efficiency of supporting processes, including the systems development process.

The Center for Devices and Radiological Health will achieve savings by:

- implementing strategic reductions of process submission enhancements to CDRH e-submission systems
- implementing strategic reductions of support and planned improvements to CDRH systems.

Data Consolidation and IT Savings

The Office of Regulatory Affairs will achieve savings by:

- streamlining user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance Services (MARCS) program, and providing the support architecture for other integrated systems.
- economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems.

The National Center for Toxicological Research will achieve savings by:

- promoting efficiency through consolidation of responsibilities and duties within the current IT Contract to realize cost savings.
- maximizing virtualization to achieve further cost efficiencies, while increasing uptime and providing faster server provisioning

FDA Headquarters will achieve savings by:

- consolidating FDA-wide enterprise data center contract support and reducing redundant IT devices.

Data Consolidation and IT Savings

FDA Current Law User Fees
+$59,295,000 / 196 FTE

1. Why is this funding necessary? FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices and reviews of other products that FDA regulates. User fees also allow FDA programs to achieve enhanced premarket review performance. Finally, fees support the programs and operations of the FDA Center for Tobacco Products.

Existing user fee laws authorize user fee increases for many of the FDA user fee programs. The authorized increases expand the available options for treating and curing diseases and addressing other important public health needs.

The following table displays funding for FY 2011 through FY 2013 for FDA current law user fees:

FDA Program Resources Table
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
PDUFA [1]	$667,057	$627,826	$702,172	$712,808	$10,636
Tobacco	$450,000	$145,213	$477,000	$505,000	$28,000
MDUFA	$61,860	$59,257	$57,605	$69,700	$12,095
ADUFA	$19,448	$16,633	$21,768	$30,530	$8,762
Food Reinspection	$0	$0	$14,700	$15,367	$667
Recall	$0	$0	$12,364	$12,925	$561
AGDUFA	$5,397	$4,686	$5,706	$7,595	$1,889
MQSA	$19,318	$14,639	$19,318	$19,318	$0
Color Certification	$7,700	$7,843	$7,843	$7,843	$0
Export Certification	$2,700	$3,337	$3,337	$4,604	$1,267
Voluntary Qualified Importer Program	$0	$0	$0	$0	$0
Priority Review Voucher			$4,582	$0	-$4,582
	$1,233,480	**$879,434**	**$1,326,395**	**$1,385,690**	**$59,295**

[1] Legislation to reauthorize PDUFA and establish new generic drug and biosimilar user fees were transmitted to Congress on January 13, 2012. PDUFA estimates for FY 2013 are preliminary and subject to further refinements.

2. What activities will the funds support?

PDUFA: +$10,636,000 / 12 FTE

In the FDA Amendments Act of 2007 (FDAAA), Congress renewed FDA's authority to collect the Prescription Drug User Fee Act (PDUFA) user fees. The authority to collect PDUFA fees is effective for five years. PDUFA expires October 1, 2012. On January 13, 2012, the Administration transmitted a legislative proposal to Congress to reauthorize PDUFA that is consistent with FDA discussions with industry and other stakeholders.

PDUFA directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA.

The requested increase of $10,636,000, for a total FY 2013 fee collection of $712,808,000, is based on the legislative proposals that the Administration is submitting to Congress to reauthorize PDUFA.

The following table displays funding for FY 2011 through FY 2013 for PDUFA.

PDUFA Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CDER	$469,559	$465,675	$490,877	$501,334	$10,457
CBER	$96,624	$79,746	$101,010	$103,163	$2,153
Field Activities	$13,608	$8,187	$14,225	$14,528	$303
FDA Headquarters (HQ)	$40,693	$28,982	$42,541	$43,447	$906
White Oak Consolidation	$3,415	$3,415	$3,595	$3,637	$42
GSA Rent and Rent Related	$43,158	$41,821	$49,924	$46,699	-$3,225
Total	**$667,057**	**$627,826**	**$702,172**	**$712,808**	**$10,636**

Tobacco Act Program: +$28,000,000 / 120 FTE

On June 22, 2009 the President signed H.R. 1256, the Family Smoking Prevention and Tobacco Control Act (the Act), into law. The Act grants FDA important new authority to regulate manufacturing, marketing and distribution of tobacco products.

The increase in tobacco user fees will allow FDA to continue to implement the Family Smoking and Prevention and Tobacco Control Act. Priority activities include:

- preventing youth from using tobacco and helping Americans quit
- promoting public understanding of the harmful constituents of tobacco products
- developing the foundation of science for regulating tobacco
- regulating tobacco to reduce the toll of tobacco-related disease, disability and mortality.

The following table displays funding for FY 2011 through FY 2013 for the Tobacco Program:

Tobacco Act Program Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CTP	$415,567	$134,145	$448,501	$472,998	$24,497
Field Activities	$5,896	$1,563	$6,250	$9,400	$3,150
FDA Headquarters (HQ)	$14,336	$3,327	$15,196	$15,196	$0
GSA Rent and Rent Related	$14,201	$6,178	$7,053	$7,406	$353
Total	**$450,000**	**$145,213**	**$477,000**	**$505,000**	**$28,000**

MDUFA: +$12,095,000 / 52 FTE

In FDAAA, Congress renewed FDA's authority to collect user fees under the Medical Device User Fee Act (MDUFA). This authority is effective for five years and directs FDA to improve the quality and timeliness of medical device review. The authority to collect fees under MDUFA expires on October 1, 2012. The Administration will transmit a proposal to Congress to reauthorize MDUFA authority for FY 2013. MDUFA provides funds to:

- ensure a sound financial footing for medical device review
- enhance the process for premarket review
- modify the third party inspection program.

MDUFA authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers who submit premarket applications and premarket notifications and annual registration fees from certain device establishments.

The terms of legislation to reauthorize MDUFA are currently under discussion. The increase of $12,095,000, for a total FY 2013 fee collection of $69,700,000, assumes that the authorities in effect for MDUFA continue in FY 2013. FDA will likely need to modify its budget request when Congress reauthorizes MDUFA and establishes new fee levels.

The following table displays funding for FY 2011 through FY 2013 for MDUFA:

MDUFA Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CBER	$ 12,009	$ 8,342	$ 11,183	$ 13,515	$ 2,332
CDRH	$ 35,627	$ 40,370	$ 33,177	$ 40,093	$ 6,916
Field Activities	$ 1,688	$ 2,009	$ 1,572	$ 1,900	$ 328
FDA Headquarters (HQ)	$6,417	$ 3,795	$5,975	$7,221	$1,246
GSA Rent and Rent Related	$6,119	$ 4,741	$5,698	$6,971	$1,273
Total	**$61,860**	**$59,257**	**$57,605**	**$69,700**	**$12,095**

ADUFA: +$8,762,000 / 0 FTE

In the Animal Drug User Fee Amendments of 2008 (ADUFA), Congress renewed FDA's authority to collect user fees for five years. ADUFA directs FDA to expedite the development of animal drugs and improve the quality and efficiency of animal drug review. ADUFA fees help ensure that FDA regulated animal drug products are safe and effective and are readily available for companion animals and animals intended for the food supply.

ADUFA contributes to a cost-efficient, high quality animal drug review process that is predictable and performance driven. The authority to collect ADUFA user fees expires on September 30, 2013. Therefore, as authorized by Section 740(c)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-12(c)(3)], the FY 2013 ADUFA budget includes a final year adjustment to assure the availability of three months of user fee revenue.

The following table displays funding for FY 2011 through FY 2013 for ADUFA:

ADUFA Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CVM	$17,209	$14,992	$19,261	$26,996	$7,735
Field Activities	$281	$277	$315	$464	$149
FDA Headquarters (HQ)	$780	$651	$873	$1,224	$351
GSA Rent and Rent Related	$1,178	$713	$1,319	$1,846	$527
Total	**$19,448**	**$16,633**	**$21,768**	**$30,530**	**$8,762**

FDA Current Law User Fees

Food Reinspection: +$667,000 / 0 FTE

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foreign and domestic foods and animal feed facilities to assess their compliance with Good Manufacturing Practice requirements and other standards. Revenue from the Food and Fees Reinspection User Fee will reimburse ORA and other FDA offices for costs associated with FTE and related expenses required to reinspect firms that fail to comply with FDA regulations designed to protect Americans from unsafe food and feed products.

The following table displays funding for FY 2011 through FY 2013 for Food Reinspection:

Food Reinspection Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
Foods Field	$0	$0	$6,825	$7,134	$309
Animal Drugs & Feeds Field	$0	$0	$2,550	$2,666	$116
FDA Headquarters (HQ)	$0	$0	$3,395	$3,549	$154
GSA Rent and Rent Related	$0	$0	$1,930	$2,018	$88
Total	**$0**	**$0**	**$14,700**	**$15,367**	**$667**

Recall Fees: +$561,000 / 0 FTE

Recall fees reimburse FDA for the cost of conducting a mandatory recall of an article of food that is adulterated or misbranded. These mandatory recalls, also known as Class I recalls, involve circumstances when the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

The following table displays funding for FY 2011 through FY 2013 for Recall Fees:

Recall Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CFSAN	$0	$0	$464	$485	$21
Foods Field	$0	$0	$9,397	$9,823	$426
CVM	$0	$0	$521	$545	$24
Animal Drugs & Feeds Field	$0	$0	$639	$668	$29
FDA Headquarters (HQ)	$0	$0	$661	$691	$30
GSA Rent and Rent Related	$0	$0	$682	$713	$31
Total	**$0**	**$0**	**$12,364**	**$12,925**	**$561**

FDA Current Law User Fees

AGDUFA: +$1,889,000 / 0 FTE

In the Animal Generic Drug User Fee Act of 2008 (AGDUFA), Congress provided FDA new authority to collect user fees to support the review of Abbreviated New Animal Drug Applications (ANADA) and related submissions. This authority, effective for five years, directs FDA to expedite the development of generic animal drugs and improve the quality and efficiency of generic animal drug review.

AGDUFA enhances the performance of the generic new animal drug review process, enables FDA to better ensure that generic new animal drug products are safe and effective, and provides access to lower cost alternatives to pioneer drugs.

Following the ADUFA model, AGDUFA provides funding to train and develop review staff. AGDUFA also provides funding to refine business processes and develop policies targeted to achieve more efficient review. The authority to collect AGDUFA user fees expires on September 30, 2013. Therefore, as authorized by Section 741(c)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j-21(c)(2)], the FY 2013 AGDUFA budget includes a final year adjustment to assure the availability of three months of user fee revenue.

The following table displays funding for FY 2011 through FY 2013 for AGDUFA:

AGDUFA Increase for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CVM	$4,632	$4,326	$4,898	$6,527	$1,629
Field Activities	$151	$151	$160	$211	$51
FDA Headquarters (HQ)	$216	$165	$228	$304	$76
GSA Rent and Rent Related	$398	$44	$420	$553	$133
Total	**$5,397**	**$4,686**	**$5,706**	**$7,595**	**$1,889**

MQSA: +$0 / +5 FTE

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography.

Congress enacted MQSA to ensure that all women have access to quality mammography to detect breast cancer in its earliest, most treatable stages. MQSA required that FDA certify mammography facilities and inspect facilities annually to ensure compliance with national quality and safety standards. The MQSA program supports FDA's strategic goal of reducing the risk of medical devices and radiation

emitting products on the market by assuring product quality and correcting problems associated with their production and use.

MQSA directs FDA to assess, collect, and use fees to cover the costs of MQSA inspections, record keeping, and annual reports. In FY 2013, FDA estimates the same funding level as in FY 2012.

The following table displays funding for FY 2011 through FY 2013 for MQSA:

MQSA Funding for FY 2013
(Dollars in thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
CDRH	$6,003	$4,912	$6,003	$6,003	$0
Field Activities	$13,077	$9,459	$13,077	$13,077	$0
FDA Headquarters (HQ)	$238	$268	$238	$238	$0
Total	**$19,318**	**$14,639**	**$19,318**	**$19,318**	**$0**

Color Certification: No change

The Federal Food, Drug and Cosmetic Act (FFD&C) requires the certification of color additives. This program, which is administered by FDA's Center for Food Safety and Applied Nutrition, involves assessing the quality and safety of color additives used in foods, drugs, and cosmetics. The Color Certification Fees paid by firms contribute to the FDA Revolving Fund for Certification and Other Services, which pays the cost of salaries and expenses of employees who conduct color certifications. FDA is estimating the same funding level in FY 2013 as in FY 2012.

The following table displays funding for FY 2011 through FY 2013 for MQSA:

Color Certification Funding for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
	$7,700	$7,843	$7,843	$7,843	$0
Total	**$7,700**	**$7,843**	**$7,843**	**$7,843**	**$0**

Export Certification: +$1,267,000 / 7 FTE

FDA is required to issue certificates for the export of food, human drugs, animal drugs, animal feed, and devices. The certificates state that the product meets certain requirements of law. The purpose of the certificates is to promote the export of products made in the United States and to facilitate international trade. FDA's ability to issue certificates in a timely fashion depends on FDA securing the resources necessary

to offset the costs associated with issuing export certificates. For FY 2013, FDA is estimating a funding level that is $1,267,000 and 7 FTE above the FY 2012 level.

The following table displays funding for FY 2011 through FY 2013 for Export Certification:

Export Certification Funding for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
	$2,700	$3,337	$3,337	$4,604	$1,267
Total	**$2,700**	**$3,337**	**$3,337**	**$4,604**	**$1,267**

Voluntary Qualified Importer Program (VQIP): +$0 / 0 FTE

The VQIP user fee supports important food safety priorities by allowing FDA to expedite imports of food that meets safety standards and other requirements. The VQIP user fee will help ensure that foods are safe, thereby allowing FDA to focus other resources on foods that have a higher risk of causing illness or could have other adverse public health consequences.

FDA anticipates that the VQIP program will be operational in FY 2014. FDA continues to develop VQIP as authorized by the Food Safety Modernization Act (FSMA). VQIP establishes a formalized voluntary program for importers to submit evidence attesting that the food complies with applicable food safety guidelines in return for expedited review of entries.

VQIP will require manufacturing facilities to be certified and allows FDA to review specific manufacturer and product information. FDA must complete the design of the program and establish criteria that importers must meet to participate in VQIP.

In addition, FDA is in the process of establishing guidance documents and updating all appropriate manuals and documents. FDA must also meet with industry and other Government agencies to brief them on VQIP and harmonize with existing initiatives like Custom and Border Protection's Customs Trade Partnership Against Terrorism (CTPAT) and Importers Self Assessment (ISA) programs.

Priority Review Voucher: -$4,582,000 / 0 FTE

The Food and Drug Administration Amendments Act of 2007 (FDAAA) established the priority review voucher program to encourage the development of treatments for tropical diseases. A priority review voucher (PRV) is issued to sponsors of approved applications for products to treat certain tropical diseases. The voucher entitles the holder to priority review for a subsequent human drug or biological product application.

FDA Current Law User Fees

The user fee submitted when a PRV application is paid, is in addition to any other fee due under PDUFA. Submissions under the PRV user fee program have been infrequent to date. FDA received one submission and a fee of $4,582,000 in FY 2011. FDA plans to obligate the funds in FY 2012. The program requires a sponsor to notify FDA of its intent to submit a PRV application 365 days prior to the submission. No sponsor notified FDA of plans to submit a PRV application in FY 2012, and FDA has not yet received a notification for FY 2013. Therefore, FDA does not anticipate receiving PRV fees in FY 2012 or FY 2013.

Priority Review Voucher User Fee Funding for FY 2013
(Dollars in Thousands)

Program	FY 2011 Enacted	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
	$0	$0	$4,582	$0	-$4,582
Total	**$0**	**$0**	**$4,582**	**$0**	**-$4,582**

3. How does this initiative support important public health priorities?

FDA user fee programs address a key priority of assuring the safety of essential food and medical products that benefit the health of Americans and the nation's animal population. User fee increases will also fund strategies to reduce the burden of illness and death caused by tobacco products.

The new Food and Feed Reinspection User Fee supports FDA efforts to assure the safety and security of the supply of food and feed. Revenue from the user fee will reimburse FDA for costs associated with reinspections of firms that fail to comply with FDA regulations designed to protect Americans from unsafe products.

The new Recall User Fee supports public health priorities by providing resources to FDA to conduct and oversee Class I recalls. FDA assesses these fees when the manufacturer or distributer of the recalled product does not voluntarily remove the harmful product from public distribution. These fees support FDA efforts to eliminate the possibility of the product causing serious adverse health consequences or death.

4. What are the risks of not proceeding with this initiative?

If FDA does not receive the additional user fee resources authorized by law, then the loss of these fees will have the following consequences for the health of Americans and the U.S. animal population:

- FDA will fail to meet the performance commitments for faster medical device review (MDUFA), faster human drug (PDUFA) and new and generic animal drug review (ADUFA and AGDUFA). The performance commitments are designed to ensure that FDA provides the public with earlier access to safe and effective

medical products, thereby saving lives, relieving suffering, and improving the quality of life.

- FDA cannot increase the availability of its experts to expand and improve consultation and outreach to industry and to reduce medical product development time.
- Rather than concentrate efforts on food safety activities to prevent unsafe products from reaching the U.S. market, FDA will have to spend budget authority to remove harmful products from public distribution rather than impose these costs on the manufacturer or distributor (Recall User Fees).
- FDA will have to pay the cost of conducting reinspections of firms that fail to comply with safety standards for food and feed rather than concentrate its resources on other activities that support the health of the American public (Reinspection User Fees).
- FDA will have to divert resources to attest to the safety of food and feed products destined for export rather than having the exporter pay these costs (Export Certification Fees).
- FDA cannot adequately develop and implement effective public health strategies to reduce the burden of illness and death caused by tobacco products (Tobacco fees).
- FDA cannot adequately sustain patient access to safe and effective new products and cannot provide rapid, transparent, and predictable review of medical product applications.
- FDA cannot maximize safe and effective use of medical products by communicating benefits and risks more effectively.
- FDA cannot prevent harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response.

5. What will FDA accomplish with the initiative?

Providing the user fee increases authorized by statute will help FDA meet performance commitments in FY 2013 and future years. This initiative benefits more than 300 million Americans, plus countless international consumers who also benefit from U.S. leadership in medical product safety and security. This initiative also offers special benefits for American pet owners, farm and ranch operations, and other animal enterprises.

Recently authorized user fees that reimburse FDA costs will allow FDA to better use appropriated resources to target high-risk products and reduce the amount of unsafe foods and the number of adverse public health events. Recall user fees will provide FDA with the resources to remove harmful foods from public distribution where the manufacturer or distributor of those foods refuses to do so voluntarily.

FDA Current Law User Fees

TITLE IV
RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding section 521 of Public Law 107–188; [$3,788,336,000] *$3,083,408,000*: Provided, That of the amount provided under this heading, [[$702,172,000] shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, shall be credited to this account and remain available until expended, and shall not include any fees pursuant to 21 U.S.C.379h(a)(2) and (a)(3) assessed for fiscal year 2013 but collected in fiscal year [2012] *2013*; [$57,605,000] shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; [$21,768,000]] *$30,530,000* shall be derived from animal drug user fees authorized by section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12), and shall be credited to this account and remain available until expended; [$5,706,000] *$7,595,000* shall be derived from animal generic drug user fees authorized by section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21), and shall be credited to this account and shall remain available until expended; [$477,000,000] *$505,000,000* shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s and shall be credited to this account and remain available

until expended; [$12,364,000] *$12,925,000* shall be derived from food and feed recall fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act [(Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353)] *(21 USC 379j–31)*, and shall be credited to this account and remain available until expended; [$14,700,000] *$15,367,000* shall be derived from food reinspection fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act [(Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353)] *(21 USC 379j–31)*, and shall be credited to this account and remain available until expended; and amounts derived from voluntary qualified importer program fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75–717), as amended by the Food Safety Modernization Act (Public Law 111–353*)(21 USC 379j-31)*, and shall be credited to this account and remain available until expended: *Provided further*, That in addition and notwithstanding any other provision under this heading, amounts collected for [prescription drug,] *animal drug user fees and animal generic drug user fees* that exceed the *respective* fiscal year [2012] *2013* limitations are appropriated and shall be credited to this account and remain available until expended: *Provided further*, That fees derived from [prescription drug, medical device,] animal drug[,] *and* animal generic drug [, and tobacco product] assessments for fiscal year [2012] *2013* received during fiscal year [2012] *2013*, including any such fees assessed prior to fiscal year [2012] *2013* but credited for fiscal year [2012] *2013*, shall be subject to the fiscal year [2012] *2013* limitations: *Provided further*, That [none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided further, That of the total amount appropriated: (1) $882,747,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $978,705,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory

Affairs, of which no less than $52,947,000 shall be available for the Office of Generic Drugs; (3) $329,136,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $166,365,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $356,909,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $60,039,000 shall be for the National Center for Toxicological Research; (7) $454,751,000 shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) not to exceed $131,639,000 shall be for Rent and Related activities, of which $43,981,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9) not to exceed $205,472,000 shall be for payments to the General Services Administration for rent; and (10) $222,573,000 shall be for other activities, including the Office of the Commissioner of Food and Drugs, the Office of Foods, the Office of Medical and Tobacco Products, the Office of Global and Regulatory Policy, the Office of Operations, the Office of the Chief Scientist, and central services for these offices:] *the Secretary may, prior to the due date for such fees, accept payment of animal drug user fees and animal generic drug user fees authorized for fiscal year 2014, and that amounts of such fees assessed for fiscal year 2014 for which the Secretary accepts payment in fiscal year 2013 shall not be included in amounts provided under this heading: Provided further*, That not to exceed $25,000 of this amount shall be for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner [: *Provided further*, That funds may be transferred from one specified activity to another with the prior approval of the Committees on Appropriations of both Houses of Congress.]

In addition, mammography user fees authorized by 42 U.S.C.263b, export certification user fees authorized by 21 U.S.C. 381, and priority review user fees

authorized by 21 U.S.C. 360n may be credited to this account, to remain available until expended.

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, [$8,788,000] *$5,320,000* to remain available until expended.

SALARIES AND EXPENSES

Contingent upon the enactment of legislation authorizing user fees with respect to biosimilar biological products and human generic drugs, such fees shall be credited to this account and remain available until expended: Provided, That, with respect to such fees authorized for fiscal year 2014, the Secretary may, prior to the due date for such fees, accept payment of such fees and such payments shall be credited to this account for fiscal year 2014.

In addition, contingent upon the enactment of legislation authorizing user fees with respect to food inspections and food facility registrations, food contact notification activities, reinspection of medical product facilities, cosmetic activities, and international express courier import activities, such fees shall be credited to this account and remain available until expended.

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for prescription drug review activities and medical device review activities: Provided, That fees of $712,808,000, for prescription drug reviews, shall be credited to this account and remain available until expended; and $69,700,000,

for medical device reviews, shall be credited to this account and remain available until expended: Provided further, That, in addition and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees and medical device user fees that exceed the respective fiscal year 2013 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug reviews and medical device reviews for fiscal year 2013 received during fiscal year 2013, including any such fees assessed prior to fiscal year 2013 but credited to fiscal year 2013, shall be subject to the fiscal year 2013 limitations: Provided further, That the Secretary may, prior to the due date for such fees, accept payment of prescription drug user fees and medical device user fees authorized for fiscal year 2014, and that amounts of such fees assessed for fiscal year 2014 for which the Secretary accepts payment in fiscal year 2013 shall not be included in amounts provided under this heading.

Language Provision	Explanation
Generic Drug Review User Fee	The Administration will propose legislation to allow FDA to collect fees to support generic drug review. The additional resources, estimated at $299,000,000 in 2013, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Reinspection of Medical Product Facilities	The Administration will propose legislation to allow FDA to collect fees for reinspection of medical product facilities. The additional resources, estimated at $14,746,000 will enable FDA to reinspect medical product facilities which is vital for ensuring compliance with prior inspections.
Biosimilar User Fees	The Administration will propose legislation to allow FDA to collect fees for approving biosimiars. The additional resources, estimated at $20,242,000, will enable FDA to establish a regulatory path for approving biosimilars.
Food Inspection and Facility Registration User Fee	The Administration will propose legislation to allow FDA to collect fees to register food facilities and conduct safety and good manufacturing practices (GMP) inspections of food manufacturing and processing facilities. The additional resources, estimated at $220,200,000, will enable FDA to conduct activities that are necessary for the safety and security of the supply chain for foods.
International Courier User Fee	The Administration will propose legislation to allow FDA to collect fees for international couriers. The additional resources are estimated at $5,580,000.
Cosmetic User Fee	The Administration will propose legislation to allow FDA to collect fees for cosmetic safety. The additional resources, estimated at $18,698,000, will allow FDA to establish and maintain a Cosmetic Registration Program.
Food Contact Notification User Fee	The Administration will propose legislation to allow FDA to collect fees for food contact and notification. The additional resources, estimated at $4,901,000, will support FDA's efficient and timely review of food contact notifications.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

Food and Drug Administration
FY 2013 Exhibit for Congressional Appropriations
Dollars in Thousands

PROGRAM	BUDGET AUTHORITY																	
	FY 2012 Enacted		Changes from FY 2012												Total Budget Authority Changes		FY 2013 Budget Authority	
			Rent and Infrastructure		Pay Increase (Commissioned Corps)	Safety Inspections in China		Advancing Medical Countermeasures		Life Sciences--Biodefense Laboratory Complex		Rent Absorption		Data Consolidation / IT Savings				
	FTE	*$000*	*FTE*	*$000*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*
Foods	**3,684**	**866,061**	**0**	**0**	**588**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-3,759**	**0**	**-7,651**	**0**	**-10,822**	**3,684**	**855,239**
CFSAN	*931*	*264,296*			*178*							*0*	*-950*	*0*	*-2,335*	*0*	*-3,107*	*931*	*261,189*
Field Activities	*2,753*	*601,765*			*410*							*0*	*-2,809*	*0*	*-5,316*	*0*	*-7,715*	*2,753*	*594,050*
Human Drugs	**2,040**	**477,810**	**0**	**0**	**336**	**0**	**0**	**3**	**840**	**0**	**0**	**0**	**-2,081**	**0**	**-4,221**	**3**	**-5,127**	**2,043**	**472,683**
CDER	*1,301*	*347,817*			*243*			*3*	*840*			*0*	*-1,327*	*0*	*-3,073*	*3*	*-3,317*	*1,304*	*344,500*
Field Activities	*739*	*129,993*			*92*							*0*	*-754*	*0*	*-1,149*	*0*	*-1,810*	*739*	*128,183*
Biologics	**905**	**212,224**	**0**	**0**	**149**	**0**	**0**	**1**	**252**	**0**	**0**	**-4**	**-923**	**0**	**-1,875**	**-3**	**-2,397**	**902**	**209,827**
CBER	*672*	*171,711*			*120*			*1*	*252*			*-4*	*-685*	*0*	*-1,517*	*-3*	*-1,830*	*669*	*169,881*
Field Activities	*233*	*40,513*			*28*							*0*	*-238*	*0*	*-358*	*0*	*-568*	*233*	*39,945*
Animal Drugs & Feeds	**710**	**138,021**	**0**	**0**	**98**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-725**	**0**	**-1,219**	**0**	**-1,846**	**710**	**136,175**
CVM	*420*	*84,699*			*60*							*0*	*-429*	*0*	*-748*	*0*	*-1,117*	*420*	*83,582*
Field Activities	*290*	*53,322*			*38*							*0*	*-296*	*0*	*-471*	*0*	*-729*	*290*	*52,593*
Device & Radiological Products	**1,611**	**322,672**	**0**	**0**	**227**	**0**	**0**	**3**	**723**	**0**	**0**	**-8**	**-1,644**	**0**	**-2,851**	**-5**	**-3,545**	**1,606**	**319,127**
CDRH	*1,139*	*241,475*			*169*			*3*	*723*			*-8*	*-1,162*	*0*	*-2,133*	*-5*	*-2,403*	*1,134*	*239,072*
Field Activities	*472*	*81,197*			*57*							*0*	*-481*	*0*	*-717*	*0*	*-1,142*	*472*	*80,055*
NCTR	**272**	**60,039**	**0**	**0**	**0**							**-2**	**-277**	**0**	**-530**	**-2**	**-808**	**270**	**59,231**
Center for Tobacco Products	**0**	**0**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
CTP		*0*			**0**											**0**	**0**	*0*	*0*
Field Activities		*0*			**0**											**0**	**0**	*0*	*0*
Other Activities	**706**	**153,704**	**0**	**0**	**105**	**19**	**10,000**	**0**	**1,299**			**0**	**-720**	**0**	**-1,358**	**19**	**9,326**	**725**	**163,030**
Office of Regulatory Affairs [Non-Add]	***4,487***	***906,790***	***0***	***0***	***626***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***-4,579***	***0***	***-8,011***	***0***	***-11,964***	***4,487***	***894,826***
White Oak Consolidation		**40,386**		**0**	**0**		**0**		**0**	*0*	**17,658**					*0*	**17,658**	**0**	**58,044**
Other Rent & Rent-Related		**65,598**		**582**	**0**		**0**		**144**				**2,937**		**0**	**0**	**3,663**	**0**	**69,261**
GSA Rent		**160,506**		**1,424**	**0**		**0**		**252**				**7,192**		**0**	**0**	**8,868**	**0**	**169,374**
															0				
Salaries & Expenses Increases	**9,927**	**2,497,021**	**0**	**2,006**	**1,502**	**19**	**10,000**	**7**	**3,510**	**0**	**17,658**	**-14**	**0**	**0**	**-19,706**	**12**	**14,970**	**9,939**	**2,511,991**
Non-Field	*5,440*	*1,323,741*	*0*	*0*	*876*	*19*	*10,000*	*7*	*3,114*	*0*	*0*	*-14*	*-5,550*	*0*	*-11,695*	*12*	*-3,255*	*5,452*	*1,320,486*
Field	*4,487*	*906,790*	*0*	*0*	*626*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*-4,579*	*0*	*-8,011*	*0*	*-11,964*	*4,487*	*894,826*
Rents		*266,490*		*2,006*	*0*		*0*		*396*		*17,658*		*10,129*		*0*	*0*	*30,189*		*296,679*
Buildings and Facilities		**8,788**		**-3,468**	**0**											**0**	**-3,468**	**0**	**5,320**
Total	**9,927**	**2,505,809**	**0**	**-1,462**	**1,502**	**19**	**10,000**	**7**	**3,510**	**0**	**17,658**	**-14**	**0**	**0**	**-19,706**	**12**	**11,502**	**9,939**	**2,517,311**

Food and Drug Administration
FY 2013 Exhibit for Congressional Appropriations
Dollars in Thousands

USER FEES														PROPOSED USER FEES												PROGRAM LEVEL	
PDUFA		MDUFMA		ADUFA		AGDUFA		Tobacco Product Fees		Food Reinspection Fees		Food Recall Fees		Generic Drug User Fee (GDUFA)		Medical Products Reinspection User Fee		International Courier User Fee		Food Establishment Registration Fee		Cosmetics User Fee		Food Contact Notification User Fee		Biosimilar User Fee		FY 2013 TOTAL Program Level	
FTE	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*	*FTE*	*$000*
0	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**48**	**7,134**	**25**	**10,308**	**0**	**0**	**0**	**0**	**3**	**721**	**220**	**189,747**	**60**	**16,332**	**7**	**4,458**	**0**	**0**	**4,047**	**1,083,939**
												2	*485*							*100*	*89,478*	*42*	*12,012*	*7*	*4,458*			*1,082*	*367,622*
										48	*7,134*	*23*	*9,823*					*3*	*721*	*120*	*100,269*	*18*	*4,320*	*0*	*0*			*2,965*	*716,317*
2,041	**511,565**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**400**	**254,542**	**18**	**2,749**	**2**	**481**	**0**	**0**	**0**	**0**	**0**	**0**	**64**	**16,594**	**4,568**	**1,258,614**
1,990	*501,334*													*250*	*202,731*													*3,603*	*1,063,869*
51	*10,231*													*150*	*51,811*	*18*	*2,749*	*2*	*481*							*5*	*1,290*	*965*	*194,745*
372	**107,460**	**37**	**14,134**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**561**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**774**	**1,317**	**332,756**
367	*103,163*	*36*	*13,515*																							*3*	*774*	*1,074*	*287,333*
5	*4,297*	*1*	*619*													*3*	*561*									*0*	*0*	*242*	*45,422*
0	**0**	**0**	**0**	**68**	**27,460**	**21**	**6,738**	**0**	**0**	**18**	**2,666**	**4**	**1,213**	**0**	**0**	**1**	**140**	**0**	**0**	**21**	**9,507**	**0**	**0**	**0**	**0**	**0**	**0**	**843**	**183,899**
				66	*26,996*	*20*	*6,527*			*0*	*0*	*2*	*545*							*11*	*5,702*							*519*	*123,352*
				2	*464*	*1*	*211*			*18*	*2,666*	*2*	*668*			*1*	*140*			*10*	*3,805*							*324*	*60,547*
0	**0**	**260**	**41,374**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**3,579**	**15**	**3,606**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1,905**	**367,686**
		248	*40,093*																									*1,382*	*279,165*
		12	*1,281*													*24*	*3,579*	*15*	*3,606*									*523*	*88,521*
																												270	*59,231*
								512	**482,398**	**0**	**0**	**0**	**0**															**512**	**482,398**
								471	**472,998**																			*471*	*472,998*
								41	*9,400*																			*41*	*9,400*
186	**43,447**	**26**	**7,221**	**4**	**1,224**	**1**	**304**	**34**	**15,196**	**7**	**3,549**	**2**	**691**	**50**	**24,196**	**10**	**6,169**	**1**	**289**	**32**	**12,544**	**3**	**980**	**1**	**267**	**5**	**1,290**	*1,087*	*280,397*
56	***14,528***	***13***	***1,900***	***2***	***464***	***1***	***211***	***41***	***9,400***	***66***	***9,800***	***25***	***10,491***	***150***	***51,811***	***46***	***7,029***	***20***	***4,808***	***130***	***104,074***	***18***	***4,320***	***0***	***0***	***5***	***1,290***	***5,061***	***1,114,952***
	3,637		**0**		**0**		**0**		**0**		**0**		**0**															**0**	**61,681**
	25,130		**1,701**		**290**		**100**		**1,628**		**619**		**259**		**6,447**		**476**		**176**		**3,031**		**504**		**64**		**576**	**0**	**98,988**
	21,569		**5,270**		**1,556**		**453**		**5,778**		**1,399**		**454**		**13,815**		**1,072**		**307**		**5,371**		**882**		**112**		**1,008**	**0**	**205,853**
2,599	**712,808**	**323**	**69,700**	**72**	**30,530**	**22**	**7,595**	**546**	**505,000**	**73**	**15,367**	**31**	**12,925**	**450**	**299,000**	**56**	**14,746**	**21**	**5,580**	**273**	**220,200**	**63**	**18,698**	**8**	**4,901**	**72**	**20,242**	**14,548**	**4,415,442**
2,543	*647,944*	*310*	*60,829*	*70*	*28,220*	*21*	*6,831*	*505*	*488,194*	*7*	*3,549*	*6*	*1,721*	*300*	*226,927*	*10*	*6,169*	*1*	*289*	*143*	*107,724*	*45*	*12,992*	*8*	*4,725*	*67*	*17,368*	*9,487*	*2,933,968*
56	*14,528*	*13*	*1,900*	*2*	*464*	*1*	*211*	*41*	*9,400*	*66*	*9,800*	*25*	*10,491*	*150*	*51,811*	*46*	*7,029*	*20*	*4,808*	*130*	*104,074*	*18*	*4,320*	*0*	*0*	*5*	*1,290*	*5,061*	*1,114,952*
0	*50,336*	*0*	*6,971*	*0*	*1,846*	*0*	*553*		*7,406*		*2,018*		*713*		*20,262*		*1,548*		*483*		*8,402*		*1,386*		*176*		*1,584*		*366,522*
																												0	**5,320**
2,599	**712,808**	**323**	**69,700**	**72**	**30,530**	**22**	**7,595**	**546**	**505,000**	**73**	**15,367**	**31**	**12,925**	**450**	**299,000**	**56**	**14,746**	**21**	**5,580**	**273**	**220,200**	**63**	**18,698**	**8**	**4,901**	**72**	**20,242**	**14,548**	**4,420,762**

NOTE: This table does not include resources for indefinite user fees for MQSA and export and color certification.

[1] **For VQIP, the FDA FY 2012 Appropriation Bill provides, "amounts derived from voluntary qualified importer program fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75–717), as amended by the Food Safety Modernization Act**

Food and Drug Administration Amounts Available for Obligation (dollars in thousands)			
	FY 2011 Actual	**FY 2012 Enacted**	**FY 2013 Request**
General Fund Discretionary Appropriation:			
Appropriation	**2,462,000**	**2,506,000**	**2,517,000**
Across-the-board reductions	-	-	-
Subtotal, Appropriation (L/HHS, Ag, or Interior).....	-	-	-
Rescission (P.L. 112-10)	(5,000)	-	-
Reappropriation	-	-	-
Proposed Supplemental Appropriation.....	-	-	-
Proposed Rescission.....	-	-	-
Proposed Reappropriation.....	-	-	-
Subtotal, adjusted appropriation.....	**2,457,000**	**2,506,000**	**2,517,000**
Real transfer from: (OPDIV).....	-	-	-
Comparable transfer from: (OPDIV).....	-	-	-
Subtotal, adjusted general fund discr. appropriation....	**2,457,000**	**2,506,000**	**2,517,000**
Trust Fund Discretionary Appropriation:			
Appropriation Lines.....	-	-	-
Transfer Lines.....	-	-	-
Subtotal, adjusted trust fund discr. appropriation.....	**-**	**-**	**-**
Mandatory Appropriation:			
Appropriation Lines.....	-	-	-
Transfer Lines.....	2,000	3,000	3,000
Subtotal, adjusted mandatory. appropriation.....	**2,000**	**3,000**	**3,000**
Offsetting collections from:			
Non-federal source:	919,000	1,321,000	1,969,000
Unobligated balance, start of year.....	-	-	-
Unobligated balance, end of year.....			
Unobligated balance, lapsing.....	-	-	-
Unobligated balance, Recovery Act start of year.....	-	-	-
Unobligated balance, Recovery Act end of year.....	-	-	-
Total obligations.....	**3,378,000**	**3,830,000**	**4,489,000**
Obligations less ARRA (if applicable).....	-	-	-

FOOD AND DRUG ADMINISTRATION
FY 2013 Congressional Justification
Summary of Changes
Dollars in thousands

	Budget Authority	User Fees	Program Level	Program Level FTE[1]
FY 2012 Enacted	**$2,505,809**	**$1,326,395**	**$3,832,204**	**13,496**
FY 2013 Program Changes:				
Pay Increase	**1,502.00**			
Pay Absorption	**(7,080.00)**			
Subtotal Pay Change:	**($5,578)**			
Budget Authority				
Commissioned Corps Pay increase	$1,502		$1,502	*0*
Rent and Infrastructure	$2,006		$2,006	*0*
Building and Facilities	($3,468)		($3,468)	*0*
Data Consolidation and Administrative Savings/Rent Absorption	(19,706)		(19,706)	(14)
Advancing Medical Countermeasures	$3,510		$3,510	7
China Import Safety	$10,000		$10,000	19
FDA Regulatory Science and Facilities	$17,658		$17,658	0
Subtotal: Budget Authority Program Changes	**$11,502**		**$11,502**	**12**
Total Budget Authority Change from FY 2012 Enacted	**$11,502**		**$11,502**	**12**
FY 2013 User Fee Changes:				
Current Law User Fees:				
PDUFA		$10,636	$10,636	12
MDUFMA		$12,095	$12,095	52
ADUFA		$8,762	$8,762	0
AGDUFA		$1,889	$1,889	0
Tobacco		$28,000	$28,000	120
MQSA		$0	$0	5
Color Certification		$0	$0	0
Export Certification		$1,267	$1,267	7
Food Reinspection User Fee		$667	667	0
Priority Review Voucher User fee		-$4,582	-4,582	0
Voluntary Qualified Importer Program (VQIP) User Fee		$0	0	0
Recall User Fee		$561	561	0
Total Current Law User Fees:		**$59,295**	**$59,295**	**196**
Proposed User Fees:				
Generic Drug User Fee (GDUFA)		$299,000	$299,000	450
Medical Products Reinspection User Fee		$14,746	$14,746	56
International Courier User Fee		$5,580	$5,580	21
Food Establishment Registration Fee		$220,200	$220,200	273
Cosmetics User Fee		$18,698	$18,698	63
Food Contact User Fee		$4,901	$4,901	8
Biosimilar User Fee		$20,242	$20,242	72
Total Proposed User Fees:		**$583,367**	**$583,367**	**943**
Total User Fee Changes from FY 2012 Enacted		**$642,662**	**$642,662**	**1,139**
Net Program Level Change from FY 2012 Enacted	**$11,502**	**$642,662**	**$654,164**	**1,151**
Total FDA Request for FY 2013	**$2,517,311**	**$1,969,057**	**$4,486,368**	**14,648**

[1] FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, 44 IDDA FTE and the associated funds.

Food and Drug Administration
FY 2013 CJ All Purpose Table - Budget Authority
(Dollars in Thousands)

Program[1]	FY 2011				FY 2012		FY 2013			
	Enacted [2]		Actuals[3]		Enacted		Request		+/- FY 2012 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:										
Foods	**3,596**	**$835,682**	**3,605**	**$836,244**	**3,684**	**$866,061**	**3,684**	**$855,239**	**-**	**($10,822)**
Center	1,022	252,322	876	252,540	931	264,296	931	261,189	-	(3,107)
Field Activities	2,574	583,360	2,729	583,704	2,753	601,765	2,753	594,050	-	(7,715)
Human Drugs	**2,126**	**$477,018**	**2,030**	**$477,502**	**2,040**	**$477,810**	**2,043**	**$472,683**	**3**	**($5,127)**
Center	1,423	345,929	1,284	346,194	1,301	347,817	1,304	344,500	3	(3,317)
Field Activities	703	131,089	746	131,308	739	129,993	739	128,183	-	(1,810)
Biologics	**875**	**$212,014**	**899**	**$211,790**	**905**	**$212,224**	**902**	**$209,827**	**(3)**	**($2,397)**
Center	650	171,157	664	171,341	672	171,711	669	169,881	(3)	(1,830)
Field Activities	225	40,857	235	40,449	233	40,513	233	39,945	-	(568)
Animal Drugs and Feeds	**654**	**$139,178**	**713**	**$139,025**	**710**	**$138,021**	**710**	**$136,175**	**-**	**($1,846)**
Center	375	85,403	420	85,499	420	84,699	420	83,582	-	(1,117)
Field Activities	279	53,775	293	53,526	290	53,322	290	52,593	-	(729)
Devices and Radiological Health	**1,519**	**$322,370**	**1,603**	**$322,182**	**1,611**	**$322,672**	**1,606**	**$319,127**	**(5)**	**($3,545)**
Center	1,066	240,486	1,127	240,695	1,139	241,475	1,134	239,072	(5)	(2,403)
Field Activities	453	81,884	476	81,487	472	81,197	472	80,055	-	(1,142)
National Center for Toxicological Research	**215**	**$60,543**	**272**	**$ 60,563**	**272**	**60,039**	**270**	**$59,231**	**(2)**	**(808)**
FDA Headquarters	**665**	**$149,900**	**673**	**$ 149,477**	**706**	**153,704**	**725**	**$163,030**	**19**	**9,326**
FDA White Oak Consolidation	**-**	**$38,459**	**-**	**$ 38,459**	**-**	**$40,386**	**-**	**$58,044**	**-**	**17,658**
Other Rent and Rent Related	**-**	**$61,095**	**-**	**$ 61,095**	**-**	**$65,598**	**-**	**$69,261**	**-**	**3,663**
GSA Rental Payments	**-**	**$150,762**	**-**	**$ 150,763**	**-**	**$160,506**	**-**	**$169,374**	**-**	**8,868**
SUBTOTAL, Salaries and Expenses	**9,650**	**$2,447,021**	**9,794**	**$2,447,100**	**9,927**	**$2,497,021**	**9,939**	**$2,511,991**	**12**	**$14,970**
Buildings and Facilities	**-**	**$9,980**	**-**	**$12,747**	**-**	**$8,788**	**-**	**$5,320**	**-**	**($3,468)**
FDA Building and Facilities	-	9,980	-	12,747	-	8,788	-	5,320	-	**(3,468)**
Natural Products Center	-	-	-		-	-	-	-	-	-
TOTAL	**9,650**	**$2,457,001**	**9,794**	**$2,459,847**	**9,927**	**$2,505,809**	**9,939**	**$2,517,311**	**12**	**$11,502**
Non-Field Activities	5,416	$1,305,740	5,315	$1,306,309	5,440	$1,323,741	5,452	$1,320,486	12	($3,255)
Field Activities	4,234	$890,965	4,479	$890,474	4,487	$906,790	4,487	$894,826	-	($11,964)
Rent Activities, B&F, and White Oak	-	$260,296	-	$263,064	-	$275,278	-	$301,999	-	$26,721

[1] FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, 44 IDDA FTE and the associated funds.

[2] FY 2011 Enacted reflects the -0.2% rescission pursuant to P.L. 112-10.

[3] FY 2011 Actuals include $88,000 in funds from the $2 Million Gulf Oil Spill supplemental appropriation.

Food and Drug Administration

FY 2013 CJ All Purpose Table - User Fees

(Dollars in Thousands)

Program[1]	FY 2011 Enacted FTE	FY 2011 Enacted $000	FY 2011 Actuals FTE	FY 2011 Actuals $000	FY 2012 Enacted FTE	FY 2012 Enacted $000	FY 2013 Request FTE	FY 2013 Request $000	FY 2013 Enacted FTE	FY 2013 Enacted $000
Salaries and Expenses, Definite Appropriations:										
Prescription Drug User Fee Act (PDUFA)										
Human Drugs (PDUFA)	**1,898**	**$479,142**	**2,031**	**$472,143**	**2,031**	**$500,895**	**2,041**	**$511,565**	**10**	**$10,670**
Center	1,849	469,559	1,980	465,675	1,980	490,877	1,990	501,334	10	10,457
Field	49	9,583	51	6,468	51	10,018	51	10,231	-	213
Biologics (PDUFA)	**346**	**$100,649**	**360**	**$81,465**	**360**	**$105,217**	**372**	**$107,460**	**12**	**$2,243**
Center	341	96,624	355	79,746	355	101,010	367	103,163	12	2,153
Field	5	4,025	5	1,719	5	4,207	5	4,297	0	90
FDA Headquarters (PDUFA)	**172**	**$40,693**	**195**	**$ 28,982**	**195**	**42,541**	**186**	**$43,447**	**(9)**	**$906**
FDA Consolidation at White Oak	-	**$3,415**	-	**$ 3,415**	-	**$3,595**	-	**$3,637**	-	**$42**
Other Rent and Rent Related (PDUFA)	-	**$23,253**	-	**$ 23,253**	-	**$17,996**	-	**$25,130**	-	**$7,134**
GSA Rental Payments (PDUFA)	-	**$19,905**	-	**$ 18,568**	-	**$31,928**	-	**$21,569**	-	**($10,359)**
Subtotal PDUFA	**2,416**	**$667,057**	**2,587**	**$627,826**	**2,587**	**$702,172**	**2,599**	**$712,808**	**12**	**$10,636**
Medical Device User Fee Act (MDUFMA)										
Biologics (MDUFMA)	**33**	**$12,559**	**37**	**$8,765**	**29**	**$11,695**	**37**	**$14,134**	**8**	**$2,439**
Center	32	12,009	36	8,342	28	11,183	36	13,515	8	2,332
Field	1	550	1	423	1	512	1	619	-	107
Devices and Radiological Health (MDUFMA)	**242**	**$36,765**	**260**	**$41,956**	**221**	**$34,237**	**260**	**$41,374**	**39**	**$7,137**
Center	230	35,627	248	40,370	209	33,177	248	40,093	39	6,916
Field	12	1,138	12	1,586	12	1,060	12	1,281	0	221
FDA Headquarters (MDUFMA)	**23**	**$6,417**	**26**	**$ 3,795**	**21**	**5,975**	**26**	**$7,221**	**5**	**$1,246**
Other Rent and Rent Related Activities (MDUFMA)	-	**$1,493**	-	**$ 1,541**	-	**$1,390**	-	**$1,701**	-	**$311**
GSA Rental Payments (MDUFMA)	-	**$4,626**	-	**$ 3,200**	-	**$4,308**	-	**$5,270**	-	**$962**
Subtotal (MDUFMA)	**298**	**$61,860**	**323**	**$59,257**	**271**	**$57,605**	**323**	**$69,700**	**52**	**$12,095**
Animal Drug User Fee Act (ADUFA)										
Animal Drugs and Feeds	**67**	**$17,490**	**69**	**$15,269**	**68**	**$19,576**	**68**	**$27,460**	-	**$7,884**
Center	66	17,209	67	14,992	66	19,261	66	26,996	-	7,735
Field	1	281	2	277	2	315	2	464	-	149
FDA Headquarters (ADUFA)	**4**	**$780**	**4**	**$651**	**4**	**873**	**4**	**1,224**	-	**$351**
Other Rent and Rent Related Activities (ADUFA)	**0**	**$182**	**0**	**$41**	-	**$204**	-	**290**	-	**$86**
GSA Rental Payments (ADUFA)	**0**	**$996**	**0**	**$672**	-	**$1,115**	-	**1,556**	-	**$441**
Subtotal (ADUFA)	**71**	**$19,448**	**73**	**$16,633**	**72**	**$21,768**	**72**	**$30,530**	-	**$8,762**
Animal Generic Drug User Fee Act (AGDUFA)										
Animal Drugs and Feeds	**21**	**$4,783**	**24**	**$4,477**	**21**	**$5,058**	**21**	**$6,738**	-	**$1,680**
Center	20	4,632	23	4,326	20	4,898	20	6,527	-	1,629
Field	1	151	1	151	1	160	1	211	-	51
FDA Headquarters (AGDUFA)	**1**	**$216**	**1**	**$165**	**1**	**228**	**1**	**304**	-	**$76**
Other Rent and Rent Related Activities (AGDUFA)	**0**	**$76**	**0**	**$26**	-	**$80**	-	**100**	-	**$20**
GSA Rental Payments (AGDUFA)	**0**	**$322**	**0**	**$18**	-	**$340**	-	**453**	-	**$113**
Subtotal (AGDUFA)	**22**	**$5,397**	**25**	**$4,686**	**22**	**$5,706**	**22**	**$7,595**	-	**$1,889**
Family Smoking Prevention and Tobacco Control Act										
Center for Tobacco Products	**370**	**421,463**	**236**	**135,708**	**392**	**$454,751**	**512**	**$482,398**	**120**	**$27,647**
Center	345	415,567	225	134,145	366	448,501	471	472,998	105	24,497
Field	25	5,896	10	1,563	26	6,250	41	9,400	15	3,150
FDA Headquarters	**32**	**$14,336**	**21**	**$ 3,327**	**34**	**15,196**	**34**	**$15,196**	**0**	**$0**
Other Rent Related Activities	-	**$8,066**	-	**$ 1,279**	-	**$1,550**	-	**1,628**	-	**78**
GSA Rental Payments	-	**$6,135**	-	**$ 4,899**	-	**$5,503**	-	**5,778**	-	**275**
Subtotal	**402**	**$450,000**	**256**	**$145,213**	**426**	**$477,000**	**546**	**$505,000**	**120**	**28,000**
Indefinite Appropriations:										
Mammography Quality and Standards Act (MQSA)										
Devices and Radiological Health	**31**	**$19,080**	**39**	**$14,371**	**34**	**$19,080**	**39**	**$19,080**	**5**	**$0**
Center	23	6,003	31	4,912	26	6,003	31	6,003	5	0
Field Activities	8	13,077	8	9,459	8	13,077	8	13,077	-	0
FDA Headquarters (MQSA)	**2**	**$238**	**2**	**$ 268**	**2**	**$238**	**2**	**$238**	-	**$0**
Subtotal (MQSA)	**33**	**$19,318**	**41**	**14,639**	**36**	**$19,318**	**41**	**$19,318**	**5**	**$0**
Export Certification	**20**	**$2,700**	**15**	**$ 3,337**	**15**	**$ 3,337**	**22**	**$ 4,604**	**7**	**$1,267**
Priority Review Vouchers	-	-	-	-	**0**	**$4,582**	**0**	**$0**	-	(4,582)
Color Certification Fund	**38**	**7,700**	**37**	**7,843**	**37**	**7,843**	**37**	**7,843**	**0**	**$0**
Indefinite Appropriations Total	**91**	**$29,718**	**92**	**$25,819**	**87**	**$30,498**	**99**	**$31,765**	**12**	**$2,534**
Food Reinspection User Fee										
Office of Regulatory Affairs	-	-	-	-	**66**	**$9,375**	**66**	**$9,800**	**0**	**$425**
Foods Program Estimate	-	-	-	-	48	6,825	48	7,134	0	309
Animal Drugs and Feeds Program Estimate	-	-	-	-	18	2,550	18	2,666	0	116
FDA Headquarters	-	-	-	-	**7**	**3,395**	**7**	**$3,549**	**0**	**$154**
Other Rent Related Activities	-	-	-	-	-	**592**	-	**$619**	-	**$27**
GSA Rental Payments	-	-	-	-	-	**1,338**	-	**$1,399**	-	**$61**
Subtotal	-	-	-	-	**73**	**$14,700**	**73**	**$15,367**	**0**	**$667**
Food and Feed Recall User Fee										
Foods	-	-	-	-	**25**	**$9,861**	**25**	**$10,308**	**0**	**$447**
Center	-	-	-	-	2	464	2	485	0	21
Field	-	-	-	-	23	9,397	23	9,823	0	426
Animal Drugs and Feeds	-	-	-	-	**4**	**$1,160**	**4**	**$1,213**	**0**	**$53**
Center	-	-	-	-	2	521	2	545	0	24
Field	-	-	-	-	2	639	2	668	0	29
FDA Headquarters	-	-	-	-	**2**	**661**	**2**	**$691**	**0**	**$30**
Other Rent Related Activities	-	-	-	-	**0**	**$248**	**0**	**$259**	-	**$11**
GSA Rental Payments	-	-	-	-	**0**	**$434**	**0**	**$454**	-	**$20**
Subtotal	-	-	-	-	**31**	**$12,364**	**31**	**$12,925**	**0**	**$561**

Food and Drug Administration

FY 2013 CJ All Purpose Table - User Fees

(Dollars in Thousands)

Program[1]	FY 2011				FY 2012		FY 2013			
	Enacted		Actuals		Enacted		Request		Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Proposed User Fees:										
Generic Drug User Fee (GDUFA)										
Human Drugs	-	-	-	-	-	-	**400**	**254,542**	**400**	**254,542**
Center	-	-	-	-	-	-	250	202,731	250	202,731
Field	-	-	-	-	-	-	150	51,811	150	51,811
FDA Headquarters(GDUFA)	-	-	-	-	-	-	**50**	**$24,196**	**50**	**$24,196**
Other Rent and Rent Related (Generic Drug)	-	-	-	-	-	-	-	**$6,447**	-	**$6,447**
GSA Rental Payments (GDUFA)	-	-	-	-	-	-	-	**$13,815**	-	**$13,815**
Subtotal	-	-	-	-	-	-	**450**	**$299,000**	**450**	**$299,000**
Medical Products Reinspection User Fee										
Office of Regulatory Affairs	-	-	-	-	-	-	**46**	**$7,029**	**46**	**$7,029**
Human Drugs Program Estimate	-	-	-	-	-	-	18	2,749	18	2,749
Biologics Program Estimate	-	-	-	-	-	-	3	561	3	561
Animal Drugs Program Estimate	-	-	-	-	-	-	1	140	1	140
Devices and Radiological Health Program Estimate	-	-	-	-	-	-	24	3,579	24	3,579
FDA Headquarters	-	-	-	-	-	-	**10**	**$6,169**	**10**	**$6,169**
FDA White Oak Consolidation					-	-	-	**$0**	-	**$0**
Other Rent Related Activities	-	-	-	-	-	-	-	**$476**	-	**$476**
GSA Rental Payments	-	-	-	-	-	-	-	**$1,072**	-	**$1,072**
Subtotal	-	-	-	-	-	-	**56**	**$14,746**	**56**	**$14,746**
International Courier User Fee										
Office of Regulatory Affairs	-	-	-	-	-	-	**20**	**$4,808**	**20**	**$4,808**
Foods Program Estimate	-	-	-	-	-	-	3	721	3	721
Human Drugs Program Estimate	-	-	-	-	-	-	2	481	2	481
Devices and Radiological Health Program Estimate	-	-	-	-	-	-	15	3,606	15	3,606
FDA Headquarters	-	-	-	-	-	-	**1**	**$289**	**1**	**$289**
Other Rent and Rent Related	-	-	-	-	-	-	-	**$176**	-	**$176**
GSA Rent	-	-	-	-	-	-	-	**$307**	-	**$307**
Subtotal, International Courier Hubs User Fee	-	-	-	-	-	-	**21**	**$5,580**	**21**	**$5,580**
Food Establishment Registration Fee:										
Foods	-	-	-	-	-	-	**220**	**$189,747**	**220**	**$189,747**
Center	-	-	-	-	-	-	100	89,478	100	89,478
Field Activities	-	-	-	-	-	-	120	100,269	120	100,269
Animal Drugs and Feeds	-	-	-	-	-	-	**21**	**9,507**	**21**	**9,507**
Center	-	-	-	-	-	-	11	5,702	11	5,702
Field Activities	-	-	-	-	-	-	10	3,805	10	3,805
FDA Headquarters	-	-	-	-	-	-	**32**	**$12,544**	**32**	**$12,544**
Other Rent Related Activities	-	-	-	-	-	-		**$3,031**	**0**	**$3,031**
GSA Rental Payments	-	-	-	-	-	-		**$5,371**	**0**	**$5,371**
Subtotal	-	-	-	-	-	-	**273**	**$220,200**	**273**	**$220,200**
Cosmetics User Fee										
Foods	-	-	-	-	-	-	**60**	**$16,332**	**60**	**$16,332**
Center	-	-	-	-	-	-	42	12,012	42	12,012
Field	-	-	-	-	-	-	18	4,320	18	4,320
FDA Headquarters	-	-	-	-	-	-	**3**	**$980**	**3**	**$980**
Other Rent Related Activities	-	-	-	-	-	-	-	**$504**	-	**$504**
GSA Rental Payments	-	-	-	-	-	-	-	**$882**	-	**$882**
Subtotal	-	-	-	-	-	-	**63**	**$18,698**	**63**	**$18,698**
Food Contact Notification User Fee										
Foods	-	-	-	-	-	-	**7**	**$4,458**	**7**	**$4,458**
Center	-	-	-	-	-	-	7	4,458	7	4,458
Field	-	-	-	-	-	-	-	0	-	0
FDA Headquarters	-	-	-	-	-	-	**1**	**$267**	**1**	**$267**
Other Rent Related Activities	-	-	-	-	-	-	-	**$64**	-	**$64**
GSA Rental Payments	-	-	-	-	-	-	-	**$112**	-	**$112**
Subtotal	-	-	-	-	-	-	**8**	**$4,901**	**8**	**$4,901**
Biosimilars User Fee Act (BSUFA)										
Human Drugs (BSUFA)	-	-	-	-	-	-	**64**	**16,594**	**64**	**16,594**
Center	-	-	-	-	-	-	59	15,304	59	**$15,304**
Field	-	-	-	-	-	-	5	1,290	5	**$1,290**
Biologics (BSUFA)	-	-	-	-	-	-	3	774	3	774
Center	-	-	-	-	-	-	3	774	3	**$774**
Field	-	-	-	-	-	-	-	-	-	-
FDA Headquarters (BSUFA)	-	-	-	-	-	-	**5**	**1,290**	5	**$1,290**
FDA Consolidation at White Oak	-	-	-	-	-	-	-	-	-	-
Other Rent and Rent Related (BSUFA)	-	-	-	-	-	-	-	576	-	**$576**
GSA Rental Payments (BSUFA)	-	-	-	-	-	-	-	1,008	-	**$1,008**
Subtotal BSUFA							**72**	**20,242**	**72**	**20,242**
Total Proposed User Fees	-	-	-	-	-	-	**943**	**$583,367**	**943**	**$583,367**
Total User Fees	**3,300**	**$1,233,480**	**3,357**	**$879,434**	**3,569**	**$1,326,395**	**4,709**	**$1,969,057**	**1,139**	**$642,662**

[1] PDUFA and MDUFA expire on October 1, 2012. Legislation to reauthorize PDUFA and establish new generic drug and biosimilar user fees were transmitted to Congress on January 13, 2012.

Food and Drug Administration

FY 2013 CJ All Purpose Table - Total Program Level

(Dollars in Thousands)

Program[1]	FY 2011				FY 2012		FY 2013			
	Enacted[2]		Actuals[3]		Enacted		Request[4]		+/- FY 2012 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:										
Foods	**3,596**	**$835,682**	**3,605**	**$836,244**	**3,757**	**$882,747**	**4,047**	**$1,083,939**	**290**	**$201,192**
Center	1,022	252,322	876	252,540	933	264,760	1,082	367,622	149	102,862
Field	2,574	583,360	2,729	583,704	2,824	617,987	2,965	716,317	141	98,330
Human Drug	**4,024**	**$956,160**	**4,061**	**$949,645**	**4,071**	**$978,705**	**4,568**	**$1,258,614**	**497**	**$279,909**
Center	3,272	815,488	3,264	811,869	3,281	838,694	3,603	1,063,869	322	225,175
Field	752	140,672	797	137,776	790	140,011	965	194,745	175	54,734
Biologics	**1,254**	**$325,222**	**1,296**	**$302,020**	**1,294**	**$329,136**	**1,317**	**$332,756**	**23**	**$3,620**
Center	1,023	279,790	1,055	259,429	1,055	283,904	1,075	287,333	20	3,429
Field	231	45,432	241	42,591	239	45,232	242	45,422	3	190
Animal Drugs and Feeds	**742**	**$161,451**	**806**	**$158,771**	**821**	**$166,365**	**843**	**$183,899**	**22**	**$17,534**
Center	461	107,244	510	104,817	508	109,379	519	123,352	11	13,973
Field	281	54,207	296	53,954	313	56,986	324	60,547	11	3,561
Devices and Radiological Health	**1,792**	**$378,215**	**1,902**	**$378,509**	**1,866**	**$375,989**	**1,944**	**$386,766**	**78**	**$10,777**
Center	1,319	282,116	1,406	285,977	1,374	280,655	1,413	285,168	39	4,513
Field	473	96,099	496	92,532	492	95,334	531	101,598	39	6,264
National Center for Toxicological Research	**215**	**60,543**	**272**	**60,563**	**272**	**60,039**	**270**	**59,231**	**(2)**	**(808)**
Tobacco Act Program	**370**	**$421,463**	**236**	**$135,708**	**392**	**$454,751**	**512**	**$482,398**	**120**	**$27,647**
Center	345	415,567	225	134,145	366	448,501	471	472,998	105	24,497
Field	25	5,896	10	1,563	26	6,250	41	9,400	15	3,150
FDA Headquarters	**899**	**212,580**	**922**	**186,665**	**972**	**222,811**	**1,089**	**280,635**	**117**	**57,824**
FDA White Oak Consolidation	-	**$41,874**	-	**$41,874**	-	**$43,981**	-	**$61,681**	-	**17,700**
Other Rent and Rent Related Activities	-	**$94,165**	-	**$87,235**	-	**$87,658**	-	**$110,262**	-	**22,604**
GSA Rent	-	**$182,746**	-	**$178,120**	-	**$205,472**	-	**$228,420**	-	**22,948**
TOTAL, Salaries & Expenses	**12,892**	**$3,670,101**	**13,100**	**$3,315,354**	**13,445**	**$3,807,654**	**14,589**	**$4,468,601**	**1,144**	**$660,947**
Export Certification	**20**	**2,700**	**15**	**3,337**	**15**	**$3,337**	**22**	**$4,604**	7	1,267
Color Certification Fund	**38**	**7,700**	**37**	**7,843**	**37**	**$7,843**	**37**	**$7,843**	-	-
Priority Review Voucher User Fee	-	-	-	-	-	**4,582**	**0**	**$0**	-	(4,582)
Buildings and Facilities	-	**$9,980**	-	**$12,747**	-	**$8,788**	-	**$5,320**	-	(3,468)
FDA Building and Facilities	-	9,980	-	12,747	-	8,788	-	5,320	-	(3,468)
Natural Products Center	-	-	-	-	-	-	-	-	-	-
TOTAL PROGRAM LEVEL	**12,950**	**$3,690,481**	**13,151**	**$3,339,281**	**13,496**	**$3,832,204**	**14,648**	**$4,486,368**	**1,151**	**$654,164**
Non-Field Activities	8,614	$2,436,050	8,581	$2,107,185	8,812	$2,519,923	9,579	$2,952,656	767	$432,733
Field Activities	4,336	$925,666	4,570	$912,120	4,685	$961,800	5,069	$1,128,029	384	$166,229
Rent Activities, B&F, and White Oak	-	$328,765	-	$319,976	-	$345,899	-	$405,683	-	$59,784
Less User Fees:										
Prescription Drugs (PDUFA)	2,416	$667,057	2,587	$627,826	2,587	$702,172	2,599	$712,808	12	$10,636
Medical Devices (MDUFMA)	298	61,860	323	59,257	271	$57,605	323	$69,700	52	$12,095
Animal Drugs (ADUFA)	71	19,448	73	16,633	72	$21,768	72	$30,530	-	$8,762
Animal Generic Drug (AGDUFA)	22	5,397	25	4,686	22	$5,706	22	$7,595	-	$1,889
Mammography Quality (MQSA)	33	19,318	41	14,639	36	$19,318	41	$19,318	5	$0
Family Smoking Preventation and Tobacco Control Act	402	450,000	256	145,213	426	$477,000	546	$505,000	120	$28,000
Export Certification	20	2,700	15	3,337	15	$3,337	22	$4,604	7	$1,267
Color Certification Fund	38	7,700	37	7,843	37	$7,843	37	$7,843	-	$0
Priority Review Voucher User Fee	-	-	-	-	-	4,582	-	$0	-	($4,582)
Generic Drug (GDUFA)	-	-	-	-	-	-	450	$299,000	450	$299,000
Food Reinspection User Fee	-	-	-	-	73	$14,700	73	$15,367	-	$667
Medical Products Reinspection User Fee	-	-	-	-	-	-	56	$14,746	56	$14,746
Food and Feed Recall User Fee:	-	-	-	-	31	$12,364	31	$12,925	-	$561
Food Establishment Registration Fee	-	-	-	-	-	-	273	220,200	273	$220,200
International Courier User Fee	-	-	-	-	-	-	21	$5,580	21	$5,580
Cosmetics User Fee	-	-	-	-	-	-	63	$18,698	63	$18,698
Food Contact Notification User Fee	-	-	-	-	-	-	8	$4,901	8	$4,901
Biosimilars User Fee	-	-	-	-	-	-	72	$20,242	72	$20,242
SUBTOTAL User Fees	**3,300**	**$1,233,480**	**3,357**	**$879,434**	**3,569**	**$1,326,395**	**4,709**	**$1,969,057**	**1,139**	**$642,662**
TOTAL USER FEES	**3,300**	**$1,233,480**	**3,357**	**$879,434**	**3,569**	**$1,326,395**	**4,709**	**$1,969,057**	**1,139**	**$642,662**
TOTAL BUDGET AUTHORITY	**9,650**	**$2,457,001**	**9,794**	**$2,459,847**	**9,927**	**$2,505,809**	**9,939**	**$2,517,311**	**12**	**$11,502**

[1] FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, 44 IDDA FTE and the associated funds.

[2] FY 2011 Enacted reflects the -0.2% rescission pursuant to P.L. 112-10.

[3] FY 2011 Actuals include $88,000 in funds from the $2 Million Gulf Oil Spill supplemental appropriation.

[4] PDUFA and MDUFA expire on October 1, 2012. Legislation to reauthorize PDUFA and establish new generic drug and biosimilar user fees were transmitted to Congress on January 13, 2012.

Food and Drug Administration
FY 2013 CJ Crosswalk - Budget Authority
(Dollars in Thousands)

Program	FY 2012 Enacted		FY 2013 Rent Absorption		FY 2013 Initiatives										Sub-Total		FY 2013 Request	
					Pay Increase (Commissioned Corps)[1]	Rent and Infrastructure	Inspections In China		Advancing Medical Countermeasures		Life Sciences – Biodefense Laboratory		Data Consolidation & IT Savings					
	FTE	$000	FTE	$000	$000	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,684**	**$866,061**	**-**	**($3,759)**	**$588**	**-**	**-**	**$0**	**-**	**-**	**-**	**-**	**-**	**($7,651)**	**-**	**($10,822)**	**3,684**	**$855,239**
Center	931	264,296	-	(950)	178	-	-	0	-	-	-	-	-	(2,335)	-	(3,107)	931	261,189
Field Activities	2,753	601,765	-	(2,809)	410	-	-	0	-	-	-	-	-	(5,316)	-	(7,715)	2,753	594,050
Human Drugs	**2,040**	**$477,810**	**-**	**($2,081)**	**$336**	**-**	**-**	**$0**	**3**	**$840**	**-**	**-**	**-**	**($4,222)**	**3**	**($5,127)**	**2,043**	**$472,683**
Center	1,301	347,817	-	(1,327)	243	-	-	0	3	840	-	-	-	(3,073)	3	(3,317)	1,304	344,500
Field Activities	739	129,993	-	(754)	92	-	-	0	-	-	-	-	-	(1,149)	-	(1,810)	739	128,183
Biologics	**905**	**$212,224**	**(4)**	**($923)**	**$149**	**-**	**-**	**$0**	**1**	**$252**	**-**	**-**	**-**	**($1,875)**	**(3)**	**($2,397)**	**902**	**$209,827**
Center	672	171,711	(4)	(685)	120	-	-	0	1	252	-	-	-	(1,517)	(3)	(1,830)	669	169,881
Field Activities	233	40,513	-	(238)	28	-	-	0	-		-	-	-	(358)	-	(568)	233	39,945
Animal Drugs and Feeds	**710**	**$138,021**	**-**	**($725)**	**$98**	**-**	**-**	**$0**	**-**	**$0**	**-**	**-**	**-**	**($1,219)**	**-**	**($1,846)**	**710**	**$136,175**
Center	420	84,699	-	(429)	60	-	-	0	-	0	-	-	-	(748)	-	(1,117)	420	83,582
Field Activities	290	53,322	-	(296)	38	-	-	0	-	0	-	-	-	(471)	-	(729)	290	52,593
Devices and Radiological Health	**1,611**	**$322,672**	**(8)**	**($1,644)**	**$227**	**-**	**-**	**$0**	**3**	**$723**	**-**	**-**	**-**	**($2,851)**	**(5)**	**($3,545)**	**1,606**	**$319,127**
Center	1,139	241,475	(8)	(1,162)	169	-	-	0	3	723	-	-	-	(2,133)	(5)	(2,403)	1,134	239,072
Field Activities	472	81,197	-	(481)	57	-	-	0	-	0	-	-	-	(717)	-	(1,142)	472	80,055
National Center for Toxicological Research	**272**	**60,039**	**(2)**	(277)	**0**	**-**	**-**	0	**-**	**$0**	**-**	**-**	**-**	**(530)**	**(2)**	**($808)**	**270**	**$59,231**
FDA Headquarters	**706**	**153,704**	**-**	(720)	**105**	**-**	**19**	**10,000**	**-**	**1,299**	**-**	**-**	**-**	**(1,358)**	**19**	**$9,326**	**725**	**$163,030**
FDA White Oak Consolidation	**0**	**40,386**	**-**	**-**	**-**	**$0**	**-**	**-**	**-**		**-**	**$17,658**	**-**	**-**	**-**	**$17,658**	**-**	**$58,044**
Other Rent and Rent Related	**0**	**65,598**	**-**	**2,937**	**-**	**$582**	**-**	**0**	**-**	**144**	**-**	**-**	**-**	**-**	**-**	**$3,663**	**-**	**$69,261**
GSA Rental Payments	**0**	**160,506**	**-**	**7,192**	**-**	**$1,424**	**-**	**0**	**-**	**252**	**-**	**-**	**-**	**-**	**-**	**$8,868**	**-**	**$169,374**
SUBTOTAL, Salaries and Expenses	**9,927**	**$2,497,021**	(14)	**$0**	**$1,502**	**$2,006**	19	**$10,000**	**7**	**$3,510**	**-**	**$17,658**	**0**	**($19,706)**	**12**	**$14,970**	**9,939**	**$2,511,991**
Buildings and Facilities	**-**	**$8,788**	**-**	**$0**	**$0**	**(3,468)**	**-**	**$0**	**-**	**$0**	**-**	**-**	**-**	**-**	**-**	**(3,468)**	**-**	**$5,320**
FDA Building and Facilities	-	8,788	-	**$0**	**$0**	(3,468)	-	**$0**	-	$0	-	-	-	-	-	(3,468)	-	5,320
Natural Products Center	-	-	-	-		-	-	-	-	$0	-	-	-	-	-	-	-	-
TOTAL	**9,927**	**$2,505,809**	**(14)**	**$0**	**$1,502**	**($1,462)**	**19**	**$10,000**	**7**	**$3,510**	**-**	**$17,658**	**0**	**($19,706)**	**12**	**$11,502**	**9,939**	**$2,517,311**
Non-Field Activities	5,440	1,323,741	(14)	(5,550)	876	-	19	10,000	7	3,114	-	-	-	(11,695)	12	(3,255)	5,452	1,320,486
Field Activities	4,487	906,790	0	(4,578)	626	-	0	0	-	-	-	-	0	(8,012)	0	(11,964)	4,487	894,826
Rent Activities, B&F, and White Oak	0	275,278	0	10,129	0	(1,462)	0	0	-	396	-	17,658	-	-	-	26,721	-	301,999

[1] There are no pay increase funds assigned to NCTR because NCTR did not have any Commissioned Corps FTEs in the end-of-fiscal-year actuals for FY 2011 or FY 2010.

Food and Drug Administration
FY 2013 CJ Crosswalk - User Fee
(Dollars in Thousands)

Program	FY 2012 Enacted		Current law User Fees												Indefinite User Fees								Food Safety Modernization Act User Fees				Proposed User Fees														Sub-total		FY 2013 Request	
			PDUFA		MDUFMA		ADUFA		AGDUFA		Tobacco		MQSA		Color Certification		Export Cert		Priority Review Vouchers		Food Reinspection User Fee		Recall User Fee		Food Establishment Registration Fee		Generic Drug User Fee (GDUFA)		Medical Products Reinspection User Fee		International Courier User Fee		Cosmetics User Fee		Food Contact Notification User Fee		Biosimilar User Fee					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**73**	**$16,686**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$309**	**0**	**$447**	**220**	**$189,747**	**0**	**$0**	**0**	**$0**	**3**	**$721**	**60**	**$16,332**	**7**	**$4,458**	**0**	**$0**	**290**	**$212,014**	**363**	**$228,700**
Center	2	464	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	21	100	89,478	0	0	0	0	0	0	42	12,012	7	4,458	0	0	149	105,969	151	106,433
Field Activities	71	16,222	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	309	0	426	120	100,269	0	0	0	0	3	721	18	4,320	0	0	0	0	141	106,045	212	122,267
Human Drugs	**2,031**	**$500,895**	**10**	**$10,670**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**400**	**$254,542**	**18**	**$2,749**	**2**	**$481**	**0**	**$0**	**0**	**$0**	**64**	**$16,594**	**494**	**$285,036**	**2,525**	**$785,931**
Center	1,980	490,877	10	10,457	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	250	202,731	0	0	0	0	0	0	0	0	59	15,304	319	228,492	2,299	719,369
Field Activities	51	10,018	0	213	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	150	51,811	18	2,749	2	481	0	0	0	0	5	1,290	175	56,544	226	66,562
Biologics	**389**	**$116,912**	**12**	**$2,243**	**8**	**$2,439**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**3**	**$561**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**3**	**$774**	**26**	**$6,017**	**415**	**$122,929**
Center	383	112,193	12	2,153	8	2,332	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	774	23	5,259	406	117,452
Field Activities	6	4,719	0	90	0	107	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	561	0	0	0	0	0	0	0	0	3	758	9	5,477
Animal Drugs and Feeds	**111**	**$28,344**	**0**	**$0**	**0**	**$0**	**0**	**$7,884**	**0**	**$1,680**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$116**	**0**	**$53**	**21**	**$9,507**	**0**	**$0**	**1**	**$140**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**22**	**$19,380**	**133**	**$47,724**
Center	88	24,680	0	0	0	0	0	7,735	0	1,629	0	0	0	0	0	0	0	0	0	0	0	0	0	24	11	5,702	0	0	0	0	0	0	0	0	0	0	0	0	11	15,090	99	39,770
Field Activities	23	3,664	0	0	0	0	0	149	0	51	0	0	0	0	0	0	0	0	0	0	0	116	0	29	10	3,805	0	0	1	140	0	0	0	0	0	0	0	0	11	4,290	34	7,954
Devices and Radiological Health	**255**	**$53,317**	**0**	**$0**	**39**	**$7,137**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**5**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**24**	**$3,579**	**15**	**$3,606**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**83**	**$14,322**	**338**	**$67,639**
Center	235	39,180	0	0	39	6,916	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	44	6,916	279	46,096
Field Activities	20	14,137	0	0	0	221	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	24	3,579	15	3,606	0	0	0	0	0	0	39	7,406	59	21,543
National Center for Toxicology Research	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**$0**
Tobacco	**392**	**$454,751**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**120**	**$27,647**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**120**	**$27,647**	**512**	**$482,398**
Center	366	448,501	0	0	0	0	0	0	0	0	105	24,497	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	105	24,497	471	$472,998
Field	26	6,250	0	0	0	0	0	0	0	0	15	3,150	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	15	3,150	41	$9,400
Headquarters and Office of the Commissioner	**266**	**69,107**	**(9)**	**906**	**5**	**1,246**	**0**	**351**	**0**	**76**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**154**	**0**	**30**	**32**	**12,544**	**50**	**24,196**	**10**	**6,169**	**1**	**289**	**3**	**980**	**1**	**267**	**5**	**1,290**	**98**	**48,498**	**364**	**117,605**
FDA White Oak Consolidation	**0**	**3,595**	**0**	**42**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**42**	**0**	**$3,637**
Other Rent and Rent Related Activities	**0**	**22,060**	**0**	**7,134**	**0**	**311**	**0**	**86**	**0**	**20**	**0**	**78**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**27**	**0**	**11**	**0**	**3,031**	**0**	**6,447**	**0**	**476**	**0**	**176**	**0**	**504**	**0**	**64**	**0**	**576**	**0**	**18,941**	**0**	**$41,001**
GSA Rental Payments	**0**	**44,966**	**0**	**(10,359)**	**0**	**962**	**0**	**441**	**0**	**113**	**0**	**275**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**61**	**0**	**20**	**0**	**5,371**	**0**	**13,815**	**0**	**1,072**	**0**	**307**	**0**	**882**	**0**	**112**	**0**	**1,008**	**0**	**14,080**	**0**	**$59,046**
Export Certification	**15**	**3,337**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7**	**1,267**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7**	**1,267**	**22**	**$4,604**
Color Certification	**37**	**7,843**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**37**	**$7,843**
Priority Review Vouchers		**4,582**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**(4,582)**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**(4,582)**	**0**	**$0**
Total	**3,569**	**$1,326,395**	**12**	**$10,636**	**52**	**$12,095**	**0**	**$8,762**	**0**	**$1,889**	**120**	**$28,000**	**5**	**$0**	**0**	**$0**	**7**	**$1,267**	**0**	**-$4,582**	**0**	**$667**	**0**	**$561**	**273**	**$220,200**	**450**	**$299,000**	**56**	**$14,746**	**21**	**$5,580**	**63**	**$10,698**	**8**	**$4,901**	**72**	**$20,242**	**1,139**	**$642,662**	**4,709**	**$1,969,057**
Non-Field	3,372	1,200,764	12	13,516	52	10,494	0	8,086	0	1,705	105	24,497	5	0	0	0	7	1,267	0	(4,582)	0	154	0	75	143	107,724	300	226,927	10	6,169	1	289	45	12,992	8	4,725	67	17,368	755	431,406	4,127	1,632,170
Field	197	55,010	0	303	0	328	0	149	0	51	15	3,150	0	0	0	0	0	0	0	0	0	425	0	455	130	104,074	150	51,811	46	7,029	20	4,808	18	4,320	0	0	5	1,290	384	178,193	582	233,203
Rent Activities, B&F, and White Oak	0	70,621	0	-3,183	0	1,273	0	527	0	133	0	353	0	0	0	0	0	0	0	0	0	88	0	31	0	8,402	0	20,262	0	1,548	0	483	0	1,386	0	176	0	1,584	0	33,063	0	103,684

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

FOODS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
(Dollars in thousands)

	FY 2011		FY 2012	FY 2013	
	Enacted	Actuals	Enacted	Request	+/- Enacted
Program Level	**$835,682**	**$836,244**	**$882,747**	**$1,083,939**	**$201,192**
Center	$252,322	$252,540	$264,760	$367,622	$102,862
FTE	1,022	876	933	1,082	149
Field	$583,360	$583,704	$617,987	$716,317	$98,330
FTE	2,574	2,729	2,824	2,965	141
Program Level FTE	**3,596**	**3,605**	**3,757**	**4,047**	**290**
Budget Authority	**$835,682**	**$836,244**	**$866,061**	**$855,239**	**($10,822)**
Center	$252,322	$252,540	$264,296	$261,189	($3,107)
Field	$583,360	$583,704	$601,765	$594,050	($7,715)
Budget Authority FTE	**3,596**	**3,605**	**3,684**	**3,684**	**0**
Center	1,022	876	931	931	0
Field	2,574	2,729	2,753	2,753	0
User Fees	**$0**	**$0**	**$16,686**	**$228,700**	**$212,014**
Reinspection			**$6,825**	**$7,134**	**$309**
Field			$6,825	$7,134	$309
FTE			48	48	0
Recall User Fee			**$9,861**	**$10,308**	**$447**
Center			464	485	21
FTE			2	2	0
Field			9,397	9,823	426
FTE			23	23	0
Food Establishment Registration Fee [1]			**$0**	**$189,747**	**$189,747**
Center			$0	$89,478	$89,478
FTE			0	100	100
Field			$0	$100,269	$100,269
FTE			0	120	120
Cosmetics User Fee [1]			**0**	**16,332**	**16,332**
Center			$0	12,012	12,012
FTE			0	42	42
Field			$0	4,320	4,320
FTE			0	18	18
Food Contact Notification User fee [1]			**0**	**4,458**	**4,458**
Center			$0	4,458	4,458
FTE			0	7	7
Field			$0	0	0
FTE			0	0	0
International Courier User Fee [1]			**$0**	**$721**	**$721**
Field			0	$721	$721
FTE			0	3	3
User Fee FTE	**0**	**0**	**73**	**363**	**290**

[1] Proposed User fee; the amount includes associated rent activity

The FDA Foods Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)

Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Food Additives Amendment of 1958*
Color Additives Amendments of 1960
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Food Allergen Labeling and Consumer Protection Act of 2004*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C.379aa-1)*
Food and Drug Administration Amendment Act of 2007*
Patient Protection and Affordable Care Act
FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The focus of the FDA Foods Program is to protect consumers and promote the public health by safeguarding America's food supply and empowering consumers to choose healthy diets. Outbreaks of foodborne illness and contamination events have a substantial impact on public health – 48 million foodborne illnesses occur every year resulting in 128,000 hospitalizations and 3,000 deaths.[1] The average cost per case of foodborne illness is $1,626 which resulted in an aggregated annual cost of illness of $77.7 billion[2]. These illnesses and deaths also disrupt the food system at great economic cost and undermine public confidence in the food supply.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

[1] CDC. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

[2] Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," Journal of Food Protection, Volume 75, Number 1, January 2012, pp. 123-131(9).

Furthermore, the excess intake of calories, dietary fat, and sodium contribute significantly to rising rates of chronic disease, including hypertension, heart disease, stroke, diabetes, and obesity. CDC data indicate that more than 30 percent of the American adult population, approximately, 60 million people[3],is obese and that 17 percent of children and adolescents aged 2 to19 years are obese.[4]

In a dynamic and ever growing global marketplace, consumers and industry rely on FDA to continue to uphold effective safety and labeling standards. FDA is responsible for all domestic and imported food from farm to table with the exception of meat, poultry, and frozen, dried, and liquid eggs. FDA regulation takes place from the products' processing, or point of U.S. entry, to their point of sale.

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported food, and $62 billion worth of cosmetics. This responsibility involves about 167,000 registered domestic food establishments, about 254,000 registered foreign facilities, and more than 3,500 cosmetic firms. FDA also promotes healthful dietary practices for American consumers by ensuring that regulated food product labels are truthful, non-misleading, and otherwise properly labeled, for example, with the Nutrition Facts Label, and by regulating the safety of food ingredients.

FDA Food Safety Strategy

Congress recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave the agency a modern legislative mandate to meet these challenges by enacting the new FDA Food Safety Modernization Act (FSMA). FSMA directs FDA to build a food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA *Food and Veterinary Medicine (FVM) Strategic Plan* takes this statutory framework into account and places high priority on the prevention of foodborne illness of unknown origins and illness that can be specifically attributed to known sources.[5] Under the leadership of the Commissioner of Food and Drugs and the Deputy Commissioner for Foods, the FDA Foods Program — including the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA), with its field forces nationwide, focuses on securing high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented and risk-based programs to protect the safety and security of foods and cosmetics and to ensure that food labels contain useful and reliable information.

[3] http://www.cdc.gov/obesity/data/adult.html
[4] http://www.cdc.gov/obesity/childhood/data.html
[5] The strategic plan can be found on the FDA web site at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

The FDA Foods Program executes its regulatory responsibilities through five sub-programs in order to achieve the goals of the *FVM Strategic Plan*:

1. Prioritizing Prevention
2. Strengthening Surveillance and Enforcement
3. Improving Response and Recovery
4. Nutrition & Labeling Strategies for Better Health
5. Reinventing Cosmetics Safety.

The first three sub-programs allow FDA to address known and unknown sources of illness across the farm-to-table continuum. *Prioritizing Prevention* resources allow FDA to establish a science-based, prevention-focused food safety system through standard-setting, industry outreach, and consumer education. Information gained from the risk analysis, regulatory science, enforcement, and response activities of *Strengthening Surveillance and Enforcement* and *Improving Response and Recovery* enables FDA to monitor the nation's food supply, identify the most significant foodborne contaminants, whether biological or chemical, evaluate the effectiveness of FDA controls for those contaminants, and take action to mitigate incidents of foodborne illness and contamination.

The remaining sub-programs allow FDA to address public health issues unique to these areas. *Nutrition & Labeling Strategies for Better Health* resources enable FDA to promote healthful dietary practices by ensuring that product labeling is informative as well as truthful and non-misleading. Lastly, FDA provides oversight of the safety of cosmetics products in the U.S. marketplace through the *Reinventing Cosmetics Safety* sub-program.

Prioritizing Prevention - Center Activities
FY 2012 Enacted Amount: $79,075,000 (All BA)

Public Health Focus

The public health focus of *Prioritizing Prevention* is to prevent food safety problems before they occur and protect the American food supply from unintentional and deliberate contamination.

FDA Food Safety Strategy

The resources in this sub-program support the *FVM Strategic Plan* goal to establish science-based preventive control standards across the farm-to-table continuum. FDA standards, guidance and industry outreach address food production and handling at the farm, processing, transportation, storage, and retail stages of the farm-to-table continuum. Outreach to consumers is the final opportunity for prevention from farm-to-table and helps consumers avoid harm from consuming contaminated food.

Prioritizing Prevention is critical to the activities of the other food safety sub-programs, as FDA uses these resources to establish the prevention-focused regulatory standards that govern the farm-to-table continuum. In turn, FDA uses the results of regulatory science, product surveillance, and risk analysis to inform standard-setting activities and focus efforts to address both known and unknown sources of foodborne illness. Enforcement and response activities, such as inspections, compliance cases, and food-related incident response, help FDA address issues that occur in the farm-to-table continuum and provide insight into areas where additional or expanded standards, controls, outreach, and education would improve food safety results.

Public Health Outcome

Driven by science and modern information technology, CFSAN develops and implements uniform, science-based standards to counter potential hazards before they harm American consumers. CFSAN FY 2012 enacted funding in this sub-program provides the resources to protect consumers and support industry through scientific and analytical tools to better identify and understand food safety risks and the effectiveness of control measures used to protect the food supply on both a premarket and postmarket basis. FDA also works with regulatory partners to strengthen and better integrate the American food safety system at the federal, state, and local levels, as well as to increase confidence that imported food is as safe as domestic.

Premarket Activities: CFSAN FY 2012 enacted programs protect the public health by assessing and evaluating the safety of infant formula prior to marketing and the safety of substances that industry intentionally adds to food and substances that may become components of food because of contact with food packaging or during food processing. CFSAN gives special priority to reviewing new ingredients, treatments, and processes that have the potential to benefit public health (e.g., through the reduction of foodborne illness by preventing or mitigating microbial contamination). Recent examples include the approval of several new preventive controls including new applications of irradiation in the treatment of food and new chemical antimicrobial treatments.

CFSAN FY 2012 enacted resources also support the development of review science to support the evaluation of submissions for new and emerging technologies and to address emerging public health challenges. Some of these include:

- food ingredients and packaging made using nanoengineered particles
- food ingredients produced from genetically engineered plants
- substances with the potential to cause allergic reactions in sensitive individuals
- substances with potential endocrine activity.

Food Ingredients and Packaging: In recent years, FDA's premarket program for food ingredients and packaging components has continued to meet its performance goals for timely review of industry submissions for premarket approval. At the same time, this program has met a number of postmarket challenges. In March 2011, FDA's Food

Advisory Committee (FAC) convened to evaluate the possible association between the consumption of synthetic color additives in food and hyperactivity in children. The Committee made the determination that relevant scientific data did not support a causal link between consumption of certified color additives in food and hyperactivity and other problematic behaviors in children. The Committee suggested that additional safety studies, such as developmental neurotoxicity testing of the color additives, be conducted and that a robust intake estimate be calculated. Additionally, 57 percent of the members of the Committee voted against additional labeling requirements for foods that contain certified color additives. FDA is currently collecting data on amounts of color additives used in food. These data will be used to estimate dietary exposure for various populations, including children. Additionally, FDA has begun a reassessment of all safety studies conducted on certified color additives that are available in its files. Based on this evaluation, FDA will determine whether and which additional safety studies are needed. CFSAN FY 2012 enacted resources also enabled FDA to remove several perfluorinated, grease-proofing compounds formerly used in food packaging from the market and take various actions to address the safety of the use of novel botanical ingredients in food.

Dietary Supplements: In July 2011, FDA issued draft guidance for the dietary supplement industry on ensuring the safety of new dietary ingredients (NDI). The draft guidance is intended to inform and assist manufacturers, distributors, and other industry entities in deciding when a premarket safety notification for a dietary supplement containing an NDI is necessary and in preparing premarket safety notifications. The draft guidance clarifies that manufacturers must notify FDA in advance when adding a new ingredient with an unknown safety profile to their products and must also provide evidence that the ingredient is safe for consumers. If the notice from a supplement firm is deemed inadequate because the new ingredient is an anabolic steroid or a material with the same chemical qualities, FDA is required by FSMA Section 113 to alert the Drug Enforcement Administration. FDA is reviewing and evaluating all comments for consideration in the final NDI guidance.

Postmarket Activities: CFSAN FY 2012 enacted programs protect the public health by providing industry with information and requirements in the form of regulations and with recommendations in the form of guidance on preventive controls. These controls help protect consumers from intentional and unintentional chemical and microbial contaminants in food products, ranging from minimally processed foods, such as fresh produce, to processed foods, such as low-acid canned foods.

FSMA-Mandated Standards: FDA announced two new regulations in May 2011, the first regulations to be issued under new FSMA authorities, that will help ensure the safety and security of food in the United States. The first rule strengthens FDA's ability to prevent potentially unsafe food from entering commerce by allowing FDA to administratively detain food that FDA has reason to believe is adulterated or misbranded. The second rule requires anyone importing food or feed into the United States to inform FDA if any country has refused entry to the same product, allowing FDA to target and prevent entry of foods that may pose a significant risk to public

health. Both rules will be followed by additional proposed rules for domestic and imported food that will help FDA continue building the new food safety system called for by Congress.

CFSAN also develops science-based safety standards to reduce risk in specific commodities and from specific pathogens. FDA released the 4th edition of the "Fish and Fishery Products Hazards and Controls Guidance" in April 2011. The guidance contains the Agency's latest recommendations to the seafood industry for reducing or eliminating food safety hazards in the fish and fishery products they process. This guidance assists processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans, and helps consumers and the public understand commercial seafood safety in terms of hazards and their controls. The guidance also fulfills a requirement of FSMA Section 103 on hazard analysis and risk-based preventive controls.

Preventing *Salmonella*: *Salmonella* is the leading pathogen contributing to domestically acquired foodborne illness resulting in hospitalization and death. FDA established standards to protect consumers from *Salmonella* and save thousands of lives over the next few years:

- In July 2011, FDA published draft guidance that provides direction to egg producers and other persons who are covered by FDA's final rule "Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030). The guidance responds to questions FDA received on the final rule since its publication in July 2009. The draft guidance assists egg producers in meeting required preventive measures during the production of eggs in poultry houses and refrigeration during storage and transportation.
- FDA also published a draft guidance for industry in March 2011 to address testing procedures for *Salmonella* species in human foods and direct human-contact animal foods, and the interpretation of test results, when the presence of *Salmonella* species in food may render the food injurious to human health and therefore adulterated under the Federal Food, Drug, and Cosmetic Act. FDA may take enforcement action where food tested positive for *Salmonella* species.

Bottled Water Safety: In October 2011, FDA published a final rule that established an allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP) in bottled water. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for DEHP at least once each year under the Current Good Manufacturing Practice (cGMP) regulations for bottled water. This final rule will ensure that FDA's standards for the minimum quality of bottled water, as affected by DEHP, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

Retail Food Safety: The activities of the retail food safety program are prevention-focused to improve food safety practices and food equipment sanitation in retail and food service establishments.

- In September 2011, FDA established a Retail Food Safety Action Plan that includes several measures to help ensure the safety of food sold in food stores, restaurants, schools, and other foodservice operations in the United States. The Action Plan focuses on improving the way managers of these establishments conduct food safety operations in their facilities, as well as improving the oversight of these establishments by public health agencies at the Federal, state and local levels. The Plan specifically calls for strengthening state and local food safety requirements that apply to these establishments and for improving training for personnel on measures to keep food safe.

- In support of the Retail Food Safety Action Plan, FDA announced a Supplement to the 2009 FDA Food Code that includes a new and important recommendation that retail food establishments employ at least one certified food protection manager to ensure adherence to safe practices and standards within the establishment. The FDA Food Code is a set of model food-safety regulations for keeping food safe at retail and food-service operations including restaurants, schools and food stores. Local, state and tribal authorities use the Food Code to develop or update their own food safety rules to be consistent with national food regulatory policy. Keeping the Food Code current with this Supplement is part of FDA's effort to promote its full adoption and implementation by State, local and tribal authorities across the United States.

- In August 2011, CFSAN released the Employee Health and Personal Hygiene Interactive Resource Disk for use by foodservice establishments and retail food stores to prevent transmission of foodborne pathogens from sick food employees. The disk includes an interactive tool to assist supervisors of these establishments make correct decisions to prevent the sick employees from working with food, as well as several FDA resource documents. The disk is a tool that quickly provides information needed by retail food establishments to help prevent transmission of foodborne diseases.

- In October 2010, FDA issued the "FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurants, and Retail Food Store Facility Types (1998-2008)." The report presents results from a 10-year study on trends in practices and behaviors commonly identified by the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks.

- CFSAN also launched a campaign to raise awareness of sanitation concerns and offer tips for cleaning and maintaining commercial deli slicers commonly used to sliced meats, cheeses, and produce in food stores, delis, restaurants, and other foodservice establishments. FDA was instrumental in improving the October

2010 revision of the American National Standard for the design and construction of new deli slicers.

Import Safety: CFSAN conducts prevention-oriented outreach and engages industry and foreign government partners in evaluation and harmonization of international food safety standards to ensure that imported food is as safe as that produced domestically.

- In September 2011, FDA participated in the opening of the International Food Safety Training Laboratory (IFSTL). IFSTL is the first-of-its-kind full time international food safety training facility whose primary focus is to train foreign government officials, third party laboratory scientists and food producers on fit-for-purpose microbiological and chemical analytical procedures. By partnering with the IFSTL, FDA has taken a leadership role in the international food safety community in establishing a platform to build collaboration and cooperation between regulatory agencies from many countries and the global food industry. The Laboratory will help FDA defend against contaminated food imports at the source, rather than at the border.

- In November 2011, FDA gathered information from regulators in other countries regarding the regulatory policies, practices and programs that they currently use to ensure the safety of foods and animal feed imported into their countries.

- In March 2011, FDA held a public hearing to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. A comparability assessment determines whether foreign countries have comparable food safety systems or robust commodity specific export programs similar to those in the United States.

- FDA reviews draft food safety and labeling laws and regulations sent to the World Trade Organization (WTO) by its members, known as WTO notifications. Experts at CFSAN examine these proposed regulations for scientific coherence, feasibility, and potential to impact public health if implemented as written. CFSAN comments are then incorporated into official United States comments sent to the WTO member proposing the given regulation. During 2011, CFSAN reviewed nearly 400 draft rules and regulations through the foreign WTO notification review process.

Food Defense: FDA continues to be active in implementing food defense strategies that help protect the nation's food supply from deliberate acts of contamination or tampering.

- In March 2011, FDA released the Food Defense Mitigation Strategies Database (MSD), one of several tools developed by FDA for the food industry. This online resource is designed for companies that produce, process, store, package, distribute, and/or transport food or food ingredients to aid them in conducting vulnerability assessments and determine suitable mitigation strategies. The

MSD provides a range of preventive measures that companies may choose to implement to better protect their facility, personnel, products, and operations.

- CFSAN partnered with USDA's Foreign Agricultural Service to implement a Food Defense International Outreach Strategy to build relationships, raise awareness and provide training on food defense planning. The team completed food defense programs, trainings, and "roadshows" in Mexico, China, the Philippines, Turkey, Kyrgyzstan, Tajikistan, Uzbekistan, and Kazakhstan. These efforts resulted in foreign government efforts to conduct vulnerability assessments, establish food defense interagency working groups, develop industry guidance, add food defense to academic curricula, and develop and implement food defense plans by industry participants in each of the countries impacted to date.

Outreach and Education: FDA conducts outreach and education to consumers, industry, and other public health agencies to promote better understanding of food safety practices and implementation of FSMA provisions. As a result, industry, consumers, and public health partners are better able to prevent foodborne contamination and illness.

- CFSAN partnered with the National Science Teachers Association (NSTA) to establish the FDA Teachers Academy in Food Science and develop web-based tutorials in Science for Food Safety and Nutrition for middle and high school science teachers. The program provides challenging hands-on activities that link food safety to students' everyday lives, covering food science from the farm to the table in a format linked to the National Science Education Standards.

- FDA also released several informative new food and feed safety videos on the "FDA You Tube" page. FDA offers these videos in seven foreign languages as a service to a broad international audience. These videos include: "Regulatory Approaches to Dietary Supplements and their Claims," "Reportable Food Registry," and "LACF [Low-Acid Canned Foods] and Acidified Foods Regulations and Requirements."

- In FY 2011, FDA held a public meeting on FSMA preventive controls for facilities, a public meeting on FSMA import safety, and a public hearing on comparability of food safety systems and import practices of foreign countries. These meetings and hearing provided a forum for FDA and the public to exchange information and share views that will aid in the development of regulations and guidance documents.

- FDA also redesigned its web page dedicated to FSMA to make it easier for consumers, industry, food safety professionals, local and state regulators, and international trading partners to obtain the latest information about FSMA and become involved through public hearings. The site consists of more than 200 web pages of information and fosters food safety awareness by aggregating links to the full text of the FSMA law which is translated into 11 languages, and

includes frequently asked questions, consumer updates, tools and resources developed by FDA, videos from FDA food safety experts, the FSMA implementation plan and progress updates, and outreach invitations and transcripts of public meetings.

Promoting Efficiency

Preventing a single fatal case of *E. coli* O157 infection saves an estimated $7 million dollars.[6] The activities in *Prioritizing Prevention* help to prevent the overall negative economic impact of foodborne illness to the economy by providing guidance to industry about safe food products and packaging. As a result, FDA protects consumers from foodborne illness and helps industry avoid the risk and expense of recalling products that do not meet safety standards.

Each year, CFSAN provides more than 100 consultations to assist industry with specific guidance to firms on how to best address safety questions relating to food ingredients and packaging. *Prioritizing Prevention* premarket review activities alert industry to potential problems with new ingredients, labeling, and infant formula. CFSAN also expedites the premarket review of FDA-regulated food ingredients and packaging, processing aids such as antimicrobials used to mitigate food contamination, and sources of irradiation that may have potential food safety benefits. These FDA activities help industry to:

- avoid potential safety problems and associated recalls
- more efficiently introduce new or changed infant formulas
- decrease the costs of innovation for food safety
- speed the entry of safe food products and technologies to market.

CFSAN also promotes the development of international, science-based, Codex product standards. Codex standards help ensure that food imports meet U.S. regulatory standards to protect American consumers, while also promoting fair trading practices that are important to the food industry.

Prioritizing Prevention - Field Activities
FY 2012 Enacted Amount: $111,373,000 (All BA)

Public Health Focus

ORA's top priorities for advancing public health and protecting consumers focus on:

- prevention through outreach coordination and technical assistance to industry
- internal and external training, which increases expertise and encourages collaboration with external stakeholders

[6] http://www.cdc.gov/foodsafety/cdc-and-food-safety.html

- preventive controls in the food supply chain from the point of production to delivery into the U.S. supply chain.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks FDA to articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

In the case of the Prioritizing Prevention, ORA contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than relying primarily on reacting to problems after they occur and implementing the provisions of FSMA is through the development of regulations, standards and guidance documents. These activities are reflected within the draft FDA Foods and Veterinary Medicine (FVM) Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

In 2011, ORA participated in outreach events at a variety of public meetings, symposiums, and conferences that are attended by regulated industry, other government agencies, and foreign regulatory bodies.

The FDA Compendium of Microbiological Protocols and Chemical Tests (COMPACT), a compilation of analytical detection methods for foods designed to support the mission of FDA was released in the Electronic Laboratory Exchange Network (eLEXNET). COMPACT serves as the primary resource in support of emergency analytical needs such as large-scale food-borne outbreak and food safety surveillance activities. eLEXNET added six new laboratories in FY 2011.

FDA began regulating firms under 21 CFR 118, better known as the Egg Safety Rule in FY 2010. Since then, ORA has conducted more than 450 inspections and collected over 150 samples including over 2,000 environmental swabs. Of the samples collected by ORA, 22 were found positive for Salmonella Enteriditis. ORA took several regulatory actions including issuance of warning letters, untitled letters, and a voluntary recall. ORA works with industry to help ensure their response measures are appropriate within the regulation, including re-inspection of firms to determine their compliance status. ORA participated in industry outreach programs with the egg producing industry, providing education on compliance with the Egg Safety Rule.

FDA analyzes trends in the regulated marketplace to assure the safety of regulated

commodities before there is a public health issue. FDA identified one such challenge related to caffeinated alcoholic beverages. ORA collected numerous samples and analyzed the products for the presence of caffeine. The analytical findings led to the issuance of several warning letters to manufacturers of these beverages offered for sale at retail locations throughout the nation, and subsequently, to cessation of marketing.

ORA awarded funds to associations under the Small Scientific Conference Grant and to state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources to foster communication and collaboration on a range of topics, including food safety, food security and protection, intervention, and prevention through the review of food supply vulnerabilities.

FDA developed and is currently implementing a new strategy, in collaboration with Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) under the Department of Homeland Security (DHS), to better prevent the entry of smuggled food/feed into the U.S., fulfilling the requirement of FSMA Section 309(a). When smuggled food/feed goes unexamined by regulators, it presents a hazard to consumers and erodes confidence in the safety of the food/feed supply. A comprehensive strategy to combat the entry of smuggled food/feed helps to protect the public health. FDA is working closely with CBP to target and examine import shipments that could conceal undeclared foods/feeds, focusing on high risk parties and imported foods/feeds that pose a significant public health risk.

FDA awarded seven grants to enhance the ability of the grantee to design, develop, and deliver food safety training and personnel certification programs by leveraging the expertise of universities, professional trade associations, and non-profit organizations. The primary focus of the awardee and FDA collaborative venture is to design, develop, and disseminate food and feed safety training programs that are consistent with the Manufactured Food and Retail Food Regulatory Program Standards, as well as third party criteria for accreditation. This venture will emphasize public health safety according to the needs of FDA and our regulatory and public health counterparts, while also fostering the development of a network of food safety professionals. FDA aims to establish a fully integrated food safety system (IFSS) that will place priority on preventing foodborne illness through the adoption and uniform application of model programs.

Promoting Efficiency

ORA conducts outreach to ensure transparency, open communication, and sharing of information and ideas with consumers, regulated industry, and the import trade community. Prioritizing Prevention activities help anticipate and prevent food safety problems, which generates efficiencies for industry, consumers, and FDA. In addition to protecting public health, prevention leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

ORA offers training to its state partners in conducting inspections of egg producers, low acid canned food manufacturers and seafood processors. By providing this training, FDA/ORA is strengthening the infrastructure of state inspection programs and furthering the implementation of an integrated food safety system.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2010: 100% Target: 70% (Target Exceeded)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)*	FY 2011: 485 Enrolled Target: 362 Enrolled (Target Exceeded)	502 Enrolled	519 Enrolled	+17 Enrolled
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2009:12.9 cases/100,000 (Historical Actual)	11.9 cases/ 100,000	11.7 cases/ 100,000	-.25 cases/ 100,000
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2009: 1.0 cases/100,000 (Historical Actual)	1.09 cases/ 100,000	1.04 cases/ 100,000	-.05 cases/ 100,000
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2009: 0.30 cases/100,000 (Historical Actual).	.29 cases/ 100,000	0.28 cases/ 100,000	-.01 cases/ 100,000
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2009: 15.0 cases/100,000 (Historical Actual)	14.5 cases/ 100,000	14.2 cases/ 100,000	-.30 cases/ 100,000
212409: Reducing foodborne illness in the population. By December 31, 2013, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 2.1 cases per 100,000. (*Outcome*)	FY 2009: 2.6 cases/100,000 (Historical Actual: average rate of SE illness: 2007 to 2009)	2.2 cases/ 100,000	2.1 cases/ 100,000	-0.2 cases/ 100,000

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities
FY 2012 Enacted Amount: $118,770,000 (All BA)

Public Health Focus

The public health focus of *Strengthening Surveillance* is to assess and communicate the specific risks associated with food products to American consumers and industry on a routine basis, as well as during foodborne illness outbreaks or cases of chemical contamination.

FDA Food Safety Strategy

The resources in this subprogram support the *FVM Strategic Plan* goals to strengthen scientific leadership, capacity, and partnership to support public health decision making and to improve effectiveness and efficiency across all levels of the food safety system. FDA evaluates risk and conducts surveillance of the nation's food supply to monitor and evaluate the safety and effectiveness of the food safety system across the farm-to-table continuum. Likewise, FDA regulatory science projects improve the Agency's ability to detect both known and unknown pathogens and better understand potential hazards. These activities inform the use of resources across all subprograms, allowing FDA to target inspections and standard-setting activities to best address known and emerging food safety concerns.

Public Health Outcome

CFSAN's FY 2012 enacted activities for this sub-program center on the use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods. These FY 2012 enacted activities also protect American consumers from harm by improving understanding of the sources of foodborne outbreaks and cases of intentional or unintentional chemical contamination, as well as the ability of the Agency to detect these types of issues in the food supply.

Postmarket Surveillance: A significant focus of CFSAN's FY 2012 enacted activities is using postmarket surveillance information and scientific methods and tools to identify and monitor food products that pose a threat to public health. For example, CFSAN contracted with IEH Laboratories to complete testing of 8,139 leafy green vegetables (spinach, iceberg lettuce, and romaine lettuce) for *Salmonella*, *Shigella* and *E. coli* in one year. This surveillance detected five *Salmonella* and two *E. coli* positive samples, resulting in five recalls that removed these adulterated products from the marketplace.

CFSAN, along with other FDA components, is working to develop adverse events early warning systems that can integrate and mine data rapidly to detect real-time signals of adverse events or consumer complaints associated with regulated products. The Reportable Food Registry (RFR) is one such improved early warning system, where food processors must report the possibility of food contamination. These reports trigger

rapid FDA and state response to determine and stop the cause before people become sick. In January 2011, FDA issued the first annual report on the RFR entitled, "A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration," covering results from September 2009 to September 2010.[7] The report shows that, in its first year, the RFR significantly strengthened the ability of FDA to track patterns of food and feed adulteration and target inspection resources to identify adulterated food/feed and prevent foodborne illnesses. The report demonstrates the Agency's success in receiving early warning on problems with food and feed through surveillance functions to better protect the public health.

Risk Analysis and Assessment: Funding for CFSAN's FY 2012 enacted activities also supports improving the availability of chemistry and toxicology information for better safety and risk assessments and more rapid response to episodes of food contamination. For instance, outbreaks of *E. coli* infections have been a continuing food safety challenge for the produce industry. CFSAN conducted several studies to determine how to minimize microbial cross- contamination during postharvest washing of fresh produce and to rapidly detect *E. coli* in fresh produce processing water. CFSAN also analyzed the gene function and survivability of *E. coli* from outbreaks associated with fresh produce. The tools and detection methods resulting from these studies will benefit both industry and regulators.

CFSAN FY 2012 enacted resources are currently supporting evaluations of gluten and several allergens, such as peanuts, eggs, and milk, in light of reports of adverse effects due to unintentional contamination of foods during food processing. CFSAN completed several scientific studies to evaluate sensitivity and specificity of current detection methods, develop new detection methods and preventive controls, improve the harmonization of international standards for validation of allergen detection methods, validate the effectiveness of cleaning procedures, and explore prevention and treatment options for food allergens.

Protecting food from intentional contamination is also a priority of *Strengthening Surveillance*. Understanding the risks and vulnerabilities for intentional contamination in the food production, processing, and distribution system strengthens the food supply against targeting for intentional contamination. The adulteration of important commodities such as gluten and milk with melamine is an example of the food safety risk posed by economic fraud. In FY 2011, CFSAN developed a new analytical method to determine the presence of six melamine substitute compounds using liquid chromatography mass spectrometry for the rapid, sensitive, and specific detection of these adulterants. CFSAN also conducted a risk assessment for intentional contamination of food and food ingredients with melamine.

In FY 2011, CFSAN expanded vulnerability and risk assessment capabilities by developing new public tools and collaborating with other federal agencies. FDA launched a new risk assessment website to provide public information on assessing risks and completed, current and planned FDA projects, and to request public input.

[7] http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM220280.pdf

The website responds to the Institute of Medicine's call for greater visibility and transparency and informs the public that FDA not only responds to emergencies but also acts to prevent such events.

In addition, FDA actively participated in the Interagency Risk Assessment Consortium (IRAC) with 18 other federal agencies and subagencies. IRAC is chartered to address the needs identified by the President's Food Safety Working Group. IRAC collaborated with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to identify updates to risk models for *Listeria monocytogenes* to reflect new data and methods. FDA is also collaborating with the USDA Food Safety and Inspection Service (FSIS) and CDC to update the 2003 quantitative assessment of the relative health risk from *Listeria monocytogenes* in 23 categories of ready-to-eat foods and develop models that predict optimal interventions for reducing listeriosis. Human listeriosis is one of the major foodborne bacterial infections causing 1,600 illnesses and 250 deaths per year in the U.S. The disease specifically affects pregnant women, the elderly and the immuno-compromised population.

Rapid-Detection Technologies: Another significant focus of CFSAN'sFY 2012 enacted activities is developing and validating new, rapid-detection technologies capable of identifying contamination that leads to foodborne illness. Current test methods require anywhere from several days to weeks to deliver results, which severely limits the ability of the FDA to respond to outbreaks and emergencies and to complete timely surveillance activities. For example, the current Salmonella Enteritidis (SE) analysis for whole shell eggs can take over two weeks. CFSAN initiated development of a new rapid-detection method using molecular serotyping on cultural isolates to reduce the time for confirmed results from two weeks to five days.

In September 2011, FDA launched two pilot projects that will evaluate methods and technologies for rapid and effective tracing of foods, including types of data that are useful for tracing, ways to connect the various points in the supply chain, and how quickly the data are made available to FDA. After the pilots are completed and additional data is gathered, FDA will initiate rulemaking on recordkeeping requirements for high-risk foods to facilitate tracing. FDA continues to explore ways to use novel technologies, such as Geographic Information Systems (GIS), to improve timely surveillance activities and FDA's ability to determine the source of foodborne contamination.

CFSAN also developed the following new, science-based, rapid-detection technologies in FY 2011 that provide information critical for quicker decision making in cases of foodborne illness or product contamination, as well as for rapid risk assessments:

- An *in vitro* high-throughput screen to detect and analyze potentially toxic substances such as heavy metals, botanicals, dietary supplements, Gulf oil dispersants, nanoparticles, and microbial and biological toxins such as the botulinum toxin and marine seafood toxins. These screens are faster, less

expensive, and are being tested for their ability to provide an alternative to current animal testing.

- A custom-designed multi-virus DNA microarray (second generation) for identification of the hepatitis A virus genotype, norovirus genogroup, and coxsackievirus serotypes. This tool helps link viral outbreaks, leading to earlier detection and identification of viruses, earlier recalls, and prevention of further illnesses.

- A serotyping scheme using a combination of an antibody-based serogrouping method and a multiplex PCR assay for identifying the major serotypes of *Listeria monocytogenes*. This method identifies the serotypes of major diseases causing *L. monocytogenes* within three to four hours and can be incorporated into FDA's regulatory analysis of food samples immediately, so that contaminated samples will be more rapidly identified and removed from the shelves, preventing further illnesses from the outbreak.

- A suite of new technologies that can be applied to outbreak analysis of enteric foodborne bacteria, such as *E. coli* and *Shigella*, with a focus on establishing important food-clinical linkage attributes. Collectively, these advancements improve food safety and may reduce economic impacts to the food industry by providing enhanced tools that redefine molecular epidemiology for traceback and source-tracking.

Using these methodologies, CFSAN is able to provide results more rapidly on a wider range of regulated products.

Promoting Efficiency

CFSAN promotes efficient food safety research and development while minimizing the cost to industry to respond to food safety concerns. CFSAN uses its regulatory expertise to perform a unique coordinating role to develop and lead important collaborations with industry. Industry relies on CFSAN to provide uniform methods and establish standards to detect food contaminants and conduct analysis of nutrients. These methods and standards promote food safety improvement and a robust and stable business environment.

CFSAN also provides essential science-based information that allows industry to efficiently and effectively respond to concerns about new chemical and microbial food safety threats – including acrylamide, perchlorate, benzene, BPA, *Cronobacter sakasakii*, and *Salmonella* – and food defense-related pathogens, such as *Clostridium botulinum* toxin. CFSAN works to quickly develop and validate methods to detect such contaminants and determine their levels in food. Likewise, CFSAN collaborates with industry to develop novel technologies to detect new and traditional foodborne contaminants.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance – Field Activities
FY 2012 Enacted Amount: $286,953,000 (All BA)

Public Health Focus

To strengthen food defense/safety, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- domestic product reconciliation examinations
- laboratory analyses including sample analysis, product testing and methods development

These activities serve to minimize consumers' risk of exposure to adulterated food products by detecting and preventing the marketing of unsafe products, removing products from the market, or ensuring that products do not reach the U.S. market. Early detection of contaminated or adulterated food products and their ingredients continues to be a priority within ORA.

Activities conducted on entries offered for import into the U.S. are driven by risk-based and intelligence gathering activities that assist in identifying entries posing the highest risk to the consumer. Surveillance inspections are conducted to assess the manufacturing of products for compliance with established regulatory requirements to protect public health. Domestic product reconciliation examinations are conducted to assure manufacturers have programs in place to ensure the safety of products received for processing and also to guard against unknown individuals entering manufacturing facilities. These activities are both food defense and food safety measures.

ORA advances regulatory science by increasing the breadth of its analytical capacity and capability, while improving laboratory efficiencies and outputs. One way ORA accomplishes these advances is through the continued development of laboratory methods to detect emerging microbiological, chemical or radiological contaminants of public health concern.

FDA Food Safety Strategy

In the case of the Strengthening Surveillance, ORA contributes to achieving the overall FDA strategy by establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and a model for evidence-based resource planning. This includes maintaining and strengthening mission-critical science capabilities, improving centralized planning and performance

measurement, and improving information sharing internally and externally including effective communication of research plans and knowledge gaps.

Public Health Outcome

In FY 2011, ORA continued its usage of the Chemistry and Microbiological Mobile Laboratories in support of FDA's food defense initiatives and surveillance of import and domestic produce. In support of FDA's continued surveillance related to the recovery mission from the Deepwater Horizon Oil Spill, the chemistry mobile laboratory was deployed to Dauphin Island, Alabama and analyzed about 1,000 finfish, shrimp and oyster samples for polycyclic aromatic hydrocarbons (PAHs). The microbiology mobile laboratory was re-deployed from a surveillance assignment in Salinas, California to Otay Mesa, California to support the 100 percent sampling and testing of Mexican Papayas implicated in an outbreak over the early late spring/early summer of 2011.

ORA and state regulatory partners under contract with FDA continued the use of environmental sampling during domestic, high-risk food facility inspections to assess the environmental conditions in which products are manufactured. These environmental samples are critical in identifying areas of concern within the production environment that have or could lead to product contamination. As a result of FDA's efforts, industry has taken many actions to recall or destroy products that were manufactured under such conditions.

For example, ORA inspected 127 soft cheese manufacturers under an assignment designed to determine the environmental conditions of these establishments. More than 10,500 environmental swabs were collected to determine the presence of *Listeria monocytogenes* in the establishments. Violative analytical findings led to voluntary recalls by the affected establishment and further regulatory actions including a product seizure.

Through implementation of Memoranda of Understanding (MOUs) with the Occupational Safety and Health Administration (OSHA) and the USDA Agricultural Marketing Service (AMS) and USDA Food Safety Inspection Service (FSIS), FDA is leveraging resources and sharing information in a way that is expected to result in the reporting of egregious food processing conditions that might otherwise go unidentified until an inspection is conducted.

ORA increased the efficiency and effectiveness of import entry review through the nationwide implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources, analyzes available data, cross-matches data looking for anomalies, and enables ORA to target its resources in a more strategic manner. ORA's implementation of PREDICT allows for the expedited clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk food products.

In FY 2011, ORA continued its efforts to improve the reliability of foreign food facility registrations by continuing a contract to perform on site firm verifications of foreign food facilities to confirm the existence of the facility and to verify the information supplied in the registration. As a result of the information obtained under these efforts, FDA initiated for-cause inspection of facilities, added facilities to import alert where the manufacturing capabilities were not what was purported in the registration, and increased targeting and review of prior notice submissions to ensure accurate data is submitted.

The ORA Prior Notice Center (PNC) exceeded the 80,000 prior notice review performance measure in FY 2011. PNC conducts targeted biosecurity analysis of food entries to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

In FY 2011, ORA funded a pilot program for further deployment of the handheld portable analytical tools that were evaluated in FY 2010. These portable analytical tools are used in the early detection of contaminated food products further back in the supply chain. Portable tools return analytical screening results within minutes of implementing the test, providing ORA field personnel with data to assist in setting collection priorities based on emergent risk profiles. The first tier of tools was deployed to several ORA field offices in FY 2010. They are the first in a series of portable analytical tools that were deployed to ORA field investigators to screen certain commodity/analyte combinations. The second wave of deployments of portable analytical tools took place in FY 2011 and included tools to check for the presence of undeclared active pharmaceutical ingredients in dietary supplement products, heavy metals in food products, and diethylene glycol substituted for glycerin.

Promoting Efficiency

FDA field operations are establishing high throughput laboratories for analyzing food samples. These laboratories will allow ORA to analyze a greater volume of food samples in less time. Through this analysis, FDA can better protect consumers, make more timely regulatory decisions, and reduce the impact on regulated industry. These efforts not only provide greater assurance that foods are safe, they also maintain the efficient flow of trade. In addition, high throughput laboratories protect the public by identifying product adulteration and environmental contamination. With this analysis, FDA and industry can efficiently address such problems and allow a firm to resume business operations as quickly as possible after correcting the food safety problem.

The field operations of the Strengthening Surveillance subprogram allow ORA to identify, validate and implement new technologies to more readily detect adulterated food imports. These technologies prevent adulterated imported food from reaching U.S. consumers and allow FDA to more efficiently maintain the flow of commerce in foods that FDA regulates.

In FY 2011, FDA funded the electronic Laboratory Information Management System (LIMS) for implementation into the field laboratories over a five year period. LIMS

directly supports management through automation of analytical processes, data collection from instrumentation, chain of custody, calibration, reagent and inventory tracking, accreditation support, reporting, trending, and general laboratory management. The project entails the development of and licenses for software, commercial off the shelf product, the purchase of equipment and lab hardware, and improvements to the server and network infrastructure. LIMS will be piloted in 4 labs in FY 2012 followed by implementation into 14 static and 2 mobile ORA laboratories over an additional four years.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2011: 7 working days Target: 9 working days (Target Exceeded)	6 working days	5 working days	-1 working days
214207: The number of self assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	NA	5	9	+4
214201: Number of prior notice import security reviews. *(Output)*	FY 2011: 88,057 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2011: 201,406 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain
214203: Number of Filer Evaluations. *(Output)*	FY 2011: 1,212 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2011: 11,789 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2011: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities

FY 2012 Enacted Amount: $25,095,000 (All BA)

Public Health Focus

The public health focus of *Strengthening Enforcement* is to prevent illnesses resulting from contaminated foods by targeting inspections and sampling and by focusing resources where they will have the greatest public health benefit.

FDA Food Safety Strategy

The resources in this subprogram support the *FVM Strategic Plan* goal to achieve high rates of compliance with preventive controls standards domestically and internationally. FDA conducts domestic and foreign inspections and leverages partner public health agencies' efforts to assure that both domestically-produced and imported foods meet preventive controls standards throughout the production and handling stages of the farm-to-table continuum. Inspections, field examples, and sample collection help FDA identify and address food safety risks, either in cooperation with industry or through enforcement actions. These activities further provide information for FDA on areas where standards and outreach are working effectively and where additional efforts are required to strengthen the food safety system, including research and risk analysis on sources of foodborne contamination.

Public Health Outcome

CFSAN FY 2012 enacted activities in this subprogram area concentrate on identifying, evaluating, and implementing risk-based programs to direct inspections, collect samples, and conduct sample analyses and field exams for the domestic and imported food supply. These efforts allow FDA to protect consumers and achieve the public health objective of preventing illnesses resulting from contaminated foods.

Risk-based Foreign Inspections: In FY 2011, CFSAN participated in the planning and coordination of more than 1,000 foreign inspections. These inspections are vital to ensure imported food is safe for American consumers. FDA also continues to conduct field assignments directing the collection and analysis of environmental samples in domestic food production facilities. In general, the purpose of these assignments is to determine if pathogens are present in the food processing environment. An annual risk-based strategy targets several commodities of interest in order to track and trend data as an indicator of industry compliance. Recent target industries included egg farms, dried spices, ready-to-eat (RTE) sandwiches, and smoked salmon processors. Under specific assignments in FY 2011, FDA collected nearly 12,000 environmental sub-samples from 156 facilities. Of these samples, 226 positives were found in 38 facilities resulting in eight compliance actions.

FSMA Enforcement Authorities: With the passage of FSMA, FDA received several new authorities designed to improve its ability to ensure that food for U.S. consumers is safe.

- In August 2011, FDA first used its administrative detention authority under FSMA to detain an order for spices, tamarinds, and chili products at a food storage warehouse after inspectors found evidence of live and dead insects in food products. The detention order resulted from inspections of the warehouse in July and August 2011. The company was previously issued a Warning Letter in April 2011, based on an inspection in early January that found evidence of rodent and insect infestation. Before this new rule, FDA would often work with state agencies to embargo a food product under the state's legal authority until federal enforcement action could be initiated in federal court. In keeping with other provisions in FSMA, FDA will continue to work with state agencies on food safety and build stronger ties with those agencies.

- In May 2011, FDA implemented a second enforcement authority that requires importers of food and feed into the U.S. to inform FDA of any country that had refused entry to the same product. This authority provides the Agency with more information about imports and allows for risk-based targeted inspections. FDA will administer the new reporting requirement through its prior notice system for incoming shipments of imported food, which was established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. With prior notice, in the event of a credible threat for a specific product or a specific manufacturer or processor, FDA will mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals. This new authority also allows FDA to make better informed decisions in managing the potential risks of imported food.

- In addition to the above, FDA now has the authority to prevent the distribution of unsafe food by suspending the registration of the processing facility. Food producing firms must be registered with FDA to market their products in the U.S. As required by FSMA, food facilities must have a written preventive controls plan that spells out potential safety problems and the steps that would be taken to prevent or minimize the likelihood of these hazards occurring. The registration could be suspended if the food processor not only fails to produce safe foods, but also takes no measures to keep those foods from reaching consumers. In addition to preventing their distribution, the processor of unsafe foods is expected to investigate what went wrong and take steps to prevent a recurrence. If this is not done, FDA may take enforcement action as appropriate.

Caffeinated Alcoholic Beverages: CFSAN continues to assess and act on emerging risks to public health resulting from new uses of food ingredients already in the market. In FY 2011, FDA responded to reports of hazardous and life-threatening behaviors following the consumption of caffeinated alcoholic beverages. CFSAN led an agency-wide enforcement effort that resulted in the issuance of Warning Letters to four companies producing these products. FDA also liaised with other stakeholder-agencies, including the Alcohol and Tobacco Tax and Trade Bureau, the Federal Trade Commission, and the Centers for Disease Control, on legal issues surrounding these

beverages and to raise public awareness of the potential risks of consumption. As a result of FDA's efforts, all four companies withdrew their products from the marketplace.

Dietary Supplements: In addition to food products, FDA also regulates dietary supplements and took several actions to ensure that manufactures are performing the proper controls during manufacturing, packaging, labeling, and holding operations. In November 2011, the Department of Justice, on behalf of FDA, filed the first permanent injunction citing the dietary supplement Good Manufacturing Practice (cGMP) Final Rule FDA 21 CFR Part 111. The injunctive relief sought by the government would permanently prohibit the dietary supplement manufacturer from the making and distributing of their 400 products in the United States. In addition to "adulterating" and "misbranding" their final products, the manufacturer and its owner failed to report serious adverse events such as spikes in blood pressure, hospitalization and a subsequent mild heart attack associated with their products.

Other notable enforcement actions that occurred in 2011 includes the seizure of 2.3 tons (U.S.) of extracts containing ephedrine alkaloids in California, a seizure for cGMP violations and illegal claims in Wisconsin, and a seizure for making unsubstantiated disease claims in Minnesota.

Promoting Efficiency

By identifying food safety risks through inspections and by removing unsafe or substandard products from the market, FDA protects consumers and also supports industry efforts to produce safer foods. FDA enforcement actions may also allow firms to avoid the potential high costs that result from consumer illness or injury caused by contaminated foods.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

Public Health Focus

One of ORA's main food safety duties is to perform risk-based inspections of food producers and provide strong, effective, and efficient enforcement of FDA laws and regulations.

The safety of our nation's food supply continues to be a top priority for regulatory agencies. ORA views state-based contracts, grants, and cooperative programs, such as the Food Inspections Contracts, as important mechanisms for providing increased enforcement activities through an enhanced integrated food safety system.

FDA Food Safety Strategy

In the case of the Strengthening Enforcement, ORA contributes to achieving the overall FDA strategy by conducting risk-based domestic and foreign food safety inspections, implementing new enforcement tools, improving mechanisms for assuring that imported foods and feeds meet preventive controls standards, and improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

Public Health Outcome

- ORA investigators conduct on-site inspections of regulated domestic and foreign food establishments
- ORA initiates enforcement actions to address violations of our public health laws and regulations.

In FY 2011, ORA performed 1,000 foreign food establishment inspections representing an increase of 640 foreign food inspections over FY 2010, and increased the overall number of foreign inspections by 54 percent. FDA uses risk factors to target firms to inspect, focusing on-site inspections in the most critical areas, and leveraging the work of our dedicated foreign inspection cadre. This includes the FDA inspection staff located at FDA's foreign offices and our district-based investigators that enhance overall coverage of the foreign establishment inventory.

The ORA Dedicated Foreign Food Cadre alone conducted 470 foreign food inspections that resulted in nine foreign establishment Warning Letters, twelve establishments being placed on Import Alert, and five foreign manufacturers voluntarily recalling their products from the U.S. market. Additionally, implementing new statutory authority provided under the Food Safety Modernization Act, two foreign food firms were placed on import alert for refusing to allow FDA to inspect their facilities.

ORA continued to protect U.S. citizens from unsafe products of foreign origin by issuing over 800 notices that extended import controls to products and establishments related to concerns that include *Salmonella*, pesticides, and non-permitted or undeclared food additives violations.

ORA awarded multiple food inspection contracts to State Agencies and territories. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections. The contracts include a subset of high risk industries such as juice and seafood Hazard Analysis Critical Control Point (HACCP), egg safety, and low acid canned foods and acidified foods. In FY 2011, 26 states received additional funding through the food contract to support the Manufactured Foods Regulatory Program Standards (MFRPS) implementation with an additional 23 states receiving funding to pursue laboratory accreditation in support of MFRPS implementation. Thirty eight states are currently enrolled in MFRPS through either the food contract or the Rapid Response Team cooperative agreement. In FY 2011, FDA also increased funding to support

Retail Program Standards.

In FY 2011, FDA classified 963 Class I, 800 Class II, and 90 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In May 2011, a new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration at an early stage in the process of case development, reduces paperwork by removing redundant and unnecessary documentation, removes a bias toward inaction by making the process less daunting and more collaborative, provides a mechanism for continuous improvement in case development, and shortens approval times. Overall, FDA pursued 12 injunction and 11 product seizure actions, and issued 324 warning letters alerting firms to violations of concern that require their immediate attention to correct and prevent the continued distribution of adulterated products in U.S. commerce.

Submission of accurate prior notice data for imported food shipments by industry ensures that meaningful food defense/security risk assessments can be completed by ORA. ORA initiated more than 1,050 compliance enforcement cases, taken in conjunction with CBP, where registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. At the request of ORA in 2011, CBP issued Letters of Reprimand to two import filers for failure to transmit accurate prior notice data relating to the importation of food products.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are found during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011 and included data for FY 2009 and FY 2010 inspections. This effort provides the public and regulated industry with more information about company practices that may jeopardize public health, as well as identifies companies that comply with the law.

With cross agency collaboration, FDA initiated and implemented a strategy to monitor the marketplace conducting undercover purchases and investigations as part of the "Operation Shady Supplement." The strategy emphasizes the development of criminal cases against distributors of tainted supplements by OCI. Additionally, FDA safeguarded the U.S. marketplace from unsafe dietary supplements by collaborating internationally with Canada's Competition Bureau and issuing warning letters to U.S. firms marketing dietary supplements in the U.S. and Canada on the internet and Facebook with unapproved disease claims.

In May 2011, FDA implemented two new enforcement authorities under FSMA, both effective in July 2011. The first allows FDA to administratively detain food that it has reason to believe is adulterated or misbranded. The products are kept out of the marketplace while FDA determines whether an enforcement action, such as seizure or injunction against distribution of the product in commerce, is necessary. FDA used this authority multiple times in 2011.

The second authority provides FDA with more information about imports and allows for risk-based targeted examinations by requiring importers of food and feed into the U.S.to inform FDA if any country has refused entry to the same product. This new data requirement also allows FDA to make better informed decisions in managing the potential risks of imported food/feed.

During FY 2011, ORA's OCI made 11 arrests, and secured 20 convictions with fines, restitutions and other monetary penalties in excess of $10 million.

A sampling of some of the specific case activity that led to these positive public health outcomes are as follows:

Misbranded products - Distribution of cheese contaminated with salmonella and E. coli – In July 2011, a Miami company and its owners were sentenced after being convicted of conspiracy and smuggling for selling imported cheese found to contain salmonella and E. coli. The cheese had been detained by FDA and was facing further examination under FDA orders for destruction after the contamination was uncovered. The husband and wife owners were sentenced to 27 months and 40 months in prison, respectively after being found guilty in a May 2011 trial.

Product tampering - **Sentencing for tampering with salsa at restaurant** – In February 2011, a woman was sentenced to seven years in federal prison for tampering with a consumer product by putting pesticide poison in salsa served to patrons at a restaurant in Lenexa, Kansas. In June 2011, her husband was sentenced to ten years in prison for his participation in the crime. The man and his wife devised the scheme after the husband lost his job at the restaurant. Nearly 50 individuals, from young children to senior citizens, became ill from the poisoning, which occurred in August 2009.

Misbranded and adulterated products - **New Jersey dietary supplement firms and owners found guilty of contempt** – In June 2011, two companies were found guilty of multiple counts of criminal contempt along with three owners and officials of the companies. In December 2011, the owner of the two companies was sentenced to 40 months in prison and fined $60,000. Two managers of the companies were sentenced to 34 months in prison each. Both firms were also ordered to pay criminal fines totaling $1 million. The OCI investigation uncovered two New Jersey dietary supplement and food manufacturers that were violating a March 2010 consent decree ordering the business to shut down after FDA inspections found that their products were misbranded and adulterated due to unsanitary conditions at the plant. Despite the court order, the

defendants set up new operations at a different location without first getting the required FDA approval.

Adulterated products - Florida Corporation and Owners Sentenced for Distribution of Contaminated, Imported Cheese – In December 2010, a Florida corporation and its two owners were sentenced for importing cheese from Nicaragua, which was subsequently placed on hold by FDA to determine if the cheese was adulterated. FDA testing determined the cheese contained bacteria. The defendants had already sold the 440 boxes of cheese after being notified about the detention. One owner was sentenced to 6 months confinement and 2 years probation while the other defendant received five years probation.

Promoting Efficiency

The Food Inspection Contract Program and similar contracts, grants, and cooperative agreements that ORA executes through this subprogram build an integrated food safety system designed to protect the nation's food supply and minimize consumers' exposure to adulterated and contaminated food products. FDA support for state inspections often supplements two to three state-funded food inspections, thereby increasing the reach of state food safety programs ensuring a broader network of food safety for consumers. Through these grants and cooperative agreements, FDA increases the efficiency of an integrated food safety system increasing our capabilities to respond to food incidents and outbreaks while facilitating the release of safe food products for U.S. consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214205: Number of domestic high-risk food inspections. *(Output)*	FY 2011: 7,218 Target: 6,806 (Target Exceeded)	7,435	7,435	Maintain

Improving Response and Recovery - Center Activities

FY 2012 Enacted Amount: $15,517,000 (BA: $15,053,000 / UF: $464,000)

Public Health Focus

The public health focus of *Improving Response and Recovery* is to protect American consumers from harm when foodborne illness outbreaks do occur.

FDA Food Safety Strategy

The resources in this sub-program support the *FVM Strategic Plan* goal to improve detection of and response to foodborne outbreaks and contamination incidents. FDA

responds to and evaluates foodborne outbreaks and contamination incidents across the farm-to-table continuum, in order to address emerging foodborne health risks and improve FDA activities across all sub-programs to better detect and prevent such issues in the future.

Public Health Outcome

CFSAN FY 2012 enacted program activities create a structure for FDA, other public health agencies, and industry to exchange information and expertise in real time during an outbreak of foodborne illness. These resources allow FDA to respond more effectively with rapid and targeted product tracing, as well as to more accurately identify the specific firms that are responsible for the food safety problem. CFSAN's activities also enable FDA to communicate more effectively with consumers to limit morbidity and mortality and help affected industries avoid adverse economic consequences.

Coordinated Outbreak Response and Evaluation (CORE) Network: In FY 2011, FDA launched the Coordinated Outbreak Response and Evaluation (CORE) Network. CORE was established by the FDA Foods Program to manage outbreak response, surveillance, and post-response activities related to incidents involving multiple illnesses. The CORE Network strengthens FDA's efforts to prevent, detect, investigate, respond to, and learn from incidents and outbreak by centralizing incident response management and focusing on ways to improve response time and standardize procedures and activities. The CORE Network's post response activities also provide valuable insight on ways to develop and implement more effective, prevention-focused, food safety practices and policies.

Response to *Listeria monocytogenes* in Cantaloupes: The CORE Network was critical to FDA's recent successful response to a multi-state outbreak of listeriosis associated with cantaloupes.

- In September 2011, FDA, in conjunction with the Centers for Disease Control and Prevention (CDC) and state health departments, began an investigation into the source of the contamination. FDA and its partners used sampling and causal assessments to determine where in the supply chain and under what circumstances the cantaloupe became contaminated with *Listeria monocytogenes,* as well as the specific strains involved. FDA also conducted timely and effective risk communication through the CORE Network to alert industry and the public to potential public health concerns associated with recent consumption of potentially contaminated cantaloupes.
- In October 2011, FDA released an assessment of the factors that may have contributed to the contamination of fresh, whole cantaloupe, such as sanitation of packing equipment and proper cooling and cold storage of the fruit.[8] FDA's findings regarding this particular outbreak highlighted the importance for firms to employ good agricultural and management practices in their packing facilities, as

[8] http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm

well as in growing fields. FDA recommended that firms employ these practices for the growing, harvesting, washing, sorting, packing, storage and transporting of fruits and vegetables sold to consumers in an unprocessed or minimally processed raw form. These results underline the importance of FDA post-response activities to strengthen the food safety system from farm-to-table.

Response to *Salmonella* Agona in Papayas: FDA worked closely with Mexico in 2011 to identify the source or sources of contamination of *Salmonella* Agona in fresh papayas entering the U.S. from Mexico and strengthen produce safety for both nations.

- FDA expanded its collaborations with counterpart agencies in the Mexican government, the National Service for Agroalimentary Public Health, Safety and Quality (SENASICA) and the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), after papayas imported from Mexico were linked to approximately 100 cases of *Salmonella* Agona in 23 U.S. states in early 2011. The response effort also included CDC and state health and regulatory officials, including those in Texas and Illinois.
- Following extensive analysis of imported papayas over a three-month period from nearly all the major papaya producing regions in Mexico, FDA issued an Import Alert to deny admission of papayas from each source in Mexico unless the importer showed they were not contaminated with *Salmonella*, such as by using private laboratories to test the papayas. FDA and Mexican officials began collaborating on laboratory methodologies used in Mexico for testing fresh papayas for Salmonella.
- FDA and Mexican officials developed a long term strategy to improve produce safety. The Mexican government and papaya industry agreed to a longer range action plan that will define proper food safety procedures throughout the chain of production and distribution in Mexico and verify that the procedures are working effectively through product testing and other government oversight. Mexican officials are overseeing the industry's implementation of the action plan with FDA collaboration. This plan is a powerful example of how FDA's post-response activities allow it to better prevent future incidents of foodborne illness.

Response to Domestic and International Disasters: CFSAN's FY 2012 enacted activities also support the ability of FDA to provide emergency response after major domestic and international disasters and protect U.S. citizens from food safety adverse effects of the disasters.

- In July 2011, the FDA chemical mobile laboratory (CML) was deployed to Dauphin Island, Alabama for extended surveillance of oil residues in the Gulf of Mexico seafood. The CML deployment is a federal and state collaboration to cross-train staff on oil spill response methods and to monitor fish samples obtained from the nation's largest saltwater fishing competition for residual oil contamination from the Deepwater Horizon oil spill of 2010. Sample results continue to show that the Gulf seafood is safe for consumption.

- FDA was heavily involved in the U.S. Government's activities to assist the Government of Japan and help ensure the safety of U.S. citizens after the Japan earthquake, tsunami, and nuclear disaster in March 2011. Immediately after the earthquake and tsunami, FDA's Office of Emergency Operations activated the Incident Management Group (IMG) to oversee, coordinate, and monitor issues related to the earthquake, tsunami, and the nuclear reactor crisis. CFSAN personnel served on the IMG, providing policy-level support for issues associated with FDA-regulated products.
- As part of the response to the explosions at Fukushima nuclear facilities, FDA promptly augmented the radiation screenings at U.S. borders of food imports from Japan. FDA also issued Import Alert 99-33 regarding the importation of all milk and milk products and fresh vegetables and fruits produced or manufactured from the four Japanese prefectures of Fukushima, Ibaraki, Tochigi, and Gunma, and providing information and updates to consumers on the FDA website. FDA continues to provide public information and address requests for information from media, industry groups, and Congress, as well as other stakeholders.
- FDA and the National Oceanic and Atmospheric Administration (NOAA) developed, validated, and are using new chemical tests to detect oil residues and oil dispersants in fish, oysters, crab and shrimp following the April 2010 Deepwater Horizon Gulf Oil Spill. FDA and NOAA added a second test for residues and dispersants in addition to rigorous sensory analysis tests for contaminants when considering reopening Gulf waters to fishing to help ensure the safety of seafood being harvested from the Gulf. This test adds another layer of information, reinforcing FDA findings to date that seafood from the Gulf remains safe for consumption. CFSAN and NOAA continue to monitor and evaluate on-going and long-term effects of the Deepwater Horizon oil spill on seafood safety, preventing consumers from being exposed to contaminated seafood caused by this environmental disaster.

Response-Related Outreach and Education: CFSAN's FY 2012 enacted resources support response-related risk communication and education efforts to inform consumers of food safety issues and improve the ability of industry and regulatory partners to address incidents of foodborne contamination.

- In July 2011, FDA released the Food Related Emergency Exercise Boxed Set (FREE-B) designed to take a whole-community approach to preparedness involving cross-discipline preparedness training for large-scale incidents through regular exercise and training, evaluation and plan revision. FREE-B allows stakeholders to examine their food emergency response functions and enable them to collaborate and communicate on a variety of human- and animal-health related incidents. Target stakeholders include government regulatory and public health entities, private sector, and non-traditional partners such as first responders, emergency management and law enforcement communities. FREE-B was developed in cooperation with the CDC and USDA's Animal & Plant Health Inspection Service (APHIS) and FSIS.

- FDA created and launched a Product Recall web page in April 2011 to respond to FSMA requirements for a more consumer-friendly recall search engine. The Product Recall Page features sorting and search functions that display recall information in an easy-to-read format, which includes frequently asked questions and informative videos. FDA also provides updates on the status of certain food recalls, such as mandatory recalls under FDA's FSMA authority. The page makes it easier and quicker for stakeholders to learn about product recalls so they can take appropriate steps to protect themselves and their families. One week after the site went live, the number of subscribers for email notifications when new information is posted nearly doubled, and the list continues to increase weekly.

CFSAN'sprogram activities for *Improving Response and Recovery* also include assessing issues and obstacles that hinder inter-agency data sharing and communication, identifying data systems useful for signal detection of potential adverse events, determining how to interconnect data systems in real time, and determining how to mine data for early signal detection. CFSAN is also working to develop unified, interoperable, information-sharing data systems between federal, state, and local agencies for effective signal detection and rapid response.

Promoting Efficiency

FDA's response and recovery activities reduce costs to industry during incidents of foodborne illness or contamination. Outbreaks of foodborne illness lead to reduced productivity and detrimental economic impact for individual food firms or for entire industry sectors through the loss of consumer confidence and protracted recalls. By quickly and effectively identifying contaminated products, FDA protects American consumers by removing products from the market place, while also helping industry to recover by accurately identifying firms that are responsible for the problem foods, as well as firms not associated with the safety problem.

<u>Improving Response and Recovery</u> - Field Activities
FY 2012 Enacted Amount: $ 49,327,000 (All BA)

Public Health Focus

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. ORA continues its work with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors.

The Reportable Food Registry (RFR) is an electronic portal to which industry, public health officials, and consumers can report when there is a reasonable probability that an article of human food will cause serious adverse health consequences or death to

humans. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

To protect consumers from foodborne pathogens and to rapidly and accurately trace and identify the sources of pathogens in the food supply, it is necessary to determine species and discriminate the pathogens isolated from food. This additional identification is needed to track pathogens to the source and origin of the food exposure whether from plant, farm, or human contamination sources.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA continues to identify and develop new investigational resources, tools, and training programs while establishing an infrastructure that will support continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on states and counties to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow states and counties to increase efficiency in the areas of response, prevention and intervention in addition to allowing for a larger pool of resources nationwide to strengthen food defense and mitigate safety issues.

Molecular techniques are available to provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide evidence for rapid traceback to contamination sources. All microbiology laboratories have equipment to perform this testing and microbiologists are certified to perform this analysis. The results of these determinations inform inspections and provide evidence on source, level and extent of contamination by food borne pathogens. The focus of the activities in this area is also to deliver a timely response to an emergent threat to minimize the impact to public health.

FDA Food Safety Strategy

In the case of the Improving Response and Recovery, ORA contributes to achieving the overall FDA strategy by investigation and adoption of innovative technologies and processes to detect and investigate such events, enhancement of the Reportable Food Registry, and effective risk communications related to outbreaks and contamination incidents. ORA is able to do this by responding to issues that occur across Farm-to-Table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

ORA continues to partner with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, Partnership for Food Protection, and 50 State Meetings. This work enables federal and

state partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern.

ORA continues to devote resources to the prompt and efficient response to foodborne outbreaks and other events associated with FDA regulated commodities. Prompt mobilization of individual resources and response teams by ORA facilitates the reduction of exposure times through early investigation initiation and the collection of samples for analysis.

As part of FDA's response to the March 2011 Japan earthquake and tsunami, FDA issued Import Alert 99-33 and Import Bulletin 99-B38 to increase surveillance of Japanese food and drug products, providing a network of coverage to ensure no radiation-contaminated product reaches U.S. consumers. As the situation developed, FDA issued revisions and updates to both the Alert and Bulletin to ensure the most appropriate coverage. Field offices conducted over 28,000 examinations and field laboratories analyzed over 1,100 samples, with no objectionable findings.

As part of FDA's response to a multi-state Salmonella Agona outbreak, FDA issued an Import Bulletin to increase surveillance of suspected food products to prevent the entry of potentially contaminated products without first being analyzed. As the situation developed, FDA revised the bulletin to ensure appropriate coverage. Eventually FDA's surveillance activities led to the issuance of a countrywide Import Alert specific to papayas from Mexico. ORA's field operations helped identify a potential source of microbiological contamination in produce, and continue to ensure that the contaminated product does not reach U.S. consumers.

Deepwater Horizon Oil Spill:

In April 2010, the Deepwater Horizon Oil Rig owned and operated by BP exploded causing release of millions of gallons of crude oil into the Gulf. FDA worked with the affected Gulf States to respond to this emergency threatening seafood safety. States closed their waters to harvesting until the oil receded. ORA developed a rapid analytical method and tested hundreds of samples to inform decisions about reopening waters to commercial fishing.

ORA continues to perform inspections, sample collections, and analyses of gulf coast seafood products to assure their safety and to support the recovery. In FY 2011, conducted 192 inspections at Gulf state seafood firms and collected 137 samples of the targeted products. ORA also deployed the Mobile Laboratory which analyzed another 1,000 seafood samples.

Phthalate Contamination of Processed Foods in Taiwan:

At the end of May 2011, the Taiwanese Food and Drug Administration shared with FDA some intelligence on uncovered adulteration of raw ingredients with phthalates which are chemicals used in the plastic industry. Phthalates were being substituted as

clouding agents in certain ingredients by various Taiwan manufacturers. Upon receipt of this information, ORA immediately mobilized its laboratories and launched a collaborative method development work force to rapidly put in place an analytical method to test samples from Taiwan. Concurrent with mobilizing its laboratories, ORA also directed its field force to start stopping and collecting imports from Taiwan suspected of being contaminated with phthalates. ORA's phthalate response continues to date with over 600 samples collected.

Promoting Efficiency

FDA improved the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams to minimize the public health consequences of a food safety incident. Better coordination promotes more efficient food safety response by federal, state, and local governments through improved coordination and stronger communication during a response.

In FY 2011, FDA improved the efficiency of field analytical resources by developing new, rapid analytical methods and portable analytical tools for field use, and deploying the mobile chemistry and microbiology laboratories to perform rapid analytical work to assess product safety.

To improve FDA's ability to support response and recovery, FDA Field operations continue to evaluate new technologies that provide faster and more efficient results. ORA is currently developing portable computer applications for use in the field during inspections. These applications are designed to assist the investigator in conducting an inspection, capture data on industry compliance with specific regulations to target outreach and follow-up activities, and to improve efficiencies in preparing reports of investigations.

Performance Measures

Subprogram 4: Improving Response and Recovery

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2011: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Nutrition & Labeling Strategies for Better Health - Center Activities
FY 2012 Enacted Amount: $18,270,000 (All BA)

Public Health Focus

The public health focus of *Nutrition & Labeling Strategies for Better Health* is to promote healthful dietary practices through truthful and informative labeling on packaged and other foods. Reducing the chronic disease burden of the U.S. population depends in large part on consumers having the knowledge to make wise food choices and the motivation to make those choices consistently throughout all stages of their lives.

Public Health Outcome

CFSAN'sFY 2012 enacted resources in this subprogram support this objective through the regulation of food labels and the promotion of education and research programs that support good nutrition and accurate labeling. FDA also develops new tools that permit consumers to make better food choices. These activities enable American consumers to make better use of current food labeling information to maintain health and reduce the risk of chronic disease and obesity.

Restaurant Menu and Vending Machine Labeling: CFSAN issued two proposed regulations on menu and vending machine labeling as mandated by the Nutrition Labeling of Standard Menu Items in Chain Restaurants under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H). Specifically, the law requires restaurants, similar retail food establishments and vending machine operators — all with 20 or more locations — to provide nutrition information for certain food items. CFSAN issued two proposed regulations in April 2011 for calorie labeling on menus and menu boards in chain restaurants and similar retail food establishments, and vending machines. The proposed regulations, when finalized, will give consumers consistent and easy-to-understand nutrition information, making it easier for them to choose healthier options that can help fight obesity. CFSAN is seeking public comment and plans to issue the final rules in early 2012.

Reduced Sodium Intake: Excess sodium is a contributory factor in the development of hypertension, which is a major risk factor for heart disease and stroke. Current data and expert analysis indicate that moderate reductions in sodium intake can prevent tens of thousands of deaths and many more related illnesses and can substantially reduce public health costs. FDA recognizes ongoing efforts by a number of members of the restaurant and packaged food industries to reduce sodium and appreciates the complexities of reducing sodium in foods.

As part of the HHS Million Hearts campaign, an initiative launched in September 2011 that aims to prevent one million heart attacks and strokes over the next five years, CFSAN conducted several activities to help consumers improve their heart health through reduced sodium intake.

- In September 2011, FDA established a public docket to obtain comments, data, and evidence relevant to the dietary intake of sodium, as well as current and emerging approaches designed to promote sodium reduction.

- In November 2011, CFSAN participated in a joint public meeting with USDA and CDC entitled, "Approaches to Reducing Sodium Consumption." The meeting provided a forum for the partnership to hear directly from outside interested persons and to foster an inclusive and productive dialogue among all interested persons involved in reducing sodium intake.

FDA is using the results of these activities to continue to support consumers in reducing their sodium intake and improve their health.

Labeling Activities: CFSAN's FY 2012 enacted resources were used to support several regulatory activities to help ensure that food labels were truthful and not misleading.

- CFSAN notified 17 food manufacturers that the labeling for 22 of their food products violated the Federal Food, Drug, and Cosmetic Act. The violations cited in the warning letters include unauthorized health claims, unauthorized nutrient content claims, and unauthorized use of terms such as "healthy," and others that have strict, regulatory definitions.

- CFSAN created and recorded a food labeling training webinar and video for FDA foreign post staff to use as a tool when aiding foreign food manufacturers on labeling their products for import into the U.S.

- CFSAN completed the Spanish translation of the Food Labeling Guide, a comprehensive booklet that explains FDA's food labeling requirements.

- CFSAN jointly sponsored with USDA a delegation to Ghana, Africa to conduct a week-long training on U.S. food labeling requirements to foreign manufacturers.

Gluten Allergy Labeling: For individuals with celiac disease, the only way to prevent harmful health effects is to adhere to a life-long diet free of gluten. In 2011, CFSAN conducted the following actions involving accurate gluten labeling of food products:

- Conducted and peer-reviewed a safety assessment of gluten exposure in individuals with celiac disease, to provide further data on a possible alternative approach to identifying a specific gluten threshold level as one of the criteria to define "gluten-free." FDA had previously issued a proposed rule in 2007 on gluten-free food labeling that used an analytical methods-based approach to propose less than 20 parts per million gluten as one of the criteria to define the term "gluten-free."

- Published a *Federal Register* notice in August 2011, reopening the comment period on the Agency's proposed rule on "gluten-free" food labeling. This notice announced the availability of the Agency's safety assessment on gluten exposure in individuals with celiac disease and solicits public comment on the safety assessment and a number of issues related to defining the term "gluten-free" in a final rule. After FDA reviews and considers the comments, the Agency intends to issue, by the end of fiscal year 2012, a final rule that defines "gluten-free" for labeling food products, including dietary supplements.

Education and Outreach to Promote Healthy Diets: CFSAN conducts several education and outreach efforts to promote healthful choices that reduce the risk of chronic disease and obesity.

- With the Cartoon Network, maintains a Nutrition Label education program called SPOT THE BLOCK, with a focus on "tweens" — children ages 9-13 — aimed at building awareness of the nutrition label and label reading skills and to make healthy food choices. Evaluation of the program shows that it is effective in getting children to respond to the messages, particularly to perceive the importance of knowing the serving sizes of the food that they eat. In addition to this effort, CFSAN also released the video "Kids 'n Fiber," to provide tips on how to incorporate fiber in a child's diet. These programs result in over 80 million web and media impressions annually, providing nutrition-focused outreach and education to both adolescents and their parents across the nation.

- CFSAN implemented a Nutrition Label Education Campaign for seniors. CFSAN developed educational tools for seniors to improve their understanding and use of the Nutrition Facts label to manage healthy eating and prevent disease. CFSAN also developed web-based materials and brochures to be distributed to seniors through senior centers and area Offices on Aging.

- CFSAN partnered with NSTA to develop a web-based tutorial on nutrition for middle and high school science teachers. The program recruits 200 teachers nationwide who commit to completing and using the tutorial, and tracks the gains in teacher understanding of good nutrition choices through pre-assessment and post-assessment.

Promoting Efficiency

Treatment of chronic diseases accounts for approximately 75 percent of the $2 trillion that America spends on health care each year.[9] This is twelve percent of the U.S. Gross Domestic Product. According to data from the CDC, chronic diseases cause seven out of ten deaths each year.[10] Poor nutrition contributes to chronic diseases such as hypertension, heart disease and stroke. CDC data indicate that more than 30 percent of the American adult population, or 60 million people, are obese.[11] FDA's Nutrition and Labeling sub-program helps reduce the burden on the U.S. economy associated with obesity and chronic diseases by helping consumers maintain health, reduce the risk of chronic disease and obesity, and make informed decisions to improve their diet and health.

[9] Anderson G. Chronic conditions: making the case for ongoing care. Baltimore, MD: John Hopkins University; 2004.
[10] http://www.cdc.gov/chronicdisease/overview/index.htm
[11] http://www.cdc.gov/obesity/data/trends.html

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (Outcome)	NA	NA	Set baseline	NA

Reinventing Cosmetics Safety - Center Activities

FY 2012 Enacted Amount: $8,033,000 (All BA)

Public Health Focus

The focus of *Reinventing Cosmetics Safety* is to protect the public health through FDA oversight of the safety of cosmetics marketed in the United States, whether manufactured domestically or imported. The cosmetic industry is changing rapidly as manufacturing becomes more global, technologies become increasingly sophisticated, and cosmetic ingredients become more complex. The industry-named category of products that straddles the line between cosmetics and drugs —"cosmeceuticals" — and products containing ingredients produced through nanotechnology present particular scientific and public health challenges.

Public Health Outcome

CFSAN 'sFY 2012 enacted resources support product surveys and laboratory investigations and allow FDA to maintain systems for voluntary cosmetic product registrations. CFSAN's cosmetics program activities include the evaluation of adverse event reports and consumer complaints. Information from these sources is essential for risk-based approaches to postmarket monitoring of cosmetic products, and outreach, inspection, and enforcement activities.

Cosmetics Safety Outreach: CFSAN conducted outreach in 2011 to improve public and industry understanding of potential cosmetic product issues and gather information on ways in which FDA can improve cosmetics safety.

- FDA developed and distributed material on why and how to report cosmetic related adverse events to CFSAN, presenting this information at several major professional conferences. This outreach effort supports FDA's ability to conduct surveillance on cosmetics products safety by helping to improve reporting frequency and quality.

- CFSAN held a public meeting with stakeholders in Washington, D.C., in November 2011, on microbiological safety issues relevant to cosmetic products. The purpose of the meeting was to provide stakeholders an opportunity to share information with FDA, consumers, and industry on variety of cosmetic microbiological safety issues. These included: the microbiological testing of cosmetics; the identity and prevalence of microorganisms that pose specific health risks in products; product and packaging characteristics that affect microbial growth and risk of infection; consumer subpopulations that may be at greater risk of infection from cosmetic products; and adverse events associated with microbial contamination of cosmetics. The meeting provided valuable information on issue areas where FDA guidance may help ensure the safety of American consumers from potential cosmetic safety issues.

Cosmetics Regulatory Science: CFSAN also conducted several cosmetics laboratory investigations in FY 2011 to inform its regulatory activities.

- CFSAN developed and validated an analytical method for determining peptides in skin matrices and cosmetic products. This method provides valuable information on skin absorption of cosmetic products.
- CFSAN developed and validated an analytical method for determining para-Phenylenediamine, a contact allergen, in cosmetic products and formaldehyde in fingernail products. Formaldehyde is a known human carcinogen and exposure is a significant consideration for consumer health and safety.

Nanotechnology: CFSAN's FY 2012 enacted activities also support several efforts focused on nanotechnology. Cosmetics represent one of the fastest growing areas for the application of this emerging technology. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties that may pose different safety issues. These cosmetics program activities support collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and the potential health hazards when used in cosmetics. CFSAN drafted guidance for industry and other stakeholders on the use of nanoscale materials in cosmetics, as part of the Agency's focus on nanotechnology safety. The guidance is expected to be published in 2012.

Promoting Efficiency

FDA administers the Voluntary Cosmetic Registration Program (VCRP), which benefits consumers and industry. Through VCRP, cosmetic manufacturers can register their manufacturing sites and submit ingredient listings for the products they market. This information allows FDA to stay abreast of the current cosmetics marketplace and guides FDA efforts to protect the health of consumers.

Information from VCRP is also critical to the activities of the Cosmetic Ingredient Review (CIR) group, an industry-sponsored organization that assesses the safety of cosmetic ingredients and makes the findings available to the public. FDA participates in the CIR,

providing information about the types of products in which cosmetic ingredients are used and their frequency of use. The CIR uses this information to assess the safety of specific ingredients and in setting overall review priorities. This safety review program facilitates more efficient product development by providing industry with information on ingredients to avoid or limit to achieve new and safer products, which is a significant benefit to industry and consumers.

Reinventing Cosmetics Safety - Field Activities
FY 2012 Enacted Amount: $3,253,000 (All BA)

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the United States.

In FY 2011, ORA issued 67 notices identifying modifications to cosmetics-related Import Alerts encompassing violations related to microbiological contamination and non-permitted or undeclared color additives (this is not inclusive of all cosmetic-related program areas). These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the U.S. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214208: Number of American consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (Outcome)	NA	Set baseline	+5% over baseline	+5% over baseline

Information Technology Investments – Foods Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $116,708,547)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure

facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

To fulfill its essential mission of protecting public health, FDA must receive, process, store, and analyze information about the products it regulates and make decisions quickly and credibly based on reliable and accessible information. FY 2012 enacted IT resources allow FDA to better protect American consumers from food safety risk across the farm to table continuum. IT systems enable FDA to conduct signal detection, identify science-based risk factors, and develop models to improve and support outbreak prevention and mitigation, compliance activities and regulatory decision making.

IT modernization efforts likewise enable the FDA to better identify and more quickly respond to foodborne outbreaks and contamination incidents. For example, FDA FY 2012 enacted resources provide tools for rapid analysis that improve FDA's ability to protect the nation's food supply from known and unknown pathogens and contaminants In FY 2011, FDA quadrupled its genomic sequencing capability, in turn, reducing food sample analysis response timeframes from weeks to days. FY 2012 enacted resources will also allow the FDA to increase its storage network to manage the exponential growth in new data produced by these cutting-edge, rapid detection tools.

FY 2012 enacted IT resources also improve the overall effectiveness of the FDA Foods Program by enabling data-driven, risk-based decision-making in addressing public health issues. For example, due to the globalization of the U.S. food supply and increased responsibility under FSMA to ensure that imported food is as safe as that produced domestically, amounts of imported foods, FDA has invested in the processing of importing data and developed automated compliance targeting assessment algorithms using a screening tool known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). PREDICT has improved the FDA's ability to prevent the entry of adulterated, misbranded, or otherwise violative goods and expedite the entry of non-violative goods. Likewise, the Reportable Food Registry (RFR) enables mandatory electronic reporting of adulterated and potentially harmful foods by industry, thus facilitating the earlier detection and removal of adulterated foods from the market place. Continued investment in RFR enables the FDA to provide data for effective risk communication related to these types of incidents and to decrease response time to foodborne outbreaks and contamination incidents.

As a result, FY 2012 enacted IT resources are critical to the success of FDA efforts to adopt a more proactive strategy for food safety. IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information, thereby improving the identification of threats to the public health, and ultimately reducing the incidence of foodborne illness outbreaks.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2008 through FY 2012 for the Foods Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$507,797,000	$507,797,000	$0	2,614
FY 2009 Actual	$712,769,000	$712,769,000	$0	2,995
FY 2010 Actual	$783,178,000	$783,178,000	$0	3,387
FY 2011 Actual	$836,244,000	$836,244,000	$0	3,605
FY 2012 Enacted	$882,747,000	$866,061,000	$16,686,000	3,757

Summary of the Budget Request

The FY 2013 budget request for the Foods Program is $1,083,939,000. This amount is an increase of $201,192,000 above the FY 2012 Enacted Level. CFSAN's amount in this request is $367,622,000, supporting 1,082 FTE. The Field amount is $716,317,000, supporting 2,965 FTE.

The FY 2012 enacted funding for the Foods Program is $882,747,000, which includes $264,760,000 for Foods Program Center activities and $617,987,000 for the Foods Program Field activities.

FDA's Foods Program executes its regulatory responsibilities through five sub-programs: 1) Prioritizing Prevention, 2) Strengthening Surveillance and Enforcement, 3) Improving Response and Recovery, 4) Nutrition & Labeling Strategies for Better Health, and 5) Reinventing Cosmetics Safety.

FY 2012 enacted funding allows the Foods Program to implement the Administration's vision of a new, integrated, and prevention-focused food safety system to better protect the American public. The initiatives proposed under the requested budget will allow FDA to achieve HHS and Presidential public health priorities, including the requirements of the landmark FDA Food Safety Modernization Act (FSMA). These resources support FDA public health objectives of preventing illnesses caused by contaminated foods, protecting consumers, and supporting improved health and nutrition.

Funding the FY 2013 request will allow the Foods Program to protect public health by:

- assessing potential safety problems

- ensuring that manufacturers use appropriate control measures to reduce or eliminate contaminants in foods
- taking steps to remove products from the market that violate safety standards
- continuing the development and implementation of an integrated national food safety system building on uniform standards.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Nutrition. The FY 2013 funding request will greatly enhance domestic and global efforts to substantially reduce foodborne illnesses caused by contamination of the food supply for years to come.

Budget Request

Data Consolidation and IT Savings
(Total Program: -$7,651,000)

The request for $855,239,000 in total budget authority for the Foods Program also reflects data consolidation and IT savings reduction of -$7,651,000 for FY 2013. The Center's portion of these savings is -$2,335,000 and the Field's portion is -$5,316,000.

The Foods Program will achieve savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- delaying or forgoing planned investments related to data transmission improvement infrastructure
- maximizing the use of local storage and minimize peak hour transmission of large files across the network to reduce the data transmission volume of the existing telecommunication infrastructure.

Rent Absorption
(Total Program: -$3,759,000)

The request for $855,239,000 in total budget authority for the Foods Program also reflects the rent absorptions of -$3,759,000 for FY 2013. The Center's portion of these savings is -$950,000 and the Field's portion is -$2,809,000.

Center Activities:

CFSAN will reduce investment in regulatory science infrastructure, including necessary equipment and technology upgrades. Lack of investment in regulatory science infrastructure will impede CFSAN's ability to develop and implement science-based standards and provide essential science-based information to industry to develop preventive controls. These tools are essential for reducing potential hazards before they harm American consumers by allowing FDA to better detect both known and unknown pathogens and better understand potential hazards. Additionally, CFSAN will be unable to keep pace with new, science-based, rapid-detection technologies and rapid risk assessments necessary to improve the effectiveness and efficiency of FDA response to foodborne outbreaks.

Field Activities:

The Field Foods Program will cut operating costs to cover the rent absorption.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

Prioritizing Prevention

Center Activities – FY 2012 Enacted Amount: $79,075,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$41,852,000 / 50 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Regulation and Guidance - FSMA Sections 101, 103, 104, 105, 106, 110, 204, 209, 210, 405 (UF +$26,846,000 / 35 FTE)

Foodborne illnesses linked to known causes are preventable if the parties involved in today's global food chain can be held accountable for implementing appropriate preventive measures at each step of the process where control of hazards is necessary. Regulations and guidance are important prevention-focused tools that guide food industry efforts and provide the framework for accountability for meeting appropriate standards called for by FSMA. The more successful the food system is in implementing

appropriate preventive measures in the production, processing, transportation, and preparation of foods, the safer the nation's food supply will be.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- develop science-based regulations and guidance documents to support industry adoption of preventive controls and produce safety standards that take account of the wide diversity of food production and processing operations
- develop performance standards for food hazards and review food safety plans for food facilities as needed
- hold public meetings and engage in extensive outreach, dialogue, and other efforts with the food industry to ensure that FDA regulations, standards and guidance documents are practical as well as protective; provide education to growers, industry, and consumers
- provide education and technical assistance to industry in the form of uniform hazard analysis standards, scientifically sound, risk-based controls for food and dietary ingredients, and model food safety plans for food and feed facilities
- encourage the use of cooperative compliance models through outreach to industry and the scientific community during the rulemaking process.
- provide training to industry, and federal and state regulatory partners in support of implementation of new FSMA standards.

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$10,548,000 / 8 FTE)

This investment will support comprehensive, prevention-focused import food and feed safety programs that will place more responsibility on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, transporters, and importers – to ensure that the food and feed imported into the United States are safe and meet regulatory requirements. In a globalized and increasingly complex world, reliance on a regulatory body to perform thorough supply chain verification through examination and/or sampling of commodities at the time they are offered for import is infeasible and cannot provide adequate assurance of product safety. To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, accredited third party certification, comparability assessments, and improved foreign inspections.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- continue to conduct foreign food safety system comparability assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs
- conduct initial assessments of recognized third party certification programs
- establish programs to recognize and accredit third party certification programs for food imports, followed by periodic systems audits
- develop and expand partnerships with other public health agencies to execute international outreach, training, capacity building, and technical support, and develop materials and information packets to support foreign inspections.

Proposed User Fee: Food Contact Substances Notification Program Fee (UF +$4,458,000 / 7 FTE)

With resources funded by user fees, CFSAN will expand and develop the Food Contact Notification Program to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable CFSAN to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Field Activities – FY 2012 Enacted Amount: $111,373,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$49,360,000 / 39 FTEs)

2013 Initiatives:

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$9,360,000 / 39 FTEs)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire two FTE with user fees to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard

- hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- hire 25 FTE with user fees to perform program oversight through ORA audits of regulatory and public health partners to measure their performance against FDA program standards
- hire six FTE with user fees to serve as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire three FTE with user fees to develop and validate certification testing instruments.

Transforming Food Safety: Regulations and Guidance (UF +$40,000,000 / 0 FTE)

To implement and enforce preventive controls in food processing facilities, FDA will train more than 9,600 ORA inspections personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

Center Activities – FY 2012 Enacted Amount: $118,770,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$31,919,000 / 23 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Integrated Food Safety System - FSMA Sections 201, 202, 203, 204, 205, 209, 210 (UF +$11,423,000 / 15 FTE)

With these resources, FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments in state, local, tribal and territorial regulatory and public health partners. These investments will provide more uniform coverage and safety oversight of the food and feed supply.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- evaluate and implement new methods, training, fit-for-purpose method extension, and new instruments to expand laboratory capacity for the integrated national food safety system
- expand the current FDA proficiency testing program to better target food safety and food defense concerns in support of the FSMA mandate for laboratory accreditation
- update Foods Program methods validation manuals, such as the Bacteriological Analytical Manual (BAM), the Pesticide Analytical Manual (PAM), and the Elemental Analysis Manual (EAM), through the provision of web services, the coordination of methods development and validation, International Standards Organization (ISO) Board membership, and funding proficiency testing needs for participating partner labs.

Transforming Food Safety and Nutrition: Risk Analysis - FSMA Sections 103, 104, 105, 106, 201, 204, 301, 203, 303, 306 (UF +$11,621,000 / 3 FTE)

FDA will improve and implement data-driven risk ranking and prioritization tools to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA's FSMA responsibilities. Currently, FDA is largely limited to reliance on epidemiological approaches to understand and prevent foodborne outbreaks. As a result of this initiative, FDA will be able to rank and prioritize food safety concerns, and identify how to best apply limited Agency resources to achieve the best possible public health outcomes.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- improve and implement data-driven risk ranking and prioritization tools, such as iRisk and iPrioritize, to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA FSMA responsibilities
- adapt risk analysis tools for use by the public and industry to improve understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards.

Transforming Food Safety: Science for Food Safety – Critical Capacity for Implementation of FSMA (UF +$8,875,000 / 5 FTE)

Scientific research and analysis provide the basis for developing appropriate regulations and guidance. This investment will allow FDA to establish food safety standards that are based on the latest scientific developments and that address hazards from farm-to-table. FDA will also apply research results to improve response speed and effectiveness.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- develop innovative methods and tools to validate preventive controls and hazard analysis and to better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins
- develop and deploy new chemical detection technologies to better identify and address chemical hazards in the food supply both before and after illness occurs
- develop new methods and platforms for rapid fingerprinting of food pathogens, along with methods for determining the geographic origin of contaminated food samples, to support rapid analysis in both laboratories and the field with high throughput and at low cost.

Field Activities – FY 2012 Enacted Amount: $286,953,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$12,961,000 / 51 FTEs)
FY 2013 increase for proposed user fees (International Courier): (+721,000; 3 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF +$11,040,000 / 43 FTE)

This investment will allow FDA to continue to administer the Foreign Supplier Verification Program (FSVP) and conduct import verification inspections using risk-based strategies to target inspections and rapid field tests to better target sampling at the border. FDA will establish and implement procedures for electronic verification of importers compliance status with FSVP. This electronic verification will allow FDA to make appropriate admissibility determinations for foods offered for import.

- hire 43 FTE to support the FSVP, which is a subcomponent of the Import Accountability Verification Program

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$1,200,000 / 5 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the states as FDA moves to national standards for laboratories.

Strengthening Surveillance and Enforcement – B. Strengthening Enforcement

Center Activities – FY 2012 Enacted Amount: $25,095,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$10,823,000 / 28 FTE)
2013 Initiatives:

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$4,325,000 / 12 FTE)

To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, accredited third party certification, comparability assessments, and improved foreign inspections.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- plan and evaluate foreign inspections conducted to prevent illness or injury from possibly unsafe or contaminated foods including foreign firm notification to request permission to conduct inspections, inspection reports review, development of decision support systems, and management of follow-up compliance actions.
- continue to develop and expand the infrastructure and processes to enable timely enforcement action and follow-up compliance actions related to foreign inspection
- conduct testing and analysis of foreign samples to inform compliance cases and entry decisions.

Transforming Food Safety and Nutrition: Domestic Inspections - FSMA Section 201 (UF +$6,498,000 / 16 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential for holding the industry accountable for their responsibility to produce safe products.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- improve enforcement tools and processes in order to successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections
- modernize and expand compliance programs to reflect changes introduced by FSMA, including planning inspection work, analyzing trends of violative firms,

and identifying firms who are non-compliant or who have not registered as a food establishment with the Agency to ensure sufficient oversight and monitoring needed to protect the public health.

These activities are new investments for FDA in FY 2013.

Field Activities – FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

FY 2013 Increase above FY 2012 Enacted Level: (+$39,164,000 / 32 FTE)
FY 2013 increase for Current Law User Fees (Food Reinspection): (+$309,000 / 0 FTE)
FY 2013 increase for Current Law User Fees (Recall): (+$426,000 / 0 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 305, 306 and 307 (UF +$10,204,000 / 30 FTE)

With this investment FDA will continue to conduct foreign food safety system comparability assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs. FDA will also increase staff to conduct accredited third party certification performance audits and assessments. FDA will work with foreign regulatory counterparts on an individual and/or coalition basis to improve information sharing, outreach to the private sector, and other collaboration to facilitate implementation of the import safety provisions of FSMA. Concurrently, FDA will use budget authority to expand critical enforcement and compliance support for foreign food facility inspections. These activities include planning inspections, notifying foreign firms to request permission to conduct inspections, reviewing inspection reports, developing decision support systems, and managing follow-up on compliance actions.

- hire 15 FTE to conduct audits of foreign regulatory bodies
- hire 15 FTE to perform performance assessments and audits of the Third-Party Certification Recognition/Accreditation Program

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$15,225,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- provide funding to federal, state, local, territorial and tribal regulatory and public health partners in the form of at least ten states grants, contracts, cooperative agreements or inter-agency agreement between federal agencies. Ten of the state grants, contracts, cooperative agreements or inter-agency agreements

between federal agencies would be funded with budget authority and ten would be funded with user fees.

- improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Transforming Food Safety: Domestic Inspections and Technology for Greater Efficiency – FSMA Sections 201 (UF +$13,000,000 / 2 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable for their responsibility to produce safe products.

The resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs and improve FDA food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. This is essential in order to achieve the most public health value from FDA inspection and compliance programs and successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote Access Devices will allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Improving Response and Recovery

Center Activities – FY 2012 Enacted Amount: $15,517,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$9,342,000 / 6 FTE)
FY 2013 Increase for Current Law User Fees (Recall): (+$21,000 / 0 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Planning and Response - FSMA Sections 202, 204, 205, 206 (UF +$9,342,000 / 6 FTE)

This initiative will enable FDA to respond effectively and reduce illness and deaths when food safety problems emerge and affect the public, despite preventive controls, as well as learn from outbreaks and other food safety incidents to inform future prevention

efforts. This funding will also support FDA's ability to enforce mandatory recall authority to respond immediately when a food company fails to recall unsafe food voluntarily. CFSAN will conduct the following activities with the user fee resources in this subprogram:

- work with government and industry partners to develop new traceback tools and systems unifying information from regulatory partners and private sources
- expand support for responsive food recall processing and case management to continue to improve the ability of FDA to execute this authority under FSMA
- enhance existing systems and expand tools and databases for surveillance, outbreak detection, outbreak response and investigation, and post-response activities under the Coordinated Outbreak Response and Evaluation (CORE) team
- enhance the Reportable Foods Registry to better support FSMA food recall requirements.

Field Activities – FY 2012 Enacted Amount: $49,327,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$240,000 / 1 FTE)

2013 Initiatives:

Transforming Food Safety: Planning and Response – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF +$240,000 / 1 FTE)

This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents, and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private

- fund one FTE to develop and implement traceback procedures

Reinventing Cosmetics Safety

Center Activities – FY 2012 Enacted Amount: $8,033,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$12,012,000 / 42 FTE)
2013 Initiatives:

Proposed User Fee: Cosmetic Safety User Fee (UF +$12,012,000 / 42 FTE)

CFSAN will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. CFSAN will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist them in their safety evaluations and product modifications. The user fees will also enable CFSAN to meaningfully participate in international harmonization efforts for cosmetic standards. As a result, FDA will be better positioned to fulfill its public health mission and will promote greater safety and understanding of cosmetic products being used regularly by consumers.

Field Activities – FY 2012 Enacted Amount: $3,253,000 (All BA)

FY 2013 Increase above FY 2012Enacted Level: (+$4,320,000 / 18 FTEs)
FY 2013 increase for Proposed User Fee- Cosmetic User Fee: (+$4,320,000 / 18 FTE)

FDA is proposing new legislative authority to require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and list their products with FDA and pay an annual fee, with a sliding scale of fees for certain small businesses. Registration will provide both FDA and industry with a better understanding of the cosmetic products being marketed. The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used regularly by consumers.

Without this initiative, FDA will continue to lack vital information necessary to provide domestic regulatory oversight and leadership, as well as leadership in international harmonization efforts. Moreover, without knowledge of the full range of cosmetic products and ingredients being marketed in the United States and the facilities that are involved in providing such products to American consumers, including foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe products.

This initiative provides long-term, stable funding for the FDA Cosmetics Program, which in turn ensures better public health protection for all Americans. The initiative will also better enable FDA to obtain critical data about the industry in an increasingly global marketplace, and provide increased public confidence and continued U.S. leadership in international harmonization efforts. These benefits are largely realized by industry in terms of increased sales and lower costs.

CFSAN Program Activity Data

PROGRAM WORKLOAD AND OUTPUTS	FY 2010 Actual	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FOOD AND COLOR ADDITIVE PETITIONS				
Petitions Filed	8	72 [2]	10	10
Petitions Reviewed [1]	13	5 [3]	10	10
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES				
Notifications Received	96	90	100 [6]	100 [6]
Notifications Reviewed [4]	73	97 [5]	96 [6]	100 [6]
INFANT FORMULA NOTIFICATIONS				
Notifications Received [7]	36	38	35	35
Notifications Reviewed [8]	39	38	35	35
FDA Review Time	90 Days	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [9]				
Submissions Received [10]	45	52	60	60
Submissions Reviewed [11]	41	52	55	55
FDA Review Time	75 Days	75 Days	75 Days	75 Days

[1] Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.

[2] Number of petitions filed for FY2011.

[3] This number is for the cohort of petitions filed in FY2011.

[4] Number reviewed includes notifications that became effective or were withdrawn.

[5] This number is greater because it includes those submission received late in the previous fiscal year where the 120-day statutory timeframe begins in FY2010 but ends in FY2011.

[6] Our current estimates assume continued funding of the FCN program.

[7] A notification may include more than 1 infant formula.

[8] Number of submissions reviewed includes some submissions that were received in the previous FY.

[9] A single notification may address one or more new dietary ingredients. For example, FDA has received at least 15 notifications that pertain to 2 up to 16 new dietary ingredients in a single notification.

[10] Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

[11] Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY when the due date occurred in the current FY.

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***10,517***	***12,517***	***12,517***
Domestic Food Safety Program Inspections	7,385	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	305		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	483		
Domestic Fish & Fishery Products (HACCP) Inspections	1,752		
Import (Seafood Program Including HACCP) Inspections	353		
Juice HACCP Inspection Program (HACCP)	220		
Interstate Travel Sanitation (ITS) Inspections	1,088		
Domestic Field Exams/Tests	4,092	3,945	3,945
Domestic Laboratory Samples Analyzed	11,240	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***999*** [2]	***1,200***	***1,200*** [1]
All Foreign Inspections	999	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***11,516***	***13,717***	***13,717***
IMPORTS			
Import Field Exams/Tests	201,406	160,200	160,200
Import Laboratory Samples Analyzed	35,292	35,300	35,300
Import Physical Exam Subtotal	**236,698**	**195,500**	**195,500**
Import Line Decisions	10,167,887	10,616,840	11,085,616
Percent of Import Lines Physically Examined	2.33%	1.84%	1.76%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	88,057	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,765***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***273***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,535	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,123	1,104	1,104
State Contract Juice HACCP	93	103	103
State Contract LACF	79	68	68
State Partnership Inspections	273	273	273
State Contract Foods Funding	$19,068,458	$11,507,200	12,312,710
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$18,270,000	$18,390,000	$18,490,000
Total State & Annual FERN Funding	**$37,338,458**	**$29,897,200**	**$30,802,710**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***21,554***	***24,513***	***24,513***

[1] For investigators hired with FY 2013 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2013 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2011 actual unique count of foreign inspections includes 35 OIP inspections (25 for China and 10 for India).

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**153**	***100***	***100***
Domestic Inspections	153	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***2***	***0***	***0***
Foreign Inspections	2	0	0
IMPORTS			
Import Field Exams/Tests	3,034	1,600	1,600
Import Laboratory Samples Analyzed	626	630	630
Import Physical Exam Subtotal	**3,660**	**2,230**	**2,230**
Import Line Decisions	2,121,088	2,389,000	2,690,751
Percent of Import Lines Physically Examined	0.17%	0.09%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT	***155***	***100***	***100***

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

Human Drugs

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

Program Resources Table

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$956,160**	**$949,645**	**$978,705**	**$1,258,614**	**$279,909**
Center	$815,488	$811,869	$838,694	$1,063,869	$225,175
FTE	3,272	3,264	3,281	3,603	322
Field	$140,672	$137,776	$140,011	$194,745	$54,734
FTE	752	797	790	965	175
Program Level FTE	**4,024**	**4,061**	**4,072**	**4,568**	**496**
Budget Authority	**$477,018**	**$477,502**	**$477,810**	**$472,683**	**-$5,127**
Center	$345,929	$346,194	$347,817	$344,500	-$3,317
Field	$131,089	$131,308	$129,993	$128,183	($1,810)
Budget Authority FTE	**2,126**	**2,030**	**2,040**	**2,043**	**3**
Center	1,423	1,284	1,301	1,304	3
Field	703	746	739	739	0
User Fees	**$479,142**	**$472,143**	**$500,895**	**$785,931**	**$285,036**
Center PDUFA	$469,559	$465,675	$490,877	$501,334	$10,457
FTE	1,849	1,980	1,980	1,990	10
Field PDUFA	$9,583	$6,468	$10,018	$10,231	$213
FTE	49	51	51	51	0
Center Generic Drugs [1]			$0	$202,731	$202,731
FTE			0	250	250
Field Generic Drugs[1]			$0	$51,811	$51,811
FTE			0	150	150
Field Reinspection [1]			$0	$0	$0
FTE			0	0	0
Field International Courier User Fee[1]			0	$481	$481
FTE			0	2	2
Field Medical Products Reinspection User Fee [1]			0	2,749	2,749
FTE			0	18	18
Center Biosimilars User Fee [1]				15,304	15,304
FTE				59	59
Field Biosimilars User Fee [1]				1,290	1,290
FTE				5	5
User Fees FTE	**1,898**	**2,031**	**2,031**	**2,525**	**494**

[1] Proposed User fee; the amount includes associated rent activity

The FDA Human Drugs Program operates under the following legal authorities:

- Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
- Public Health Service Act of 1944 (42 U.S.C. 201)
- Federal Advisory Committee Act (FACA) of 1972 as amended
- Orphan Drug Act of 1983 (21 U.S.C. 360ee)
- Drug Price Competition and Patent Term Restoration Act of 1984 (Section 505(j) 21 U.S.C. 355(j)) (a.k.a. “Hatch Waxman Act”)
- Prescription Drug Marketing Act (PDMA) of 1987 (21 U.S.C. 353)
- Anti-Drug Abuse Act of 1988
- Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
- Orphan Drug Amendments of 1988

- Generic Drug Enforcement Act of 1992
- Prescription Drug User Fee Act (PDUFA) of 1992
- FDA Export Reform and Enhancement Act of 1996
- Food and Drug Administration Modernization Act (FDAMA) of 1997*
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Best Pharmaceuticals for Children Act (BPCA) of 2002
- Freedom of Information Act (FOIA) as amended in 2002 (5 U.S.C. § 552)
- Pediatric Research Equity Act (PREA) of 2003
- Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
- Food and Drug Administration Amendments Act (FDAAA) of 2007*
- Public Health Service Act of 2010 (42 U.S.C. 262)
- Protecting Patients and Affordable Care Act of 2010*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of prescription, generic, and over-the-counter (OTC) drug products that are available to the American public. The Program is also responsible for monitoring marketed drug products to ensure patient safety, and monitoring drug quality to ensure the safety of the drug supply chain. The Human Drugs Program, which consists of CDER and ORA's field drugs program, operates with funding from appropriations and user fees.

Responsibilities and functions carried out by the Center for Drug Evaluation and Research (CDER) are a result of a series of statutory mandates beginning with the earliest days of the FDA and the Pure Food and Drugs Act of 1906. The Food, Drug, and Cosmetic (FD&C) Act of 1938 required that new drugs demonstrate safety before becoming available for public consumption. The Drug Amendments Act of 1962 (also known as the Kefauver-Harris Act) stipulated that a drug should be “effective for its intended use”. These statutory requirements contributed to the establishment of CDER's mission of assuring that safe and effective drugs are available to the American people.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA) which has, through a series of reauthorizations over the past 20 years, significantly increased FDA’s resources to review human drug applications. The increase in funding from PDUFA has improved FDA's ability to review applications and increase access to drug products in a timely manner. The Food and Drug Administration Amendments Act (FDAAA) of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products. FDAAA expanded the Center’s authorities and responsibilities for ensuring a more robust program for monitoring and managing drug safety after new drugs have been approved for marketing.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

CDER's mission is to promote and protect public health by ensuring that safe and effective drugs are available to Americans. This mission supports FDA priorities of improving health care quality and reducing health care costs.

CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. CDER is also responsible for monitoring the safety and effectiveness of drugs once they are marketed and consumed, as well as assessing the quality of drugs in order to protect the supply chain. In addition, CDER regulates print and broadcast drug advertisements to ensure that health care providers and patients receive truthful, balanced information about drugs.

The Office of Regulatory Affairs (ORA) supports the Human Drugs Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies, and by assessing industry compliance with applicable regulations to protect the public health. To provide this support, ORA conducts risk-based domestic and foreign pre-market and post market inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMP). In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods.

In FY 2011, ORA working with CDER, established a staff of highly trained individuals primarily focused on conducting human and animal drug quality inspections of high risk firms. This joint effort between the Center and ORA to provide training and developmental experiences to drug investigators ensures the highest level of competence and professionalism in the drug inspection program. The Pharmaceutical Inspectorate will be maintained in coming years by providing continuing developmental and training opportunities coupled with opportunities to inspect establishments globally to sustain the level of competence. In addition, ORA will continue to develop all drug investigators to reach this level of competence. At the borders, ORA determines product admissibility by performing entry reviews, field exams, and sample collections to ensure that products coming into the United States are coming from approved sources and are properly registered. Through its laboratories, ORA conducts surveillance analyses of prescription and over-the-counter (OTC) products to verify compliance with labeled identity, potency and content uniformity. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) and the Forensic Chemistry Center complement the regular Field force activities by expanding efforts to develop cases that address the marketing of counterfeit products.

The Human Drugs Program executes its regulatory responsibilities in five subprograms including New Drug Review, Generic Drug Review, Drug Quality, Post Market Safety Oversight, and Oversight of Drug Promotion.

New Drug Review – Center Activities FY 2012 Enacted Amount: $440,970,000 (BA: $119,256,000 / UF: $321,714,000)

Public Health Focus

The New Drug Review function within the Human Drugs Program involves evaluating the safety and efficacy of medical products before those products are marketed to the public.

Key functions in the New Drug Review subprogram include:

- Clinical Review - Pharmaceutical companies must conduct clinical research to test their products. Once the company has completed its research and submitted the findings and conclusions to FDA, CDER assembles a team of physicians, statisticians, chemists, pharmacologists and other scientists to review the company's data on the proposed use of the drug. If a drug is shown to be effective and if its health benefits outweigh its risks, FDA approves the drug for sale. By setting clear standards for the evidence required to approve a drug, FDA helps bring safe and effective new drugs to American consumers.

- Bioresearch Monitoring – CDER monitors pharmaceutical companies' research in clinical trials to ensure the safety of people who volunteer for studies and to maintain the quality and integrity of scientific data. CDER conducts on-site inspections of clinical trial study sites, institutional review boards, sponsors, study monitors, and contract research organizations.

- Pharmaceutical Science and Chemistry Review – Evaluating the safety and efficacy profile of new drugs would be impossible without an understanding of how the chemicals involved act in the human body. CDER maintains a corps of highly talented scientists, clinicians and pharmacists who ensure that the new drug review process results in a thorough understanding of how drugs are designed, produced, and delivered to the patient in order to ensure that drugs available to the American public are safe and effective.

- Pediatrics – CDER plays a major role in protecting children who need prescription or OTC drug products by working with companies to conduct studies of children's products. Due to the inadequacy of pediatric use information found in the majority of prescription medications, Congress enacted several legislative initiatives to promote drug development for children. As a result of these initiatives, the number of ongoing pediatric clinical trials and the number of drug products appropriately labeled for children have increased dramatically.

- Review of over-the-counter (OTC) Products – CDER reviews and evaluates OTC drugs to ensure that they are safe, effective, and of high quality. CDER also informs consumers about how to best use OTC products by providing clear, easy-to-read drug information. These drugs play an increasingly vital role in America's health care system. The trend to self-medicate has increased greatly in recent years as health care costs have risen and consumers want to treat minor ailments with OTC drug products.

- Pre-Approval Inspections – Before an application for a new drug product is approved, FDA inspects the product manufacturer to ensure that manufacturing and development

facilities meet FDA's standards for good manufacturing practices. FDA inspectors must ensure that a drug product is manufactured with reliable consistency and high quality.

Public Health Outcome

Efficient, accurate, and thorough reviews allow for the availability of safe and effective drug products to consumers. Without consistent dedication to conducting thorough reviews, the public might be at risk of adverse events resulting from unsafe drug products on the market. The pre-market activities associated with reviewing new drugs and inspections of facilities are conducted to pursue FDA's mission to promote and protect the public health.

CDER's ongoing efforts to pursue modernization and efficiency, while maintaining safety and efficacy of its approved products, will make new medical treatments available to patients sooner, and improve patients' confidence in new drug products.

Promoting Efficiency

Modernization is a critical component to improving efficiency at CDER. Developing and adopting standards for receipt and processing of electronic data will help to minimize the use of paper submissions – which must be stored year after year, at increasing cost – and take advantage of advanced computing techniques to review enormous quantities of data associated with a drug submission.

Currently, CDER has a plan for developing data standards. The plan addresses challenges concerning the volume and complexity of drug-related information submitted to CDER for regulatory review. The lack of standardized data affects CDER's review processes by curtailing a reviewer's ability to perform integral tasks such as rapid acquisition, analysis, storage, and reporting of regulatory data. Improved data quality, accessibility, and predictability will allow more time for reviewers to carry out complex analyses, ask in-depth questions, and address late-emerging issues. This will improve the Center's ability to evaluate applications for new drugs and conduct in-depth reviews of drug products.

New Drug Review – Field Activities FY 2012 Enacted Amount: $35,684,000 (BA: $25,666,000 / UF: $10,018,000)

Public Health Focus

ORA's public health focus under the New Drug Review subprogram is to assess whether methods and facilities used for manufacturing, processing, and testing of products submitted under New Drug Application (NDA) are adequate to ensure strength, quality, and purity.

ORA inspects establishments to verify their ability to manufacture products to the specifications stated in the application. ORA also confirms the authenticity of the data contained in the application and reports any information which may impact the firm's ability to manufacture the product in compliance with GMP. Inspectional coverage is

necessary to assure that NDAs are not approved if the applicant has not demonstrated the ability to operate with integrity and in compliance with all applicable requirements.

ORA conducts Bioresearch Monitoring Program (BIMO) inspections of scientific studies which are designed to develop evidence to support the safety and effectiveness of investigational drugs. Physicians and other qualified experts ("clinical investigators") who conduct these studies are required to comply with applicable statutes and regulations intended to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects.

Public Health Outcome

In an effort to increase public awareness and knowledge, FDA shares a series of lists on its website containing information on clinical investigators who:

- received notification from the Agency of the intent to initiate administrative proceedings to determine if the person should be disqualified from receiving investigational products
- are disqualified or 'totally restricted' and are no longer eligible to receive investigational drugs, biologics, or devices
- have been recommended for disqualification
- All clinical investigators who agreed to certain restrictions
- agreed to restrictions which have been subsequently removed
- provided FDA with adequate assurances of their future compliance with requirements applicable to the use of investigational drugs and biologics.

FDA also makes available a separate list of firms or persons who have been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act.

Based on referrals from the OCI and other sources, ORA debarred fifteen individuals with criminal convictions from participating in certain aspects of human drug industry activities.

Promoting Efficiency

Through its pre-approval inspection coverage, ORA prevents unsafe and ineffective drugs from being marketed to the public while assuring the release of safe products into the US market. ORA also assures that a manufacturing establishment named in a drug application is capable of manufacturing a drug in compliance with Current Good Manufacturing Practice (CGMP), and that data that supports drug review are accurate and complete. These efforts also provide industry with assistance in addressing possible safety issues related to products as well as provide guidance through inspectional findings on current manufacturing processes.

Through the post approval program, ORA audits drug manufacturing establishments to assure that any changes in manufacturing and process control comply with CGMP

regulations, to assure that all changes are documented in supplemental applications or annual reports, and to confirm that requirements concerning Adverse Reaction Reports, NDA Field Alerts, and Annual Reports are being met. Both foreign and domestic establishments are covered by this program. These efforts allow the Agency to provide guidance and assistance to manufacturers, through inspectional findings, to ensure product development is in accordance with FDA regulations and assurance of product safety for products currently in the US market.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)*	FY 2010: 98% Target: 90% (Target Exceeded)	90%	90%	Maintain
223202: Percentage of Priority NDAs/BLAs within 6 months *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain

Generic Drug Review – Center Activities
FY 2012 Enacted Amount: $87,936,000 (BA only)

Public Health Focus

CDER's generic drug review activities are part of the larger generic drugs program, which includes additional activities throughout the Center. The generic drug review subprogram concentrates specifically on the review function. Other non-review work (mainly post market work) within the generic drugs program is captured within other parts of CDER's budget.

Generic drugs are widely known to be a cost-effective treatment alternative. According to generic drug industry estimates, generic drug products saved consumers approximately $931 billion between 2001 and 2010. In CY 2010,, generic drug products saved $158 billion, or an average of $3 billion per week. Further investments in FDA's generic drug program will generate additional savings for consumers in the future.

Every year, FDA expands the availability of high-quality generic drug products and provides consumers and healthcare providers with information on both safety and effectiveness. With each new generic version of a brand-name drug FDA approves, consumers have an additional option to save money on their prescription drug needs. In FY 2011, CDER approved, or tentatively approved, 597 generic drug applications, the equivalent of more than two approvals or tentative approvals each business day. To measure its performance, CDER tracks the number of actions taken on Abbreviated New Drug Applications (ANDA). The total number of actions includes approvals, tentative approvals, not approvable actions, and approvable actions on applications. CDER took 2,276 actions in FY 2011 compared to 2,079 in FY 2010.

Key functions in the Generic Drug Review subprogram include:

- Generic application review – The basic requirements for approval of generic drugs are the same as for new drug approvals, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of the original product. Prior to approval, generic drug sponsors are required to demonstrate bioequivalence - that the active ingredient in a generic product is absorbed at a rate and extent similar to the brand name product. Medical reviewers from the Office of Generic Drugs (OGD) often consult with reviewers from the Office of New Drugs (OND) to address clinical questions regarding the referenced brand-name drug.

- Pre approval and Bioequivalence lab inspections – As with new drug products, before an application for a generic drug product can be approved, FDA must inspect the product manufacturing facility to ensure that manufacturing and development facilities meet FDA's standards for good manufacturing practices. In addition, FDA inspects the laboratories where bioequivalence studies were conducted to ensure the accuracy and integrity of the data submitted in the generic drug application.

- Regulatory policy – FDA frequently receives citizen petitions for or against an upcoming FDA action on a generic drug application. A citizen petition is a vehicle that stakeholders outside of FDA may use in order to suggest that FDA take – or refrain from taking – an action. FDA has received numerous petitions asking FDA not to approve particular generic drugs unless certain criteria set forth in the petition are met. In most cases, the petitions raise scientific issues relating to the standards for approval of the applications. CDER must evaluate and respond to each of these citizen petitions.

- Research into bioequivalence technologies – Some types of drugs are very difficult for generic companies to duplicate. This is attributed, in part, to utilization of novel delivery technologies to which the human body's reactions are highly variable (for example, patches worn on a patient's skin, injections, etc.) In cases like these, FDA is eager to understand how to assess bioequivalence as a way to encourage development of generic alternatives, opening the doors to lower prices and better access to drugs for patients.

All of the key functions listed above must be conducted in order to ensure the safety, efficacy, and quality of each generic drug. CDER's Office of Generic Drugs is responsible for conducting reviews of generic drug applications. The overall Generic Drug Review subprogram includes efforts from other offices within CDER and ORA to accomplish the key functions mentioned above.

Public Health Outcome

The availability of generic drugs directly impacts public health by making safe, affordable drug products accessible to the public. With increasing health care costs, many Americans face challenges in acquiring the drug products necessary for proper medical treatment. The availability of safe, effective, and affordable generic drugs supports the FDA mission of promoting and protecting the public health.

Promoting Efficiency

CDER takes several steps to improve the efficiency of generic drug review. CDER expedites applications that, at the time of submission, are the first generic application for an innovator product that had no patent or exclusivity protection. The dramatic increase of generic drug applications creates a greater need for CDER's ability to process applications more efficiently. Steps to improve current processes and to improve the content and completeness of generic drug applications include:

- The Generic Initiative for Value and Efficiency, which focuses on using existing resources to help FDA modernize and streamline the generic approval process.
- *Question-based Review* to assist sponsors in providing information that demonstrates their understanding of the manufacture of the product.
- *Posting bioequivalence information,* including data tables, information about laboratory tests, and necessary studies.
- *Focused hiring* which will increase staff in critical review components.
- *Holding joint meetings and workshops* with academia and industry to improve knowledge of the submission process and quality of applications.
- Encouraging electronic submission of applications.

Data standardization will also support improved efficiency in the generic drug review process, similar to how it promotes efficiency in the review process for innovator drug products. By converting to paperless, electronic data submissions and providing reviewers with standardized formats of data, the time to review and approve is likely to be reduced. This will improve the thoroughness and timeliness of the generic drug review process.

Generic Drug Review – Field Activities FY 2012 Enacted Amount: $8,029,000 (BA only)

Public Health Focus

ORA's public health focus under the Generic Drug Review subprogram is to assess whether the methods and facilities used for the manufacturing, processing, and testing of products submitted under an Abbreviated New Drug Application (ANDA) are adequate to ensure strength, quality, and purity.

Public Health Outcome

ORA supports the generic drug program through pre-approval and post-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with CGMP. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness and regulatory compliance.

Promoting Efficiency

ORA achieves program efficiencies by ensuring through its inspection program that generic drugs marketed in the United States are shown to be both safe and effective

prior to marketing and widespread use in the general population, allowing for the marketing of lower cost generics to US consumers. In FY2011, ORA collaborated with CDER to develop a priority listing of Approved New Drug Applications (ANDA) inspections, aiding in targeting inspectional resources and creating Agency efficiencies by identifying generic drug manufacturing facilities for inspection to coincide with Center reviews of applications.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year *(Output)*	FY 2011: 2,276 Target: 2,000 (Target Exceeded)	2,000	2,000	Maintain

Drug Quality – Center Activities

FY 2012 Enacted Amount: $100,171,000 (BA: $44,020,000 / UF: $56,151,000)

Public Health Focus

CDER's drug oversight activities begin when sponsors test drug products in animals. This oversight continues in clinical development during the first human trials. CDER's role extends into post market safety activities after the sponsor receives FDA approval to market a drug product, and once the product is used by a diverse population. Generic drug products also receive CDER scrutiny to ensure that they have demonstrated equivalent performance to the innovator product. CDER is fully engaged in enforcement actions against drug products that exist outside of the FDA approval system such as counterfeit and marketed unapproved products.

CDER provides comprehensive regulatory coverage of the production and distribution of drug products and manages inspection programs designed to minimize consumer exposure to defective drug products. CDER evaluates the findings of inspections that examine the conditions and practices in plants where drugs are manufactured, packed, tested, and stored. CDER also monitors the quality of finished drug products in distribution through sampling and analysis.

In addition to setting standards for safety and effectiveness testing, CDER also sets guidelines for drug quality and manufacturing processes. CDER has a team of inspectors and quality management experts who ensure that any change to a manufacturing process does not adversely affect the safety or efficacy of the drug produced. CDER evaluates reports about suspected problems from manufacturers, health care professionals, and consumers.

Public Health Outcome

Assessment of drug quality promotes the initiative to supply the public with drugs that are both safe and effective. This decreases risks of adverse events resulting from poor-quality or defective drug products. As a result, consumers face fewer risks associated with unsafe drugs, and public health is protected from exposure to drug products that do not meet FDA standards of quality.

Promoting Efficiency

CDER's drug quality activities aim to eliminate production inefficiencies and undue risks for consumers by implementing improved policies that make better use of limited resources, and result in more targeted, effective inspections.

The Drug Quality subprogram focuses on improving efficiency in critical pharmaceutical quality attributes, such as chemistry, pharmaceutical formulation, stability, manufacturing processes, bioavailability, and product performance.

Long term goals include:

- Emphasizing quality by design in the evaluation of critical aspects of pharmaceutical quality.
- Focusing on manufacturing science.
- Integrating review and inspection functions.
- Using modern statistical methodologies.

FDA inspections and sampling – from clinical to manufacturing – provide feedback to the firm on its state of compliance and result in corrective actions that the firm can bring forward to other relevant activities. Better compliance results in less waste and rework, fewer and less costly manufacturing changes, and fewer product recalls.

Drug Quality – Field Activities FY 2012 Enacted Amount: $91,884,000 (BA only)

Public Health Focus

ORA minimizes consumers' risk of exposure to defective drug products by conducting inspections, monitoring imports, and collecting and analyzing product samples of domestic and foreign drug manufacturers. These activities prevent marketing of, or remove from the market, violative drug products, thereby ensuring the products do not reach the U.S. market. Early detection of contaminated or defective human drug products and their ingredients continues to be a priority within ORA.

ORA field offices investigate and build enforcement cases using a number of enforcement tools such as seizures, injunctions, and prosecutions. ORA is also responsible for oversight and monitoring of recalls conducted by the drug industry, assuring that the companies' recall efforts progress satisfactorily and are effective in removing defective products from commerce

Public Health Outcome

In FY 2011, ORA entered into a 3 year Cooperative Research & Development Agreement (CRADA) with the United States Pharmacopeia (USP), the worldwide recognized standard-setting authority for prescription and OTC drug products, to participate in the establishment of USP reference standards for drug quality assessments. This CRADA provides ORA with the ability to utilize highly advanced equipment to participate in collaborative standard assessments to ensure that both novel and existing drug standards and methodologies referenced by regulated industry meet required specifications, while bolstering and expanding efforts to promote drug quality, purity, and efficacy via ORA field laboratory support to USP. The CRADA allows for ORA and USP collaboration in the following efforts: USP Monograph Modernization – revising and/or replacing USP monographs which require modernization in order to ensure the quality and potency for active pharmaceutical ingredients and their utilization in the manufacturing of drug products.

Throughout FY 2011, select ORA field laboratories actively participated in a Pharmacy Compounding Validation pilot program. The program, which ensures specialized drug products are analyzed appropriately to ensure quality, consistency, and efficacy for pharmacy compounded products, called for ORA laboratories to perform method verification for 10 proposed USP pharmacy compounding monographs. The program resulted in the laboratories completing 9 verifications, and the findings and recommendations for issues to be addressed prior to final classification of the proposed monographs by USP were shared with USP. The tenth assessment is slated for completion in FY2012.

In FY 2010, ORA began work with CDER to identify handheld portable analytical tools for use in the field for the early detection of contaminated drug products. ORA qualified a variety of tools and began a multi-tiered implementation program. The implementation program allows ORA to phase in each class of tool for daily use by ORA field investigators at specific U.S. ports of entry.

To date, ORA has deployed 2 classes of portable analytical tools for use in limited pilot programs. The first class of tools allows for field staff to perform a limited analytical screen of drug products at the time they are offered for import into the U.S. to determine if toxic elements are present in the drug product. This tool has the capacity to test for additional elements as reference standards and methods continue to be developed within ORA. The second class of tools allows ORA import staff to detect suspected counterfeit drugs or packaging, providing ORA field personnel with advanced technology to assist in screening imported drugs and identify suspect shipments. As a result of the completed pilot deployment of one class of tools in limited locations, ORA has performed more than 230 field examinations. The second pilot program is ongoing. ORA will continue the phased development and deployment of the remaining classes of tools through FY 2012.

ORA continues to see an ever increasing number of drug products being offered for import into the U.S through international mail and courier facilities. ORA works with other government agencies in joint operations to address these shipments. In FY 2011, ORA worked with Customs and Border Protection (CBP) through joint operations such as monthly Operation Safeguard blitzes to monitor these shipments through targeted blitzes

at various mail and courier facilities to detect counterfeit and unapproved versions of approved medications. Additionally, ORA participated in Operation Pangea IV, a global collaborative effort amongst government agencies in 43 countries, to perform targeted blitzes throughout the year targeting counterfeit drug products sold via the Internet. In FY 2011, ORA issued or updated 16 Import Bulletins and issued more than 110 identifying modifications to drugs related to Import Alerts encompassing numerous human drug products, combination drug products and drug firms determined to be manufacturing or shipping unapproved pharmaceutical products. These actions were a result of ORA import surveillance collections and testing of regulated drug products at the time they were offered for import into the U.S. as well as for cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

ORA exceeded the FY 2011 performance goal targets, and completed more foreign drug inspections than in the history of the program, for high risk foreign drug surveillance inspections by working with our Global offices and continued staffing of the ORA dedicated foreign drug cadre, consisting of 15 experienced drug investigators, which augments the existing foreign inspection program.

In response to post-marketing complaints of contamination of purported sterile marketed products manufactured in India, ORA investigators in the Global office performed inspections of manufacturing establishments while ORA field investigators completed follow up inspections of domestic facilities involved in the issue. ORA investigations, both domestic and foreign, identified violations of post-marketing adverse drug experience reporting and resulted in subsequent recalls of three marketed products.

In January 2011, FDA worked to stop importations of “Fruta Planta,” a product implicated in the death of a Florida woman. The product, labeled as a dietary supplement, contained the active pharmaceutical ingredient sibutramine, which can cause serious adverse reactions, including death. Sibutramine is known to substantially increase blood pressure and pulse rate and may present a significant risk for people with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. ORA subjected the product to detention without physical examination and also worked with our CBP partners to seize a number of shipments. FDA also issued a warning to consumers not to use the product.

In FY 2011, ORA continued to staff the Commercial Trade Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA works closely with other government agencies on issues including products with undeclared active pharmaceutical ingredients and other unapproved drug products.

ORA monitors recall of human drugs that have been found to present safety concerns, and assures the adequacy of the firm’s recall to effectively remove defective products from commerce. Through the classification process, the Center determines the level of public health risk the product presents. Appropriate public notification is also a

component of the agency's recall program. In FY2011, FDA classified and issued recall numbers for 91 Class I; 1,279 Class II; and 246 Class III recalls of human drug products. ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011, and included data for FY2009 and FY2010 inspections. The Agency is committed to updating the data periodically, but at least twice per year and has already updated the data to include the first six months of FY2011. This action will provide the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

In FY2011, the agency's MARCS-Compliance Management System has indicated three approved CDER injunctions and two seizures for drug products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

An example of recent enforcement actions include FDA's March 2011 filing of a consent decree of permanent injunction against a large manufacturer of over-the-counter drug products and two of the firm's officers. The manufacturer failed to comply with current good manufacturing practice (cGMP) requirements as required by federal law in the manufacture of multiple liquid drug products. Inspections at multiple manufacturing facilities of this corporation, beginning in CY 2009, found violations of cGMP requirements. Deficiencies at these facilities resulted in several extensive recalls, including an April 30, 2010, recall of lots of several liquid products indicated for children. The consent decree required the firm to destroy all drugs under their control that have been recalled from multiple facilities since December 2009.

In February 2011, FDA seized all lots of a drug solution used to treat pain and inflammation associated with ear infections. Sale of the product in the United States violated federal law because the product does not have FDA approval and its labeling did not include adequate directions for use. The seizure, estimated to be worth more than $16 million, was the final step in a regulatory process stemming from a 2009 inspection of the manufacturer and a Warning Letter that was issued in 2010.

In FY 2011, ORA inspected several firms potentially involved in the manufacture of drug products of concern in an outbreak of *Bacillus cereus*. ORA's inspection at a manufacturer of multiple human drug and medical devices found multiple violations of cGMP requirements, including failure to adequately investigate drug products that did not meet specifications. The inspectional findings led to the recall of several drug products and the seizure of more than $6 million in products. A variety of drug products were seized, including povidone-iodine and benzalkonium chloride antiseptic products, cough and cold products, nasal sprays, suppositories, medicated wipes, antifungal creams, hemorrhoidal wipes, in-process drug products, and raw materials. FDA sought an injunction, and a consent decree of permanent injunction was entered in June 2011.

In FY 2011, ORA issued 108 warning letters to prevent the continued distribution of adulterated human drug products in U.S. commerce.

In FY 2011, FDA issued numerous press releases citing concerns about dietary supplements that contained active pharmaceutical ingredients. The press releases warn about potentially harmful marketed dietary supplements, citing the product lots of concern when the information is available and providing guidance to consumers on possible interactions with other medications. The releases also provide a next step if a consumer has a product of concern.

In December 2010, FDA issued a warning to consumers to avoid a dietary supplement because the product contained a variation of an active drug ingredient. In May 2011, FDA identified a dietary supplement of concern that was deemed to be counterfeit and containing active pharmaceutical ingredients. FDA's analysis of the product identified two lots of counterfeit dietary supplements.

ORA and CDER co-led an FDA and FTC joint enforcement and outreach initiative targeting fraudulent products to treat and prevent sexually transmitted diseases (STDs). FDA and FTC issued 12 joint warning letters and FDA issued one independent letter to internet and retail firms marketing supplements and external products to treat STDs. A national roll-out for the initiative featured a press call led by ORA and a public health physician, consumer education materials, a podcast and a video.

In September 2011 in coordination with ORA's Health Fraud communication campaign, ORA launched the Health Fraud website to help raise awareness and educate consumers, many of whom include vulnerable and underserved populations, on scams that can lead to ineffective or delayed treatment and cause serious or even fatal injuries. Videos and print materials have been developed in both English and Spanish and can be accessed through the FDA website.

In cooperation with CDER, the Office of Criminal Investiagations (OCI), the Office of Regional Operations (ORO) and CFSAN, ORA initiated and implemented a strategy to monitor the marketplace, conduct undercover purchases and investigations as part the "Operation Shady Supplement" enforcement initiative. An updated strategy emphasizes the development of criminal cases against distributors of tainted supplements by OCI. In addition, a CDER-issued sampling assignment to intercept and analyze imported samples at international mailrooms is being conducted in several districts. A white paper that describes the results of the sampling assignment will be presented at the Bilateral meeting with China in December 2011. At the meeting, CDER and ORA will again convey to the Chinese government the serious health threat posed by tainted supplements and ingredients from China and will attempt to gain cooperation from the Chinese authorities to combat the problem

In collaboration with Canada's Competition Bureau, FDA issued two ORA -recommended warning letters to US firms marketing dietary supplements in the US and Canada on the internet and Facebook with unapproved disease claims. The warning letters were intended to target the rapidly expanding promotion of health products with illegal and deceptive claims on social networking media sites such as Facebook. The Competition

Bureau also issued warning letters to the firms. One of the firms has complied and follow-up continues with the other firm.

For the 2011 Internet Week of Action, the ORA Office of Enforcement (OE) reviewed nearly 1,700 websites identified by OCI that sell unapproved prescription drugs with or without a prescription. OE captured more than 1,000 violative websites to be used as evidence to support CDER warning letters to website operators. This annual international enforcement initiative was announced in a press rollout in late September 2011.

ORA drafted a new Compliance Policy Guide (currently in final clearance status with the Department) describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection. This CPG will facilitate the Agency's ability to prevent the introduction of foods and medical products in US commerce from facilities that have delayed, denied, or moved to avoid an FDA inspection.

In instances of criminal activity, ORA's OCI is expanding efforts to develop cases that address the marketing of counterfeit products. The increasing globalization of crime has created new challenges to law enforcement. OCI coordinates counterfeit drug investigations with several foreign counterparts, especially those in China, Israel, Canada and the United Kingdom. These efforts continue to produce positive outcomes for both OCI and its foreign counterparts. OCI continues to aggressively pursue counterfeit drug investigations with law enforcement partners in foreign countries as well as with Federal, State, local, tribal, and territory law enforcement here in the U.S.

During FY 2011, ORA's OCI made 258 drug related arrests, and secured 214 drug related convictions with fines, restitutions and other monetary penalties in excess of $981 million.

A sampling of some of the specific case activity that led to these positive public health outcomes are as follows:

- **Misbranded drugs sold over online search engine GOOGLE Inc – One of the largest forfeitures in the United States -** In August 2011, OCI successfully completed an investigation involving illegal sales and marketing over the Internet conducted by online search engine Google Inc. Google agreed to forfeit $500 million for allowing online Canadian pharmacies to place advertisements through its AdWords program targeting consumers in the United States, resulting in the unlawful importation of controlled and non-controlled prescription drugs. The OCI investigation revealed that Google took steps to block pharmacies in countries other than Canada from advertising in the U.S. through AdWords. Google continued to allow Canadian pharmacy advertisers to target consumers in the United States. Google was aware that U.S. consumers were making online purchases of prescription drugs from these Canadian online pharmacies, and that many of the pharmacies distributed prescription drugs, including controlled prescription drugs, that were based on an online consultation rather than a valid prescription from a treating medical practitioner. At the time, Google was also on notice that many pharmacies accepting an online consultation rather than a prescription charged a premium for doing so because individuals seeking to obtain

prescription drugs without a valid prescription were willing to pay higher prices for the drugs. In addition, Google also provided customer support to some of these Canadian online pharmacy advertisers to assist them in placing and optimizing their AdWords advertisements, which assisted with improving the effectiveness of their websites.

- **Counterfeit Drug/Misbranded Products** - In June 2011, a foreign national from China was sentenced to serve 87 months in federal prison for trafficking and attempting to traffic in counterfeit goods, namely counterfeit versions of the pharmaceutical weight loss drug known as Alli. In addition, the defendant was ordered to pay restitution totaling approximately $505,000 to the victims of his crime, including an emergency room doctor who suffered a mild stroke from ingesting the counterfeit medication.

  The OCI investigation was initiated in January 2010, to target the manufacturer of tainted weight loss products and counterfeit drugs that were the subject of a series of FDA public alerts issued in 2008, 2009, and 2010. The OCI investigation determined that a foreign national from China was responsible for illegally manufacturing and importing the counterfeit Alli. The foreign national was arrested in March 2010.

  As a result of the investigation, FDA warned the public about counterfeit Alli, a popular over the counter weight loss drug manufactured by Glaxo-Smith Kline. The counterfeit versions of Alli were being sold in the United States, among other ways, through internet auction websites.

- **Misbranded and unapproved imported drugs - Sentencing in major fraudulent dietary supplement investigation –** In March 2011, an individual was sentenced to three months in prison for importing and distributing more than four million diet pills that contained a controlled substance, an anti-seizure medication, and a chemical solvent that is considered a possible carcinogen. This individual pled guilty to an 18 count superseding indictment, including 11 counts of mail fraud, one count of conspiracy to smuggle illegal merchandise, and six counts of distribution of a Schedule IV controlled substance known as Sibutramine. The OCI investigation led to the conviction and sentencing of the defendant who owned and operated a business which imported and distributed a variety of beauty products, including diet pills. The defendant attempted to smuggle the pills using packages with customs declarations that falsely described the capsules as gifts worth minimal amounts. The defendant was also ordered to pay a fine in the amount of $5,000, complete three years of supervised release including eight months of home detention, forfeit $250,000, and pay a special assessment of $1,800.

- **Misbranded drugs - Former CEO sentenced to prison –** In March 2011**,** a former CEO and Chairman of the Board of a Missouri-based drug manufacturer pled guilty to two federal charges of misbranding drugs and was sentenced to a one month term of imprisonment and fined one million dollar fine. In addition, the defendant was also required to pay $900,000 forfeiture to the United States.

The defendant admitted that during the summer of 2008, the company shipped oversized morphine tablets to retailers in San Francisco, California and Canada. The drugs' labeling was false and misleading because it stated that the drugs were of uniform strength when the tablets of the drugs were oversized and contained more of the active ingredient of the drug than what was specified on the labels. The California morphine tablets weighed over twice the specified amount, while the Canada morphine tablets were 65% stronger than what the label claimed. Both of the misbranded morphine tablets had the same color and engraving as a normal and correctly sized tablet. The company conducted a safety assessment in May 2008 concluding that oversized morphine tablets raised potential safety concerns for patients, including the possibility of acute over-dosage, respiratory depression, stupor, coma, and even death.

- **Doctor Sentenced in Foreign-Sourced IUD Investigation –** In September 2011, a doctor in Arkansas was sentenced to five years probation, fines and community service after an OCI investigation led to a conviction on one count of misdemeanor misbranding of a drug and one count of health care fraud. The doctor obtained, and implanted in patients, Mirena IUDs (Intrauterine Devices) from foreign sources that were not approved for use in the United States. The IUD's were labeled in Scandinavian and Turkish languages. The doctor committed health care fraud by billing a state Medicaid program, TRICARE and private insurance companies as if he were providing the beneficiaries with the FDA approved IUD's instead of the unapproved versions he had obtained at a lower cost.

OCI Proactive Ongoing Initiatives:

- **Operation Pangea -** For the past four fiscal years, OCI has participated in Operation Pangea, which is an International Internet Week of Action (IIWA). For FY11, OCI coordinated with the FDA Office of Enforcement (OE) and Center for Drug Evaluation and Research (CDER), to target approximately 1,000 websites for illegal activity associated with prescription drugs. This year, both CDER and OCI sent representatives to INTERPOL in Lyon, France to provide hands-on assistance at the command post. As in previous years, CDER issued warning letters against approximately 700 websites. Additionally, OCI worked directly with the domain name registrars, Internet service providers, and payment providers and was successful in getting approximately 600 of the approximately 1,000 websites permanently shut down. The project received positive press, and was highlighted in the IIWA Reports prepared by INTERPOL and distributed world-wide. (Operation Pangea is led by Permanent Forum on International Pharmaceutical Crime (PFIPC) in cooperation with INTERPOL)

- **Internet Investigations -** Drug investigations involving the Internet are conducted by OCI and provide some of the most egregious threats to the public health. OCI is responsible for conducting criminal investigations of internet pharmacy sites and other internet drug sites whose operations involve potential criminal activity. These complex and resource intensive investigations have become increasingly global in nature as criminals based in foreign countries masquerading behind the anonymity of the internet offer counterfeit and unapproved drugs to U.S.

consumers, circumventing U.S. Customs and FDA regulations. Suspect websites are researched and possible violations identified. OCI field offices receive investigative assignments which often include undercover buys and other resource intensive activities. OCI continues to foster strong working relationships with other law enforcement agencies in the U.S. and overseas to identify and prosecute violators who use the internet to sell drugs that threaten the health and safety of the American public. OCI has been identified by our domestic and foreign law enforcement peers as an expert and global leader in Internet investigations. Additionally, in FY11, OCI provided multiple Internet investigation training courses (both domestic and foreign) to our regulatory counterparts from many countries, including: Canada, Italy, United Kingdom, Ireland, Israel, Romania, Estonia, Poland, Czech Republic, and others.

- **H1N1 Epidemic** - During the H1N1 epidemic, OCI conducted a significant number of test purchases of Tamiflu products from internet pharmacies. None of the test purchases required a prescription. As a result of these efforts, FDA issued an alert to consumers after it was determined that a potentially harmful product represented as "Generic Tamiflu" sold over the internet did not contain Tamiflu's active ingredient, oseltamivir. Instead it contained cloxacillin, an ingredient in the same class of antibiotics as penicillin, which could result in injury or death for consumers who are allergic to it.

- **Pharmaceutical Fraud Program (Health Care Fraud and Abuse Control Investigations) -** In FY 11, OCI continued the coordination and communication between criminal investigators, regulatory components of FDA, and the United States Attorney's Offices investigating health care fraud-related investigations. As a result of the investigative efforts during FY 11, OCI secured two indictments; a physician and clinical research coordinator were indicted on charges of falsifying study data in a clinical trial. The indictment alleges the defendants falsely stated physical examinations had been conducted on two unqualified test subjects, signed false statements to FDA indicating the clinical study was being conducted in accordance with proper protocol and arranged for the unqualified subjects to have office visits while the executive director was at lunch to conceal the fact the test subjects were ineligible. The ineligible test subjects were employees of the research institute and under the required age to participate. In addition, sixteen criminal investigations were initiated including the following: 1) four investigations involving allegations of off-label drug promotion by different manufacturers of brand name drugs; 2) one investigation involving allegations of off label drug promotion and other violative promotional issues by a manufacturer of brand name drugs including unsubstantiated superiority claims and omission of risk information; 3) one investigation involving a medical device manufacturer pertaining to issues involving a recalled device product; 4) one investigation involving allegations that a company withheld nonclinical studies from FDA regarding Investigational Device Exemption applications because the studies demonstrated that the products in the applications could be hazardous to patients, and; 5) nine investigations involving allegations of clinical trial fraud and/or application fraud.

- **National Document Center -** In FY 2011, OCI received special funding from the Department of Justice (DOJ) to apply towards the completion of the recently established OCI National Document Center. This center supports OCI criminal investigations in order to obtain substantive data relating to fraudulent activity involving FDA regulated products in order to maximize monetary recoveries related to illicit proceeds. Many OCI investigations are complex and very document intensive which require a scanning and optical character resolution (OCR) solution, in order to search, identify, extract and analyze key information relating to fraudulent activity involving FDA regulated products. This information is often required by United States Attorney's Offices (USAO's) who are accepting the cases for federal prosecution. The OCI Document Center is being used for, but not limited, to OCI criminal investigations such as those that include the Off-Label Promotion of FDA approved drugs and medical devices, application fraud, clinical investigator fraud, healthcare fraud involving FDA regulated products, and import investigations involving any criminal investigations national in-scope or document intensive cases involving FDA regulated products.

Promoting Efficiency

The Predictive Risk-based Evaluation for Dynamic Import Compliance Testing (PREDICT) tool allows ORA to focus resources on high risk commodities, providing greater assurance that imported products are safe and effective for use by U.S. consumers. Expedited clearance of low risk products helps ensures that products are available in the U.S. market providing consumers and health care providers with the commodities of necessity.

ORA continues to identify violations during inspections of foreign facilities to establish pre-emptive import controls. These internal actions provide for the increased surveillance of products regulated in the violative firms to ensure a higher level of scrutiny if products are offered for import into the United States.

In May, 2011 a new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration at an early stage in the process of case development; reduces paperwork by removing redundant and unnecessary documentation; removes a bias toward inaction by making the process less daunting and more collaborative; provides a mechanism for continuous improvement in case development; and shortens approval times. In order to achieve these changes, the Compliance Management System (CMS) was modified to capture milestones and allow concurrent review; the RPM was updated to incorporate the significant process changes; and a training video was developed on the new procedures.

ORA coordinates information sharing with the Veteran's Administration (VA) regarding the regulatory compliance of drug establishments. This collaboration has resulted in the VA's removing products from its hospitals that violate safety standards. Because of this information sharing, the VA has implemented stricter policies to ensure products purchased are produced in compliance with FDA's GMPs, thereby ensuring the quality of medical products available on the Federal Supply Schedule.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2011: 788 Target: 750 (Target Exceeded)	750	750	Maintain

Post Market Safety Oversight – Center Activities

FY 2012 Enacted Amount: $187,275,000 (BA: $77,389,000 / UF: $109,886,000)

Public Health Focus

FDA must be vigilant in protecting Americans from injuries and deaths caused by unsafe, illegal, fraudulent, substandard, or improperly used products. Pre-marketing clinical trials do not enable CDER to discover and consider all factors about the safety of a drug before its approval. As a result, a degree of uncertainty always exists about the risks of drugs. If CDER detects any new and unexpected health risks, it takes the necessary steps to promote the safety of the public by informing the public of such risks and removing unsafe drugs from the market.

Key functions in the Post Market Safety Oversight subprogram include:

- Surveillance, risk management and safe use – A primary function of post market drug surveillance involves a team of epidemiologists and safety evaluators who collect and analyze drug use and adverse event report data for both brand and generic drug products. CDER collects and stores adverse drug event reports from healthcare professionals, consumers, and manufacturers in its Adverse Event Reporting System (AERS). This system, housing millions of adverse drug event reports, is an essential tool for effective post market safety monitoring. Safety evaluators use AERS data, combined with drug usage and population-based data, to monitor approved drugs and watch for any new, unanticipated risks associated with marketed products. If evaluators detect any new risks, FDA takes steps to inform the public and change how a drug is used or, if necessary, removes a drug from the market. In-depth analyses of some of these concerns inform efforts to refine the communication of drug risks and benefits and may highlight the need to develop or refine risk management programs such as Risk Evaluation Mitigation Strategies (REMS). In some cases, FDA works with external stakeholders to encourage safe use. These targeted outreach efforts will work with the broad healthcare community to positively influence and support the safe and appropriate use of approved medications.

- Medical error prevention – CDER avoids brand names that look or sound like the names of existing products in order to promote safe use of human drugs. CDER identifies and avoids brand names, labels, labeling, and packaging that might contribute to problems or confusion in prescribing, dispensing or administering drug products.

CDER investigates the causes and contributing factors to reports of medical errors and, as needed, recommends revisions to the label, labeling and/or packaging of these products to avert further error.

FDAAA contains important authorities to require sponsors to conduct post market studies and clinical trials, make Safety Labeling Changes (SLC), and develop and comply with Risk Evaluation and Mitigation Strategies (REMS). The REMS authority has enabled FDA to transition away from mostly voluntary Risk Minimization Action Plans (RiskMAPs) to enforceable risk management programs (REMS) to ensure the benefits of the drugs outweigh their risks. During FY 2011, FDA required approximately 90 postmarketing studies or clinical trials to assess safety issues for drugs and invoked its safety labeling change authority 24 times. During FY 2011, FDA also approved new REMS for 44 products. Six of the 44 REMS approved contained the more restrictive Elements To Assure Safe Use (ETASU).

Public Health Outcome

CDER's post market safety activities exist to monitor the safety and efficacy of drugs that are currently on the market, and to identify and communicate any risks associated with drugs previously approved by the Agency. The efforts and activities associated with post market safety allow FDA to discover risks associated with drug products that could not have been discovered during the initial review. As a result, public health is increasingly protected, and the public benefits from risk mitigation and adverse event monitoring. By successfully communicating potential risks from drugs available to consumers, FDA provides health care providers and patients with the necessary information to avoid using unsafe products and decrease adverse events from consumption of unsafe drugs.

Promoting Efficiency

Post market safety oversight programs will become more efficient as adverse events are reported electronically. Data standardization will improve post market safety oversight by supporting modernization at FDA. By adopting data standards for premarket studies, FDA will be able to integrate pre-market clinical study data with post market data stored in FDA's Adverse Event Reporting System (AERS). This will improve FDA's ability to detect safety signals quickly and efficiently. As safety signals are more efficiently detected and communicated, patients will face fewer risks associated with drug products.

Post Market Safety Oversight – Field Activities
FY 2012 Enacted Amount: $4,414,000 (BA only)

Public Health Focus

ORA's public health focus under the Post Market Safety Oversight subprogram is to reduce adverse events such as injuries and deaths associated with unsafe, illegal, fraudulent, substandard, or improperly used products. ORA's inspection activities include inspections of Adverse Event Reporting and also Risk Evaluation Mitigation Strategies (REMS). The REMS inspection is an evaluation of compliance with the risk evaluation plan which was mandated by the Food and Drug Administration Amendments Act (FDAAA).

Public Health Outcome

ORA's activities to reduce adverse events involves the review of manufacturers' adverse event and complaint files during inspections to determine if the firm is submitting all adverse drug event reports to FDA in accordance with regulatory time frames. ORA also conducts follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. The final activity involves investigations of reported errors and product recalls so that program managers can collect information and develop error reduction strategies with manufacturers and the medical community in order to better protect the public health.

In FY 2011, ORA field laboratories expanded drug surveillance activities to include a toxin/poison screen for select post market drug products. In addition, ORA laboratories also increased microbiological screening for drug products as well as vitamin API screening for economic adulteration concerns.

In March 2011, FDA filed a consent decree of permanent injunction against a large manufacturer of over-the-counter drug products and two of the firms officers for failing to comply with current good manufacturing practice requirements as required by federal law in the manufacture of multiple liquid drug products. Inspections at multiple manufacturing facilities of this corporation beginning in CY 2009 found violations of current good manufacturing practice requirements. Deficiencies at these facilities resulted in several extensive recalls, including an April 30, 2010, recall of lots of several liquid products indicated for children. The consent decree required the firm to destroy all drugs under their control that have been recalled from multiple facilities since December 2009.

In February 2011, FDA seized all lots of drug solution used to treat pain and inflammation associated with ear infections. Sale of the product in the United States violated federal law because the product does not have FDA approval and its labeling did not include adequate directions for use. The seizure, estimated to be worth more than $16 million, was the final step in a regulatory process stemming from a 2009 inspection of the manufacturer and a Warning Letter that was issued in 2010.

In FY 2011, ORA inspected several firms potentially involved in the manufacture of drug products of concern in relation to an outbreak of *Bacillus cereus*. ORA's inspection at a manufacturer of multiple human drug and medical devices found multiple violations of cGMP requirements, including failure to adequately investigate drug products that did not meet specifications. The inspectional findings led to the recall of several drug products and the seizure of more than $6 million in products. A variety of drug products were seized, including povidone-iodine and benzalkonium chloride antiseptic products, cough and cold products, nasal sprays, suppositories, medicated wipes, antifungal creams, hemorrhoidal wipes, in-process drug products, and raw materials. FDA sought injunction and a consent decree of permanent injunction was entered in June 2011.

In FY 2011, FDA issued numerous press releases citing concerns of dietary supplements that contained active pharmaceutical ingredients. The press releases warn about potentially harmful marketed dietary supplement citing product lots of concern when available and providing guidance to consumers related to possible interactions with other medications and next steps if a consumer has a product of concern.

Promoting Efficiency

Congress requires that adverse drug experience information relating to all prescription drugs be made available to FDA. To meet this requirement, FDA operates an inspection program to verify that regulated industry is submitting adverse drug experience reports to FDA in accordance with required time frames. The secondary focus of this program is to verify the completeness and accuracy of adverse event data submitted to FDA. In so doing, FDA is able to take appropriate action to protect the public health.

As a result of the FDA Office of Criminal Investigation's investigative efforts that uncovered fraudulent and criminal activity and led to numerous arrests, convictions, and fines/restitution, ORA was able to identify and remove counterfeit, and misbranded drugs from being sold in the U.S. market. In so doing, FDA was able to reduce or avoid adverse events such as injuries and deaths to American consumers, resulting from the distribution and sale of these unsafe and unapproved products, thereby protecting the public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)*	FY 2011: 99 million Target: 70 million (Target Exceeded)	100 million	100 million	Maintain

Oversight of Drug Promotion – Center Activities

FY 2012 Enacted Amount: $22,342,000 (BA: $19,216,000 / UF: $3,126,000)

Public Health Focus

Prescription drug information available to physicians and consumers is critical for the safe and effective use of these products for patients. CDER promotes and protects the health of Americans by ensuring that prescription drug advertisements and other promotional materials are truthful and fairly balanced. CDER operates a comprehensive program of education, surveillance and enforcement about drug advertising and promotion to achieve this objective. These programs involve various activities:

- Professional promotion - Drug advertising and promotion intended for healthcare professionals must be truthful, fairly balanced, and not misleading. As part of its program to ensure compliance, CDER issues both advisory comment letters on proposed promotional materials when requested as well as enforcement letters to address violative promotion that is occurring.
- Direct-to-consumer (DTC) advertising – CDER also regulates the promotion of prescription drugs that is aimed at the consumer audience such as television and

magazine advertisements. Regulations require that these advertisements present accurate information and fairly represent both the benefits and risks of the drugs being advertised. Pharmaceutical companies are required to submit all drug advertisements to FDA for review at the time of first use in the public. CDER uses a risk-based approach to its monitoring and enforcement to prioritize the review of promotion that is likely to have the most impact on public health. This includes advertisements that will be widely circulated or that are likely to impart misleading impressions of a drug to consumers. For example, it reviews all broadcast DTC advertisements because of the widespread audiences who are reached by these messages.

Public Health Outcome

Without suitable information regarding various drug products, consumers would face greater risks of inappropriate or unsafe use of drugs. By reviewing advertisements intended for medical professionals, CDER monitors the information disseminated to health care providers and requires that it be truthful, fairly balanced, and not misleading. Medical professionals who are well-informed in part due to these advertising messages are better equipped to treat patients appropriately.

DTC advertisements are regulated to help ensure that consumers are well-informed about the drugs prescribed to them. The promotional messages are required to be accurate and fairly balanced so that the public receives useful information. These efforts are intended to raise the public's awareness about drug information and mitigate risks that could occur due to a lack of awareness or misleading information.

Promoting Efficiency

CDER's Data Standards initiative will enhance the review of drug advertisements directed to healthcare professionals and consumers. With standardized data, personnel who review drug advertisements will be able to better prioritize their reviews as well as increase the amount of advertisements reviewed by reducing the amount of time per review.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)*	N/A	Issue draft guidance	Issue final guidance and establish a baseline	N/A

Information Technology Investments – Human Drugs Program
(FY 2012 Enacted Amount displayed as a non-add item: $88,326,683)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

The ever increasing complexity of the human drug review process and the regulatory environment imposes new challenges for FDA and requires continuous streamlining of operations to fully leverage electronic information that has become available over the last decade. Digitization provides the means to take full advantage of the new opportunities in the 21st century. Digitization is a long-term effort with the aim to establish an integrated information environment that can transform business operations and drive efficiency. Digitization supports the following business objectives:

- Improve decision making via real-time information
- Standardize and simplify systems, processes and information
- Eliminate redundancy and improve consistency of information through automation and integration.

The following key initiatives are part of the digitization effort for CDER:

- Integrated Master Data Management is an effort to consolidate data from various disparate systems into a single repository of master data. This will enable data quality and consistency of master data across core business applications.
- The Facilities / Sites Inspection Management initiative focuses on providing an automated system for monitoring registration and listing compliance, for identifying manufacturers in the global supply chain, and improving reporting and analysis capabilities.
- Approved Drug Publishing is an effort to modernize current work processes and systems for the Orange Book. This involves consolidation of data sources related to drug information while automating the data collection processes to provide accurate and up to date information of available drugs in the marketplace.
- The Regulatory Review Management Solution (DARRTS) provides capabilities for managing new drug applications, abbreviated new drug applications, pediatrics,

meetings, post-marketing requirements and commitments, as well as FDAAA provisions. There is a need for further enhancements to include biologics applications and cope with upcoming user fee tracking requirements for generic drugs, prescriptions drugs and biosimilars. In addition, the DARRT System requires a fundamental technology refresh and redesign to meet the growing demands and improve overall efficiency of the system in support of a lean management approach and smarter regulation.

- Scientific Review: With the increase of standardized data submitted such as CDISC's Study Data Tabulation Model (SDTM), Standard for Exchange of Non-clinical Data (SEND), Analysis Data Model (Adam), as well as Health Level 7 Individual Case Safety Report (ICSR), there is an opportunity to analyze, compare and evaluate study data. There is a need to provide the reviewers with state-of-the-art analysis tools that can support regulatory decision-making. The objective of this effort is to provide reviewers with access to scientific review tools in order to perform quantitative analysis of data using pre-defined templates and standardized reports.

- Adverse Event Management provides the solutions to enable safety investigators to analyze safety signals using state-of-the-art pharmaco-vigilance and surveillance tools ensuring the safety of marketed drugs after approval by monitoring adverse events and medication errors.

- The expansion of new user fee programs for biosimilars and generic drugs introduces a new level of complexity in terms of fee structures and payment volume. A sophisticated user fee management solution is required to enable fee establishment, collection and payment tracking.

- There is a need for efficient management of resources by consolidating financial information into a single core financial system and improving tracking capabilities of budgetary information. Industry-proven financial tracking solutions will improve CDER's ability to efficiently manage and track its resources.

Panorama is a strategic initiative to improve the management and administration of CDER's regulatory work processes in support of lean management by applying best-in-class portfolio management systems and tools that can be integrated with CDER's core business applications. The aim is to improve the effectiveness and efficiency of regulatory operations.

Five-Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$680,926,000	$353,909,000	$327,017,000	2,996
FY 2009 Actual	$802,492,000	$437,385,000	$365,107,000	3,630
FY 2010 Actual	$883,459,000	$462,243,000	$421,216,000	3,835
FY 2011 Actual	$949,645,000	$477,502,000	$472,143,000	4,061
FY 2012 Enacted	$978,705,000	$477,810,000	$500,895,000	4,071

Summary of the Budget Request

The FY 2013 budget request for the Human Drugs Program is $1,258,614,000. This amount is an increase of $279,909,000 above the FY 2012 Enacted Level. The Center for Drug Evaluation and Research (CDER) amount in this request is $1,063,869,000, supporting 3,603 FTE. The Field amount is $194,745,000, supporting 965 FTE.

The FY 2012 Enacted funding for the Human Drugs Program is $978,705,000, which includes $838,694,000 for the Human Drugs Center activities and $140,011,000 for the Human Drugs Field activities.

FY 2012 Enacted funding allows the Human Drugs Program to meet its mission of ensuring that human drugs that are available to the American public are safe and effective. This is accomplished by reviewing new drug applications to make sure that safety and efficacy are demonstrated – a process that draws on the expertise of a wide range of medical and health-services personnel – and then by monitoring drugs after they have been released to the market for signs that could not have been detected in clinical trials. Manufacturers of drug products are periodically inspected to ensure that those products are made to high standards. Even when safe and effective drugs are made to exacting standards, misuse (intentional or accidental) can occur; CDER is working to improve the safe use of medical products by deliberately examining the communication of risks and benefits associated with those products to consumers and healthcare professionals.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to protect patients.

Budget Request

Pay Increase (Commissioned Corps) (Total Program: +$336,000)

The request for $472,683,000 in total BA for the Human Drugs Program reflects a pay increase for the Commissioned Corps. The Center's portion of this increase is +$243,000 and the Field's portion is +$92,000.

Data Consolidation and IT Savings (Total Program: -$4,222,000)

The request for $472,683,000 in total budget authority for the Human Drugs Program (Center and Field) also reflects data consolidation and IT savings reduction of -$4,222,000 for FY 2013. The Center's portion of these savings is -$3,073,000 and the Field's portion is -$1,149,000.

Center Activities

2013 Initiatives

Data Consolidation and IT Savings (-$3,073,000)

The Center for Drug Evaluation and Research (CDER) will achieve savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- consolidating analysis initiatives and streamlining existing databases to improve efficiency.

Field Activities

2013 Initiatives
Data Consolidation and IT Savings (-$1,149,000)

The Office of Regulatory Affairs (ORA) will achieve savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- streamlining user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance Services (MARCS) program, and providing the support architecture for other integrated systems.
- economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems.

Rent Absorption (Total Program: -$2,081,000)

The request for $472,683,000 in total budget authority for the Human Drugs Program also reflects rent absorption costs of -$2,081,000 for FY 2013. The Center's portion of these savings is -$1,327,000 and the Field's portion is -$754,000.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

New Drug Review

Center Activities – (FY 2012 Enacted Amount: $440,970,000 (BA: $119,256,000 / UF: $321,714,000)

FY 2013 Total Increase above FY 2012 Enacted Level: $23,401,000 / 69 FTE
FY 2013 Increase for PDUFA: $7,257,000 / 7 FTE

2013 Initiatives:

Protecting Patients Initiative: Biosimilars User Fee (+$15,304,000 / 59 FTE)

With the resources in this FY 2013 budget initiative, CDER will continue to coordinate with the rest of FDA on continued and additional activities to operate the 351(k) review program for approving biosimilars. CDER will also conduct research required to develop biosimilar reference standards to assure the manufacturing quality of biosimilars. The following activities will be conducted as a result of increased resources from the biosimilars user fee:

- Review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and investigational new drug applications (INDs). CDER will also issue action letters that communicate decisions on biosimilar biological product applications.
- CDER will coordinate with the rest of FDA to develop regulations and guidance documents to facilitate the development of biosimilars.

The biosimilars user fee will supplement base spending from appropriations and enable FDA's biosimilar program to progress by continuing to identify scientific, regulatory, and policy issues surrounding biosimilar biological product development. Reducing this uncertainty will increase the investment in this promising area and lead to quicker development and the launch of biosimilars, resulting in lower costs for life-saving treatments for many Americans.

Advancing Regulatory Science Initiative: Medical Countermeasures (+ $840,000 / 3 FTE)

Under MCM Pillar 1, CDER will coordinate with other parts of FDA on the Public Health and Security Action Teams (PHSAT) to foster support for MCM drug product review, and continue to assess Medical Countermeasure (MCM) safety and efficacy during public health emergencies. CDER will also support review of MCM drug applications and continue a highly-interactive review process for MCM products. CDER will hire additional personnel to serve as valuable reviewers and liaisons among FDA, PHSATs, and drug sponsors throughout the review process.

Field Activities FY 2012 Enacted Amount: $35,684,000 (BA: $25,666,000 / UF: $10,018,000)
FY 2013 Total Increase above the FY 2012 Enacted Level: (+1,503,000 / 5 FTE)
FY 2013 Increase for PDUFA: (+$213,000 / 0 FTE)

2013 Initiatives:

Protecting Patients Initiative: Biosimilars User Fee (+$1,290,000 / 5 FTE)

FDA will develop scientific and regulatory policies to facilitate the review and availability of biosimilars. ORA will hire investigators to conduct 30 domestic and 12 foreign biosimilars pre-approval inspections per year. After receiving the necessary training, the full performance year for achieving the domestic inspections will be FY 2015. For foreign inspections, full performance will occur in FY 2016.

Generic Drug Review

Center Activities – (FY 2012 Enacted Amount: $87,936,000 (BA: $87,936,000)

FY 2013 Total Increase above FY 2012 Enacted Level: $166,938,000 / 200 FTE
FY 2013 Increase for Proposed User Fees (GDUFA): $166,938,000 / 200 FTE

Protecting Patients Initiative: Generic Drug User Fee (+166,938,000 / 200 FTE)

The generic drug user fee will provide additional resources to support the generic drugs program. These resources will support additional FTEs to enhance generic drug review, reducing the backlog of existing applications and allowing FDA to review incoming applications more quickly.

Additional resources from GDUFA will support enhancements to the following CDER activities:

- Increase the capacity for generic drug review by hiring additional staff to reduce and eventually eliminate the backlog of existing applications and review incoming generic drug applications more quickly.

- Enhance the review process by improving efficiency and transparency, and communicating responses and assessments more quickly to sponsors.

- Strengthen regulatory science by conducting research to establish standards that will lead to generic drugs in new product categories.

This initiative will enable CDER to address the increased number of generic drug applications and the changes in the generic drug industry with the move to foreign manufacturing. This initiative will also support IT infrastructure needs and database enhancement to support the generic drug review process. Improvements in IT and current data systems will promote efficiency of generic drug reviews. Addressing these important issues will result in more timely availability of generic drug products and increased patient access to affordable generic drug products.

Field Activities FY 2012 Enacted Amount: $8,029,000 (BA: $8,029,000 / UF: $0)

FY 2013 Total Increase above the FY 2012 Enacted Level: (+$16,311,000 / 46 FTE)
FY 2013 Increase for Proposed User Fees (GDUFA): (+$16,311,000 / 46 FTE)

2013 Initiatives:

Protecting Patients Initiative: Generic Drug User Fee (+16,311,000 / 46 FTE)

ORA supports the generic drug program through increased pre-approval ANDA inspections to verify application data and assess the firm's ability to manufacture products in accordance with CGMPs. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness and regulatory compliance.

Drug Quality

Center Activities – (FY 2012 Enacted Amount: $100,171,000 (BA: $44,020,000 / UF: $56,151,000)

FY 2013 Total Increase above FY 2012 Enacted Level: $15,157,000 / 20 FTE
FY 2013 Increase for PDUFA: $1,400,000 / 1 FTE
FY 2013 Increase for Proposed User Fees (GDUFA): $13,757,000 / 19 FTE

Protecting Patients Initiative: Generic Drug User Fee (+$13,757,000 / 19 FTE)

Part of the goal of the generic drug user fee program is to ensure that participants in the U.S. generic drug system comply with U.S. quality standards. This initiative will enhance CDER's drug quality efforts related to generic drugs by requiring the identification of facilities involved in the manufacture of generic drugs and associated active pharmaceutical ingredients.

These resources will support the enhancement of current databases used to track generic drug manufacturing facilities to support compliance efforts. As a result, CDER's ability to protect public health in the complex global supply environment will be enhanced, and the safety of the supply chain will be increasingly protected.

This initiative will also support upgrades and enhancements to equipment and data systems used to promote the safety of the generic drug supply. Travel related to overseas investigations will also be supported due to the shift to foreign manufacturing of generic drug products.

Field Activities (FY 2012 Enacted Amount: $91,884,000) (BA: $91,884,000 / UF: $0)

FY 2013 Total Increase above the FY 2012 Enacted Level: (+$38,730,000 / 124 FTE)
FY 2013 Increase for Proposed User Fees (Reinspection): (+$2,749,000 / +18 FTE)
FY 2013 Increase for Proposed International Courier User Fee: (+$481,000 / +2 FTE)
FY 2013 Increase for Proposed User Fees (GDUFA): (+$35,500,000 / 104 FTE

2013 Initiatives:

Protecting Patients Initiative: Generic Drug User Fee (+35,500,000 / 104 FTE)

ORA supports the drug quality program through increased post-market GMP surveillance inspections in order to assess the finished dosage form (FDF) and active pharmaceutical ingredient (API) generic drug firms' abilities to manufacture their products in accordance with CGMPs.

Post Market Safety Oversight

Center Activities – (FY 2012 Enacted Amount: $187,275,000 (BA: $77,389,000 / UF: $109,886,000)

FY 2013 Total Increase above FY 2012 Enacted Level: $23,763,000 / 33 FTE
FY 2013 Increase for PDUFA: $1,727,000 / 2 FTE
FY 2013 Increase for Proposed User Fees (GDUFA): $22,036,000 / 31 FTE

Protecting Patients Initiative: Generic Drug User Fee (+22,036,000 / 31 FTE)

Additional resources from GDUFA will support post market surveillance of generic drug products. These resources will support surveillance of generic drug usage patterns and adverse events. Database enhancements and IT infrastructure to promote post market surveillance will also be supported. Improved data collection and surveillance will further protect the public from experiencing adverse events resulting from generic drug products.

This initiative will also support post market assessment of generic drugs and their brand-name counterparts, and is likely to foster stronger public confidence in generic drugs because of proactive responses to product concerns. As a result, CDER's capacity to support the mission of promoting and protecting public health will be improved.

Field Activities (FY 2012 Enacted Amount: $4,414,000) (BA: $4,414,000 / UF: $0)

Oversight of Drug Promotion

Center Activities – (FY 2012 Enacted Amount: $22,342,000 (BA: $19,216,000 / UF: $3,126,000)

FY 2013 Total Increase above FY 2012 Enacted Level: $73,000 / 0 FTE
FY 2013 Increase for PDUFA: $73,000 / 0 FTE

Human Drugs Program Activity Data (PAD)

CDER Workload and Outputs				
New Drug Review	**FY 2010 Actual**	**FY 2011 Actual**	**FY 2012 Estimate**	**FY 2013 Estimate**
Workload – Submissions/Filings/Requests				
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	103	100	100	100
Efficacy Supplements	108	112	112	112
Manufacturing Supplements	1,789	1,872	1,872	1,872
Commercial INDs (Drugs and Biologics) with Activity	5,784	5,961	5,961	5,961
Sponsor Requests: IND-Phase Formal Meetings	1,729	1,725	1,725	1,725
Sponsor Requests: Review of Special Study Protocols	323	291	291	291
Submissions of Promotional Materials	79,596	80,083	80,000	80,000
Outputs – Reviews/Approvals				
Reviews: Priority NDA/BLA	24	39	39	39
Reviews: Standard NDA/BLA	144	137	137	137
Approvals: Priority NDA/BLA	15	24	24	24
Approvals: Standard NDA/BLA	76	73	73	73
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	11.8	18.9	18.9	18.9
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	17.7	16.5	16.5	16.5
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	9	6.8	6.8	6.8
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10	12.6	12.6	12.6
Reviews: NDA Supplementals	2,838	3,085	3,085	3,085
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic*	5,348	5,882	6,470	7,117
*FY 2011 actual data are currently not available for this category; the FY 2011 estimate has been included.				
Biologic Therapeutics Review				
Workload – Submissions/Filings/Requests				
Receipts: Commercial IND/IDE (Biologics Only)	82	81	81	81
Receipts: IND/IDE Amendments (Biologics Only)	16,677	15,275	15,275	15,275
Outputs – Reviews/Approvals				
Reviews: Total Original License Application (PLA/ELA/BLA)	9	7	7	7
Approvals: PLA/BLA	8	5	5	5
Reviews: License Supplement (PLA/ELA/BLA)	219	298	298	298
Generic Drug Review				
Workload – Submissions/Filings/Requests				
Receipts: Abbreviated New Drug Applications (ANDA)	813	893	900	800
Outputs – Reviews/Approvals				
Actions – ANDA	2,079	2,276	2,000	2,000
Approval Actions - ANDA (both Tentative and Full Approvals)**	565	597	600	650
Median Review Time from ANDA Receipt to Approval (months)	27.85	29.52	30.00	29.00
Actions - ANDA Supplementals (Labeling and Manufacturing)	3,681	4,350	4,500	5,000
**Assumes additional generic drug user fee resources in FY 2013.				
Over-the-Counter Drug Review				
OTC Monographs Under Development***	28	28	28	28
OTC Monographs Published**	6	6	5	5
***Category includes Proposed Rules and Final Rules				
Best Pharmaceuticals for Children Act				
Labels Approved with New Pediatric Information	6	4	5	5
New Written Requests Issued	16	13	25	16
Pediatric Exclusivity Determinations made	3	5	5	5
Post Exclusivity Safety Report	9	12	9	9
Patient Safety				
Workload – Submissions/Filings/Requests				
Submissions: Adverse Event Reports	717,061	755,289	830,818	913,899
Electronic Submissions: % of Total Adverse Drug Reaction Reports	73%	77%	80%	85%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	87%	87%	90%	90%
Submissions: Drug Quality Reports	7,827	8,545	12,000	12,000
Outputs – Reviews/Approvals				
Safety reviews completed by Office of Surveillance & Epidemiology	1,972	2,244	2,600	3,000
Number of drugs with Risk Communications	100	150	200	200
Administrative/Management Support				
Workload				
Number of Advisory Committee Meetings	50	37	42	45
Number of FOI Requests	2,455	2,490	2,500	2,500
Number of FOI Requests Processed	2,733	2,854	2,700	2,700
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	72	92	100	100
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	237	231	241	251
Number of Citizen Petitions Completed [1] (excluding suitability petitions and OTC monograph-related petitions)	79	97	90	90

[1] Citizen Petitions completed may include petitions filed in prior years.

Combined Field Activities – ORA
Program Activity Data

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,215***	***2,325***	***2,325***
Pre-Approval Inspections (NDA)	140	197	197
Pre-Approval Inspections (ANDA)	64	153	153
Bioresearch Monitoring Program Inspections	512	453	453
Drug Processing (GMP) Program Inspections	1,193	1,023	1,023
Compressed Medical Gas Manufacturers Inspections	296	317	317
Adverse Drug Events Project Inspections	84	147	147
OTC Monograph Project and Health Fraud Project Inspections	68	184	184
Domestic Laboratory Samples Analyzed	1,311	1,310	1,310
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***727*** [2]	***676***	***676*** [1]
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	177	117	117
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	105	62	62
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	177	231	231
Foreign Drug Processing (GMP) Program Inspections	518	488	488
Foreign Adverse Drug Events Project Inspections	5	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,942***	***3,001***	***3,001***
IMPORTS			
Import Field Exams/Tests	9,080	6,200	6,200
Import Laboratory Samples Analyzed	369	370	370
Import Physical Exam Subtotal	**9,449**	**6,605**	**6,605**
Import Line Decisions	477,818	557,223	649,825
Percent of Import Lines Physically Examined	1.98%	1.19%	1.02%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***150***	***150***	***150***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	122	122	122
State Partnership Inspections: GMP Inspections	5	2	2
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***3,092***	***3,151***	***3,151***

[1] For investigators hired with FY 2013 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2013 funding increase for inspections will allow OIP to conduct an additional 120 foreign human drug safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2011 actual unique count of foreign inspections includes 42 OIP inspections (14 for China and 28 for India).

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT[1]

The following table displays funding levels for FY 2011 through FY 2013.

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Budget Request	FY 2013 +/- FY 2012
Program Level	$23,678,688	23,678,688	$23,678,688	0
Orphan Product Grants[a]	$14,035,060	$14,035,060	$14,035,060	0
Pediatric Consortia Grants[b]	$3,000,000	$3,000,000	$3,000,000	0
Program Administration[c,d]	$6,643,628	6,563,628	$6,563,628	0

[a]Orphan Product Grants are part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.

[b]Pediatric Device Consortia Grants are part of the aggregate amount of budget authority contained in the CDRH budget line item of the All Purpose Tables.

[c]Program Administration is part of the aggregate amount of budget authority contained in the Other Activities budget line item of the All Purpose Tables.

[d]FY 2011 included a supplemental increase of $1,280,000 to implement FDAAA, which supported Orphan Product Grants. FY 2012 and 2013 both include a $1,200,000 supplemental increase for Orphan Product Grants.

The FDA Office of Orphan Products Development operates under the following legal authorities:

Federal Food, Drug and Cosmetic Act (21 U.S.C. 321-399).
Orphan Drug Regulations (21 CFR 316)
Safe Medical Device Act of 1990 (as amended) (21 U.S.C. 351-353, 360, 360c-360j, 371-375, 379, 379e, 381)
Humanitarian Use Device and Humanitarian Device Exemption Regulations: (21 CFR 814 Subpart H)
PHS Act (42 U.S.C. 241). Section 301
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.)

Allocation Method: Direct Federal/Intramural; Grants.

[1] The Office of Orphan Products Development is shown for illustrative purposes and is not contained as a separate line item in the All Purpose Tables.

Program Description and Accomplishments

Public Health Focus: Since its inception in 1982, the public health programs of the Office of Orphan Products Development (OOPD), located in the Office of the Commissioner, have been dedicated to promoting and advancing the development of innovative products (drugs, biologics, medical devices, and medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. These are products necessary to treat a patient population that otherwise would be considered too small for profitable research, development, and marketing. OOPD has five public health sub-programs: orphan product grants which provide funding for clinical research in rare diseases, orphan drug designations, humanitarian use device designations, pediatric device consortia grants, and outreach activities. These programs directly support the HHS priority to accelerate scientific advances in lifesaving cures and quality health outcomes. OOPD administers the major provisions of the Orphan Drug Act (ODA) of 1983 which provide incentives for sponsors to develop products for rare diseases.

Public Health Outcome: The ODA has been very successful; 394 orphan designated drugs and biological products for rare diseases have been brought to market since 1983. In contrast, the decade prior to 1983 saw fewer than ten such products come to market. OOPD also administers the designation of humanitarian use devices under the Food Drug and Cosmetic Act. Fifty-three (53) humanitarian use devices have been approved for marketing to treat rare diseases and conditions. In addition, OOPD interacts with the medical and research communities, professional organizations, academia, and the pharmaceutical industry, as well as rare disease groups to stimulate orphan product development. It provides research study design assistance to sponsors of orphan products and encourages well-controlled clinical studies.

Promoting Efficiency: OOPD activities support FDA's strategic public health goals by enhancing the process of developing promising new products into safe, effective, and accessible treatments for patients. OOPD also empowers patients and patient groups with vital information and linkages between researchers, patients, and patient advocacy organizations. As more therapies are developed for rare diseases and conditions, and patients and providers become more educated about these therapies, there will be a positive impact on public health. Furthermore, the discovery and innovation of medical products for smaller populations has potentially positive public health implications for personalized health care in the future.

Orphan Product Grants Activity

Public Health Focus: OOPD supports new and continuing extramural research projects that test the safety and efficacy of promising new drugs, biologics, devices, and medical foods for rare diseases and conditions through human clinical trials. Orphan product grants are a proven method of successfully fostering and encouraging the development of new safe and effective medical products for rare diseases/conditions. In general, OOPD grant funding is for up to three years for Phase 1 trials, and up to four years for Phase 2 and 3 trials. Because grants are for up to four years, at any one time, there are typically 65 to 85 ongoing grant-funded projects. A major portion of the appropriated

funds for a given fiscal year are used to continue funding of grants approved in previous fiscal years.

Public Health Outcome: Forty-six (46) products that received development support from the Orphan Products Grants Program have been approved by the FDA for marketing. These include treatments for: Fabry Disease (approved in 2003), Mucopolysaccharidosis Type II, also known as Hunter Syndrome (2006), Phenylketonuria (PKU) (2007), ventilator dependent tetraplegic patients (approved 2008), relapsed T-cell Non Hodgkins Lymphoma (2009), refractory gout (approved 2010), Dupuytren's Disease (2010), and recently approved scorpion antivenom (2011).

In FY 2011, OOPD funded 14 new grants (out of 94 applications) and provided funding or continued support for approximately 54 other ongoing clinical study projects. Research projects that recently were awarded new grants include studies for the treatment of Chemotherapy-Resistant Recurrent Ovarian Cancer, Episodic Ataxia Type 2, Hypophosphatasia, Long-chain Fatty Acid Oxidation Disorders, Juvenile Neuronal Ceroid Lipofuscinosis, Myotonic Dystrophy Type 1, Anterior Sclerosis, and Thrombotic Thrombocytopenic Purpura.

Promoting Efficiency: Funding clinical trials for promising orphan products continues to reap significant public health benefits to society. [2] Not only have 46 products been approved using data obtained from OPD grants, but hundreds of publications in peer-reviewed journals have resulted from OPD funded studies that have changed the state of medical care for Americans with rare diseases. Grants ensure that product development occurs in a timely manner with a very modest investment.

FDA grant funds are covering less and less of the cost for conducting clinical trials. The cost of clinical trials continues to increase far faster than the rate of inflation. For example, pediatric study costs increased eight-fold between 2000 and 2006 as a result of more complexity.[3] In addition, the design of clinical trials is even more complicated for rare diseases because there are fewer available patients. FDA plays an integral role in the development of products for rare diseases and conditions in the U.S. Therefore, the appropriation levels for FDA's Orphan Product Grants Program are of increasing concern to the rare disease community. There are few DHHS clinical grants focused on products for Americans with rare diseases. This public health concern gained greater visibility when the Institute of Medicine (IOM) completed its study on rare diseases. The IOM stated, "Because funding has not kept pace with inflation, the grants program cannot operate at the same level as it did in the 1990s much less at an enhanced level to accelerate the orphan product development."[4]

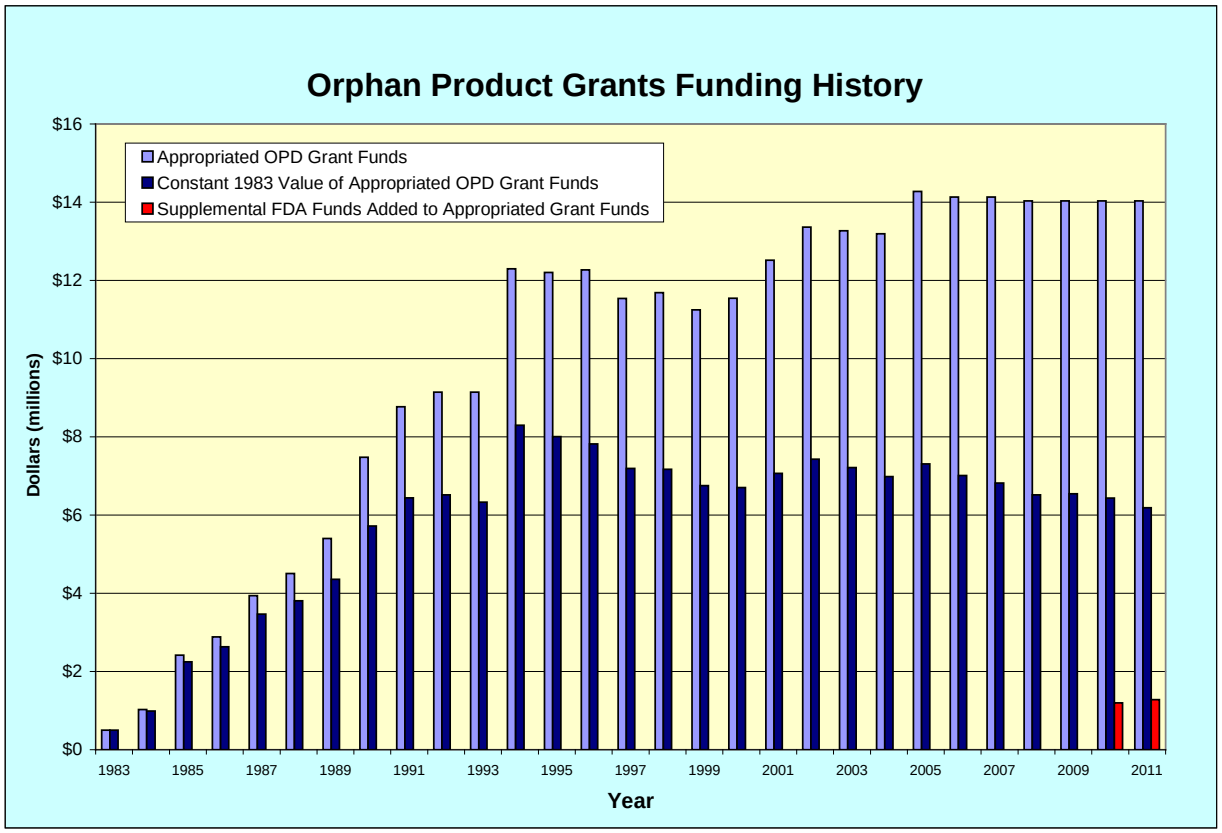
---

[2] Johnston SC , Rootenberg JD, Katrak S, Smith WS, Elkins JS. "The impact of an NIH program of clinical trials on public health and costs." *The Lancet*, April 22, 2006, Vol. 367, pp. 1319-1327.

[3] Kaitin KI, editor. Pediatric study costs increased 8–fold since 2000 as complexity level grew. *Tufts Center for the Study of Drug Development Impact Report* 2007 Mar/Apr;9(2)

[4] Field, M.J. and T.F. Boat, editors. Rare Diseases and Orphan Products: Accelerating Research and Development. *Institute of Medicine.* 2010.

Because of the increased costs of clinical trials, FDA increased the maximum grant award amount and maximum number of grant years. As a result of no increases in the amount of appropriated grant funds, the number of new grants awarded is decreasing. To help make up the difference, in FY 2010 and FY2011, the amount of grant funds appropriated was supplemented with $1.20 million and $1.28 million respectively from Program Administration to support three additional grants.

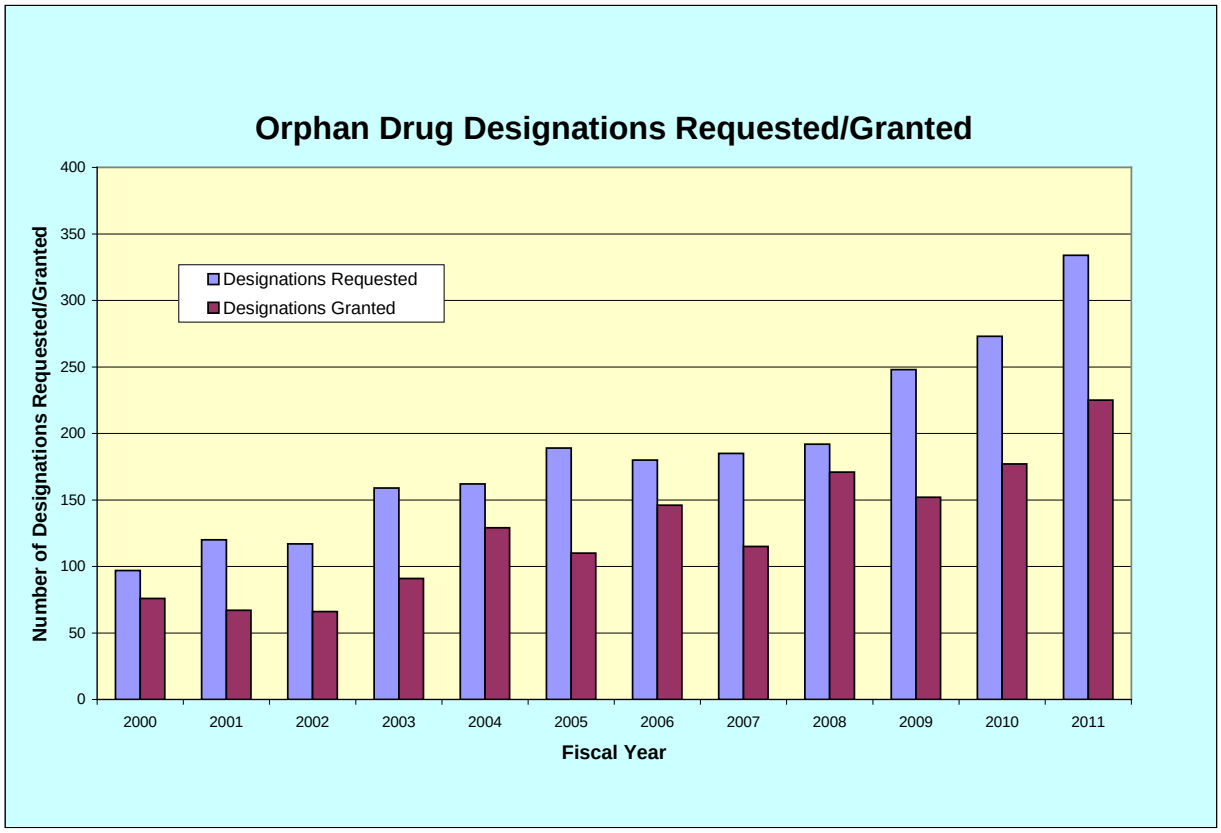


Orphan Drug Designation Activity

Public Health Focus: There are an estimated 7,000 rare diseases, with a public health impact directly affecting more than 25 million (and many millions of family members more) in the U.S. Between 85 and 90 percent of these are serious or life-threatening. In enacting the ODA in 1983, Congress sought to provide incentives to promote the development of drugs (including antibiotics and biological products) for the treatment of rare diseases. OOPD evaluates applications for orphan drug designations from sponsors who are developing medical products to treat rare diseases or disorders that affect fewer than 200,000 persons in the U.S. These medical products may be able to obtain an orphan designation if the sponsor is not expected to recover the costs of developing and marketing the product. After a designation is made, the developer of a designated orphan product is guaranteed seven years of market exclusivity for a specific indication following the approval of the product by FDA.

Public Health Outcome: Of the 2,533 orphan designations issued by OOPD since 1983, 394 have resulted in marketing approval with orphan exclusivity. During FY 2011, OOPD received 334 new applications for orphan designation, the most ever in a single

year. These included potential treatments for many kinds of cancers, amyotrophic lateral sclerosis, sickle cell disease, and pediatric multiple sclerosis. OOPD designated 225 orphan drugs in FY 2011.



The number of requests for orphan designation has tripled since 2000 (see chart above). OOPD anticipates that the workload associated with the orphan designation requests will continue to increase in the future. Not only are the requests increasing, but the complexity of the science of potential orphan drugs is increasing. There are many more entrepreneurial ideas and concepts being considered in the areas of pharmaco-genomics and individualized medicine that challenge our reviewers. In FY 2011, 28.6 percent of all the new molecular entities (NME) approved by the FDA were orphan designated drugs and biologics.

FDA approved 25 orphan designated drugs for marketing in FY 2011. One recent example is the marketing approval in August 2011 of Anascorp for the treatment of scorpion envenomations requiring medical attention. Poisonous scorpion stings affect 12,000 patients per year in the United States. The marketing approval of this drug was supported in part through funding by the OOPD Orphan Products Development grant program. This drug received orphan status in June 2000.

Promoting Efficiency: OOPD facilitates the designation and development of orphan drugs by reviewing applications and designating orphan drugs; acting as an intermediary between sponsors and FDA medical product review divisions in the drug development process to help resolve any outstanding problems, discrepancies, or misunderstandings

in the regulatory review process; providing expertise in clinical trial design and outcome review; and assisting in the development of medical countermeasures through the orphan drug designation process.

Humanitarian Use Device Designation Activity

Public Health Focus: The purpose of the Humanitarian Use Device (HUD) program is to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year.

A device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. FDA, therefore, developed and published a regulation to carry out provisions of the Safe Medical Devices Act of 1990 to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations. This regulation became effective on October 24, 1996. A HUD designation from OOPD is required for a device prior to applying for a Humanitarian Device Exemption (HDE) from the Center for Devices and Radiological Health (CDRH). An HDE for a specific device allows the sponsor to bring the device to market for the small patient population after demonstrating the safety and probable benefit of the device. It is a marketing approval that is exempt from the full effectiveness requirements of sections 514 and 515 of the Safe Medical Devices Act of 1990; however, the sponsor cannot realize a profit from an HDE.

Most recently, the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85) allows HDE approved devices intended for use in pediatric patients or in a pediatric subpopulation (device would be intended for pediatrics and adults) and approved on or after September 27, 2007, to be sold for profit.

Public Health Outcome: In FY 2011, OOPD received 21 new HUD applications and designated 11 devices. An additional eight devices were designated based on HUD applications originally submitted in prior years for a total of 19 HUD devices designated in FY 2011.

In FY 2011, three devices received an HDE approval. They include: a device for amyotrophic lateral sclerosis (ALS) patients to assist with breathing, a device used in the treatment cerebral aneurysms, and a device to create a bypass without clamping the intracranial artery during neurosurgery.

In addition, since the 2007 amendments allowing a profit for HDE approved pediatric devices, the number of pediatric devices seeking a HUD designation has increased from an average of one per year to an average of five per year.

Promoting Efficiency: OOPD conducts activities leading to HUD designations, including: reviewing applications and designating humanitarian use devices; facilitating the HDE approval process to help resolve any outstanding issues; and providing expertise to sponsors in approaches to the various types of marketing approvals for medical devices.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)*	FY 2011: 451 Target: 312 (Target Exceeded)	425	450	+25
293202: The number of medical devices provided development assistance by the Pediatric Device Consortia. (O*utput)*	FY 2011: 90 Target: 90 (Target Met)	100	110	+10

Pediatric Device Consortia Grants Activity

Public Health Focus: There exists a great public health need for medical devices designed specifically for children. The development of pediatric medical devices currently lags five to ten years behind those for adults due to the lack of commercial incentives for pediatric medical device development. Children differ from adults in terms of their size, growth, development, and body chemistry, adding to the challenges of pediatric device development. Such needs include the de novo development of pediatric medical devices, as well as the specific adaptation of existing adult devices for children. Thus, as part of the 2007 FDAAA legislation, Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007. Section 305 of this Act mandates demonstration grants for improving pediatric device availability, to be administered for the creation of pediatric device development consortia. The demonstration grants are not limited to addressing diseases or conditions that are considered to be rare.

Public Health Outcome: So far, five Pediatric Device Consortia have been established under this program; collectively they are facilitating the early development of over 90 potential medical devices for children." The five consortia are as follows:

- The Pediatric Cardiovascular Device Consortium, based out of Boston Children's Hospital,
- The UCSF Pediatric Device Consortium, based out of the University of California at San Francisco (http://www.pediatricdeviceconsortium.org/),
- The Michigan Pediatric Device (M-PED) Consortium, in partnership with the Pediatric Medical Devices Institute, of Roanoke, VA, based out of the University of Michigan (http://peddev.org/),
- The MISTRAL (Multidisciplinary Initiative for Surgical Technology Research Advanced Laboratory) Collaborative based out of SRI International in Stanford, California (http://mistralpediatric.org/).
- Atlanta Pediatric Device Consortium, based out of Atlanta, Georgia.

Promoting Efficiency: The goal of FDA's Pediatric Device Consortia Grant Program is to support the development of nonprofit consortia designed to stimulate projects which will promote pediatric device development. The consortia facilitate the development, production, and distribution of pediatric medical devices by:

- encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers
- mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing
- connecting innovators and physicians to existing Federal and non-Federal resources
- assessing the scientific and medical merit of proposed pediatric device projects
- providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs.

Outreach Activity

Public Health Focus: OOPD participates in significant outreach activities by providing information on approved therapies for rare diseases for the patient community and advocacy groups; by speaking at meetings and conferences on the FDA approval processes, the Orphan Products Grants Program, and the science of developing therapeutic products for rare diseases/conditions; and by assisting patients and advocacy groups on issues of concern related to rare diseases and orphan products, such as drug shortages.

Public Health Outcome: In FY 2011**,** OOPD received more than 90 invitations/requests to speak/participate at orphan drug stakeholder meetings. OOPD made presentations and participated in 73 of these meetings, often to explain how orphan drugs and humanitarian devices could be developed with ODA incentives and HDE provisions. The meetings ranged in size from small patient advocacy groups with less than 250 patients in this country to international meetings that discuss global issues. The attendance at these meetings ranged from 30 professionals to over 500 patients and families. At these meetings, the missions of OOPD and FDA were explained, and the questions and concerns from stakeholders were addressed. Examples of public health related OOPD outreach activities in FY 2011 include:

- Co-sponsored an extramural training course in Maryland on the important aspects of designing and analyzing clinical trials in small populations
- Co-sponsored 5 workshops (Virginia, California, Minnesota (2), and India) for product sponsors on preparing an application for requesting an orphan drug designation or HUD designation.
- Presented at the International Rare Disease Research Consortium in Reykjavik, Iceland,
- Presented at the Genetic Diseases in Children - Advancing Research and Care, sponsored by the New York State Department of Health,
- Presented at the Phelan McDermid Syndrome Symposium in New York, New York.

Promoting Efficiency: OOPD's public health outreach activities increase the feasibility and level of sponsor interest in orphan products development through the orphan grants program, orphan designations programs, and HUD program. OOPD frequently meets with companies that have expressed an interest in commercializing new products for rare diseases to encourage them to go forward with development and to advise them on possible approaches to follow while gathering information that will lead to the approval of their product. The design of clinical trials is more complicated for rare diseases because there are fewer available patients and the complexity of the science of potential orphan drugs is increasing. There are many more entrepreneurial ideas and concepts being considered in the areas of pharmaco-genomics and individualized medicine that are challenging to develop but potentially useful to patients with rare diseases. OOPD also provides valuable expertise in addressing regulatory concerns through facilitation with the FDA review divisions.

Five Year Funding Table

The following table displays funding levels from FY 2008 through FY 2012 for the Office of Orphan Products.

Fiscal Year	Program Level
FY 2008 Actual	**$17,691,161**
FY 2009 Actual	**$19,840,060**
FY 2010 Actual	**$22,785,290**
FY 2011 Actual	**$22,175,488**
FY 2012 Enacted	**$23,678,688**

Budget Overview and Supported Activities

The FY 2013 budget request for the Office of Orphan Products Development is $23,678,688. This amount is showing no increase above the FY 2012 Enacted Level.

Office of Orphan Products Development
Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2010 Actual	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
GRANTS PROGRAMS				
New Orphan Product Grants Awarded	18	14	8	8
Total Pediatric Consortia Grants (new and continuations)	4	5	4	4
ORPHAN DRUG REQUESTS, DESIGNATIONS, AND MARKET APPROVALS				
New Designation Requests	273	334	340	350
Designations	177	225	225	230
Market Approvals	11	25	24	24
HUD REQUESTS AND DESIGNATIONS				
New Designation Requests	28	21	25	25
Designations	14	19	12	12

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

BIOLOGICS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$325,222**	**$302,020**	**$329,136**	**$332,756**	**$3,620**
Center	$279,790	$259,429	$283,904	$287,333	$3,429
FTE	1,023	1,055	1,055	1,075	20
Field	$45,432	$42,591	$45,232	$45,422	$190
FTE	231	241	239	242	3
Program Level FTE	**1,254**	**1,296**	**1,294**	**1,317**	**23**
Budget Authority	**$212,014**	**$211,790**	**$212,224**	**$209,827**	**-$2,397**
Center	$171,157	$171,341	$171,711	$169,881	-$1,830
Field	$40,857	$40,449	$40,513	$39,945	-$568
Budget Authority FTE	**875**	**899**	**905**	**902**	**-3**
Center	650	664	672	669	-3
Field	225	235	233	233	0
User Fees	**$113,208**	**$90,230**	**$116,912**	**$122,929**	**$6,017**
Center PDUFA	$96,624	$79,746	$101,010	$103,163	$2,153
FTE	341	355	355	367	12
Field PDUFA	$4,025	$1,719	$4,207	$4,297	$90
FTE	5	5	5	5	0
Center MDUFMA	$12,009	$8,342	$11,183	$13,515	$2,332
FTE	32	36	28	36	8
Field MDUFMA	$550	$423	$512	$619	$107
FTE	1	1	1	1	0
Center Biosimilars User Fee [1]				774	774
FTE				3	3
Field Medical Product Reinspection[1]			$0	$561	$561
FTE			0	3	3
User Fees FTE	**379**	**397**	**389**	**415**	**26**

[1] Proposed User fee; the amount includes associated rent activity -

FDA's Biologics Program operates under the following legal authorities:

Public Health Service Act
Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Medical Device Amendments of 1976*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Safe Medical Devices Act of 1990*
Medical Device Amendments of 1992*
Food and Drug Administration Modernization Act of 1997*
Medical Device User Fee and Modernization Act of 2002*
Public Health Security and Bioterrorism Preparedness Response Act of 2002*
Project BioShield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005*

Food and Drug Administration Amendments Act of 2007*
Biologics Price Competition and Innovation Act of 2009*
Patient Protection and Affordable Care Act, 2010*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA Biologics Program began in 1902 with the passage of the Biologics Control Act, which established the authority to regulate biological products and ensure their safety for the American public. This program was initially located in the Department of Treasury's Hygienic Laboratory, which in 1930 became the National Institutes of Health (NIH). In 1972, the Biologics Program was transferred from NIH to FDA and became the Bureau of Biologics. The Bureau of Biologics merged with the Bureau of Drugs in 1982 to form the National Center for Drugs and Biologics. In 1988, the National Center split, creating the FDA Biologics Program, which consists of the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA)'s Field Biologics.

CBER ensures the safety, purity, potency and effectiveness of biological products, including vaccines and allergenic products, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of a wide variety of human diseases, conditions or injuries. Most products that CBER regulates are complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science.

In addition, CBER protects the public health against the threat of emerging infectious diseases, neglected tropical diseases, and potential bioterrorism agents through preparedness planning and licensure to make available safe and effective medical products used to diagnose, treat or prevent disease.

The Field Biologics component in ORA supports the Biologics Program activities by assessing industry compliance with the applicable regulations to protect the public health. ORA achieves this by conducting domestic and foreign inspections, performing entry review of imported products, investigating complaints, monitoring recalls of violative products and recommending regulatory actions to the Center.

The Biologics Program is funded by Budget Authority (BA) and User Fees (UF), with the latter used for prescription drug (including biological drug product) and medical device review activities. Regulatory responsibilities for the Program are executed in three subprograms: 1) Vaccines Premarket Review and Postmarket Safety (including

* Authorities under this act do not appear in sequence in the United States Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

allergenic products such as an extract used to diagnose and treat allergies to bee stings); 2) Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety; and 3) Blood and Blood Products Premarket Review and Postmarket Safety. The activities and FY 2012 Enacted funding in these subprograms are as follows:

Vaccines Premarket Review and Postmarket Safety – Center Activities
FY 2012 Enacted Amount: $135,148,740 (BA: $75,552,840 / UF: $59,595,900)

Public Health Focus

On a daily basis, vaccines touch the lives of people in the United States and millions of others globally, and have either nearly eliminated or reduced preventable infectious diseases with fewer people experiencing the devastating effects of measles, pertussis, polio, and other illnesses such as influenza. The Vaccines Premarket Review and Postmarket Safety subprogram plays a critical role in facilitating the development of these important medical products, as well as increasing the availability of safe and effective vaccines that preserve public health by preventing and controlling infectious diseases.

The public health focus of this subprogram is to ensure that safe and effective vaccines, allergenic extracts and related biologic products are available in the United States.

CBER accomplishes its public health objectives and goals by evaluating investigational new drug applications (INDs) for vaccines and related biological products and biologics license applications (BLAs) and supplements submitted by manufacturers of preventive vaccines and related biological products for infectious diseases to determine their safety and effectiveness, and taking appropriate regulatory actions. In addition to its regulatory responsibilities, CBER plans and conducts mission-oriented research related to the development, manufacture, and evaluation of safe and effective vaccines and related products. CBER also develops guidance, policies, and procedures governing the premarket evaluation of safety and effectiveness of vaccines and related products and conducts outreach to consumers and to regulated industry.

Serving as a key contributor to the global efforts to select yearly seasonal influenza vaccine strains, CBER is a part of the World Health Organization (WHO) Reference Laboratories network. CBER is active in efforts to generate appropriate reference virus strains and reference reagents for both seasonal and pandemic influenza vaccine production. CBER also collaborates with national and international health agencies to facilitate harmonization of policies and strengthen global regulatory and scientific infrastructure, including those in less developed regions of the world. For example, the Meningitis Vaccine Project, a partnership between the international non-profit organization Program for Appropriate Technology in Health (PATH) and WHO spearheaded the development of a new vaccine. FDA developed an affordable technology for manufacturing the vaccine and transferred this technology to PATH who

worked with a manufacturer to make millions of doses of the vaccine for less than 50 cents a dose, allowing widespread use in Sub-Saharan Africa.

CBER collaborates with federal partners to develop their capacity to do safety surveillance, both in ongoing activities and in response to emerging safety signals, including the Vaccine Adverse Event Reporting System (VAERS) database, which is operated jointly with the Center for Disease Control and Prevention (CDC). CBER is seeking to improve real-time surveillance methods and developing advanced methods to detect serious and unexpected adverse events using novel statistical approaches in large population-based databases.

CBER is working to expand surveillance capacities with federal and international partners, including the CDC, Center for Medicare and Medicaid Services, Indian Health Service, Departments of Defense and Veterans Affairs, WHO, and the Pan American Health Organization to improve post-marketing surveillance strategies for monitoring influenza vaccine safety in a diverse population. To enhance surveillance, CBER is developing the Mini-Sentinel's Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, the largest electronic real-time active surveillance system for vaccine safety in the United States. When PRISM is fully operational CBER will conduct near real-time surveillance for new vaccines and will analyze rare health outcomes that have been heretofore challenging to assess. CBER also reviews pharmacovigilance plans for original BLAs and supplements to strengthen manufacturer's plans for monitoring safety after licensure.

Public Health Outcome

CBER's expertise in the areas of research, vaccine manufacturing, and regulatory science facilitates the availability of safe and effective vaccines for the United States. For the past several years, CBER has been anticipating and addressing challenges associated with using new technologies in the development and licensure of vaccines to prevent infectious diseases. A comprehensive, multi-faceted approach to these challenges is utilized by CBER:

- Conducting cutting-edge biomedical research in CBER laboratories for vaccine development. This research facilitates the development and evaluation of vaccines. CBER scientists apply up-to-date scientific concepts from their research to the regulation of vaccines. Two examples of CBER's cutting edge research include the development of an in vitro system to assess the preclinical safety of adjuvants and the application of massive parallel sequencing to monitor the genetic consistency of certain live viral vaccines. Additional research examples include CBER's collaboration with Biomedical Advanced Research and Development Authority (BARDA), CDC and NIH on the "Influenza Manufacturing Improvement Initiative." This project is working toward: 1) optimizing the production of high yield virus reassortants for use as candidate vaccine viruses; 2) developing improved new methods for determining vaccine potency and the calibration of potency reagent standards; and 3) evaluating and validating new rapid sterility testing methods.

Additionally, CBER launched several research programs on developing new animal models for evaluating vaccines including “Development and Use of Mouse Models of Anthrax.”

- Routinely convening and participating in public workshops on emerging scientific and regulatory issues. Public meetings, such as Vaccines and Related Biological Products Advisory Committees, bring together a panel of outside independent technical experts from various scientific disciplines to assist FDA in analyzing detailed data and understanding its public health significance. For example, CBER led in developing and convening a public workshop with the National Institute of Allergy and Infectious Diseases (NIAID)/NIH to facilitate development and evaluation of the safety and effectiveness of next-generation smallpox vaccines. CBER also provided webinars for industry on IND basics and sponsor meetings and outreach to consumers by developing a webinar on “FDA’s Role in Protecting Your Child’s Health Through Safe and Effective Vaccines.”

- Issuing guidance documents to convey regulatory requirements and recommendations and to provide a scientific framework for developing vaccines. The guidance documents facilitate CBER’s regulatory and scientific exchange with industry for discussing regulatory pathways to licensure of vaccine candidates produced using new technologies to facilitate the development and availability of vaccines.

The result of CBER’s scientific guidance to the vaccine industry and optimization of the vaccine review and licensing process to encourage the development of new vaccines has facilitated the availability of many important safe and effective vaccines in recent years such as:

- Cervarix- prevention of cervical cancer due to HPV types 16 and 18 in females 10 to 25 years of age.

- Fluarix- expanded indication for prevention of influenza in individuals three years of age and older, making available an additional vaccine for children.

- Fluzone High-Dose- prevention of influenza in individuals 65 years of age and older.

- Menveo- prevention of meningitis in individuals 11 to 55 years of age.

- Prevnar 13- prevention of invasive disease caused by 13 different serotypes of the bacterium *Streptococcus pneumoniae* and for the prevention of otitis media caused by the seven serotypes shared with Prevnar. It is for use in infants and young children ages six weeks through five years.

- Zostavax- prevention of herpes zoster (shingles) in individuals 50 years of age and older.

- Ixiaro- prevention of disease caused by Japanese encephalitis virus in individuals 17 years of age and older

- Vaccines to protect against the pandemic (H1N1) 2009 influenza virus.

- Approval of the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States.

Under the Prescription Drug User Fee Act (PDUFA) program, FDA agreed to pursue a comprehensive set of application review performance goals. [1] During FY 2010, CBER exceeded PDUFA goals for standard (ten months) and priority (six months) BLA/New Drug Applications (NDAs) and efficacy supplements by reviewing and acting upon 100 percent of applications within the target timeframe.

CBER's laboratory research enables scientists to assist manufacturers in a number of ways such as: preparing antisera which is used to determine the potency of vaccines, examining the genetic makeup of potential high growth viruses in order to develop reference vaccine viruses which optimally grow in eggs or cell cultures, and developing assays to determine the presence of contaminating infectious agents in cell cultures. CBER also conducts final lot release testing to ensure product safety and effectiveness prior to a manufacturer releasing the product to the public.

CBER monitors the safety of vaccines after licensure to ensure their safety under conditions of routine use in the general population. CBER reviews, interprets, and analyzes adverse event reports collected through VAERS for signals of possible new safety issues associated with vaccine use in the general population. As part of post-marketing commitments or requirements to further evaluate the safety and effectiveness of vaccines, CBER evaluates the results of clinical and epidemiologic studies that manufacturers conduct after a vaccine is licensed to monitor for new safety issues. In addition, CBER collaborates with CDC to perform studies and rapid-cycle analysis through the CDC's Vaccine Safety Datalink, an active surveillance system with eight health-maintenance organizations.

In collaboration with CDC, CBER closely monitors the continued safety of all influenza vaccines during and after their use by the public. During the 2009 H1N1 influenza pandemic, the PRISM program was the first vaccine safety system to integrate nine different state or metropolitan vaccine registries to enable the capture of vaccines administered in nontraditional health care settings, such as mass immunization clinics. PRISM provided improved statistical power to detect rare outcomes, including Guillain-Barre Syndrome, that have been previously associated with influenza vaccines.

[1] CBER is showing its performance measures goal table by subprogram, but several of the measures are PDUFA goals that span several subprograms. Performance results for PDUFA measures contained in the subprogram performance tables will be stated in the subprogram narratives.

CBER completed preliminary studies to evaluate the use of mass spectrometry to determine the absolute amount of hemagglutinin in reference standards and define initial sample conditions. Because investigations were delayed until the delivery of required equipment, CBER was not able to complete verification studies required to achieve the FY 2011 target for the influenza performance goal. The preliminary studies provided encouraging results suggesting that such methods undergo further evaluation for potential implementation in vaccine reagent production. Studies are ongoing to determine the absolute amount of hemagglutinin in the reference standards.

Promoting Efficiency

Improving the efficiency of lot release of biological products enables FDA to ensure an adequate supply of licensed products while reducing the processing time for manufacturers to meet FDA requirements. Because of the H1N1 influenza pandemic in 2009, CBER needed to optimize lot release efficiency to get the much needed vaccine out to the public in a timelier manner. CBER piloted an electronic lot release submission program for the 2009 Monovalent H1N1 Influenza Virus Vaccine campaign. Due to the pilot's success, CBER implemented the new system for the 2010-2011 seasonal influenza vaccine lot releases. The results were that almost all lot release protocols were submitted electronically, resulting in decreased release time and more rapidly available vaccines to the public. CBER is in the process of expanding the program to offer electronic lot release to all products so biological products can reach the public more efficiently and effectively.

Vaccines Premarket Review and Postmarket Safety – Field Activities
FY 2012 Enacted Amount: $5,842,000 (BA: $4,383,000 / UF: $1,459,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness of vaccines and allergenic products for the prevention and treatment of human diseases or conditions and helps to defend the public against the threats of emerging infectious diseases and bioterrorism. ORA accomplishes this public health mission by conducting inspections, both domestically and abroad, and by performing entry review and import field exams on imported products.

Public Health Outcome

Inspections are conducted at manufacturing facilities and clinical study sites, including clinical investigators and institutional review boards. These inspections are conducted before products are approved or licensed for use (premarket) and in the postmarket arena after approval or licensing. Inspections are conducted in part to assure:

- rights of human subjects participating in clinical trials are protected through proper oversight.

- data submitted to FDA and used in support of applications are valid and reliable.
- laboratories are competent and adhere to applicable regulations.
- compliance with current good manufacturing practices and other applicable FDA regulations.

In FY 2011, ORA continued to staff the Commercial Trade Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA is working closely with other government agencies to ensure coverage of products within the biologics and vaccines program.

In 2011, an ORA inspection of a foreign influenza vaccine manufacturer revealed that the firm failed to adequately evaluate strain changes and changes to the manufacturing process prior to manufacturing the 2010 seasonal influenza vaccine and also failed to conduct adequate investigations into deviations of products marketed in the United States. The firm was issued a Warning Letter for these and other deficiencies observed. The inspection team also included CBER product specialists and coordinated activities with the foreign Competent Authority. The results of this inspection not only serve to help protect the American public from potentially ineffective and contaminated influenza vaccine, but also the foreign country's population.

Promoting Efficiency

ORA continues to staff a dedicated team of investigators with specialized training and experience, whose primary responsibility is to conduct inspections of all vaccine manufacturers. This team approach ensures consistent inspections of the manufacturers and application of the regulations while ensuring experienced investigatory staff are performing timely, comprehensive and efficient investigations. These actions facilitate the marketing and release of products in a timely manner, ensuring for safe products to reach consumers in the United States in an efficient manner.

The ORA team works collaboratively with CBER product specialists to conduct inspections of vaccine manufacturers. This comprehensive approach provides a single, robust inspection which makes inspections faster and more efficient and assures products are safe and effective for use by consumers in the United States. These efficiencies benefit both industry and consumers in the United States by facilitating the marketing and/or the release of safe products in a timely manner.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. *(Output)*	FY 2011: The studies were delayed in FY 2011 awaiting the delivery of required equipment. In FY 2011, CBER did complete preliminary studies to evaluate the use of mass spectrometry to determine the absolute amount of hemagglutinin in reference standards and define initial sample conditions. (Target not met but improved)	Evaluate and compare new methods to determine the potency of influenza vaccines	Develop and evaluate new methods to produce high-yield influenza vaccine reference strains	N/A

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety – Center Activities

FY 2012 Enacted Amount: $53,837,190 (BA: $32,625,090 / UF: $21,212,100)

Public Health Focus

The public health focus of the Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety subprogram is to facilitate the safe and effective development of novel biologic products by issuing guidance and regulations, developing policy, and providing education and outreach activities to the regulated community. Regulated products in this subprogram include but are not limited to: human cells, tissues, and cellular and tissue-based products (HCT/Ps); gene therapies used to treat or cure a

broad range of diseases and medical conditions, tumor vaccines, xenotransplantation, stem cell therapies; and combination products such as bioengineered tissues. With the aging population in the United States and advances in medicine, tissue transplantation, gene therapies, and cell therapies (including stem cells) the use of stem cells are rapidly growing industries that have the potential to provide significant improvements in the nation's health while also fostering economic growth. This growth can be illustrated by the number of musculoskeletal tissue transplants which have increased from approximately 350,000 in 1990 to currently more than two million per year. In 2009, President Obama issued Executive Order 13505, "*Removing Barriers to Responsible Scientific Research Involving Human Stem Cells"* which has resulted in an increase in research and development in the use of human embryonic stem cells. More work remains to understand how to use stem cells for therapies to treat disease and it is imperative that FDA remain up-to-date on scientific development in this rapidly developing area so that policies reflect the most current scientific knowledge. To stay at the forefront and address regulatory science gaps in our understanding of stem cell-based therapies, CBER interacts with industry and other stakeholders to better anticipate scientific and regulatory challenges that may arise in the review of investigational and licensing applications for novel stem cell products. For example, FDA and NIH have developed a partnership to identify key needs that can be addressed jointly with the goal of moving pluripotent stem cell therapies into the clinic. In their first joint effort, the agencies co-sponsored a March 2011 workshop entitled "Pluripotent Stem Cells in Translation: Early Decisions," which also included participation from industry, academic and clinical scientists.

Public Health Outcome

Advances in science and technology show great promise for the development of new safe and effective biological products. Examples include cellular and gene therapy products, therapeutic cancer vaccines, immunotherapy, and combination products. CBER will advance regulatory research that supports product review and the corresponding review processes to reflect the new generation of product evaluation tools and the innovative products expected over the next decade. For example, CBER recently approved the product, Laviv (azficel-T), which is the first and only FDA-approved personalized aesthetic cell therapy for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults.

Gene therapy products are a novel and rapidly evolving product class that require early scientific and regulatory interaction and guidance. While gene therapy products have the potential to treat illness and cure disease, they also have the potential to result in serious adverse events. CBER is working to address the use of these products by issuing regulatory guidance documents for industry. The goal in all stages of product development is to promote the development of safe and effective products. As an effective means to address issues regarding potential risks and benefits of innovative gene therapy products, CBER works closely with NIH, academia, industry, patient advocacy groups and various professional associations.

CBER also conducts webinars for industry including presentations on IND basics, sponsor meetings and chemistry, manufacturing and control information for gene therapy INDs and cellular therapy products. Within FDA, CBER and the Center for Devices and Radiological Health (CDRH) are participating in several initiatives to address combination products and partnerships with other federal agencies to advance tissue-engineering science, and facilitate the development of safe and effective bioengineered tissue products.

Many developmental pathways for cell and gene therapy products are in their infancy with no precedents to guide their development. It is crucial for CBER to ensure product safety at each stage along the developmental path. Some of the risks that could potentially cause adverse events with cellular and gene therapies include inadvertent germline transmission of infectious disease, poor survival of the cells in the patient, migration of the cells to the wrong part of the body and excessive cell growth and malignancy. Some examples of ensuring safety include:

- Studying the causes and mechanisms that may underlie adverse events in cell and gene therapies, addressing the regulatory and scientific challenges in the characterization of these products, and developing animal models to test safety

- Expanding in-house regulatory research while working collaboratively with other government agencies, such as the NIH and the National Institute of Standards and Technology, to identify, develop, and evaluate methods to characterize products that will be predictive of clinical function

- Regulating xenotransplantation products (the transplantation of nonhuman tissues or organs into human recipients) and working with international scientific societies, national health authorities, and the WHO to help the global community develop xenotransplantation guidelines

- Implementing a transparent approach to ensure the safety of products used in clinical trials and studying mechanisms that underlie xenotransplantation adverse events associated with administration of xenotransplantation products
- Ensuring the safety of many types of human tissues and cells that are transplanted during various medical procedures to restore proper function to patients (skin replacement following severe burns, bone, tendons and ligaments used to repair musculoskeletal injuries, blood stem cell transplants in patients with hematologic malignancies and other life-threatening diseases and corneas used to restore eyesight)

- Implementing a risk-based comprehensive approach for assuring HCT/P safety and to prevent the transmission of infectious disease from HCT/Ps, including developing new guidance to convey current recommendations for complying with the HCT/P regulations

- Monitoring tissue safety and meeting regularly to address tissue safety and policy issues through the interdisciplinary CBER Tissue Safety Team and CBER Tissue Policy Team.

BLAs for cell and gene therapy products are covered by the PDUFA program, which enables the Biologics Program[2] to ensure the timeliness and predictability of FDA review of new cell and gene therapy products for sponsors and consumers. Under the PDUFA program, FDA agreed to pursue a comprehensive set of application review performance goals. During FY 2010, CBER exceeded the goals for standard (ten months) and priority (six months) BLA/NDAs and efficacy supplements by reviewing and acting upon 100 percent of applications within the target timeframe.

CBER participated in the first step of inventorying the regulatory frameworks specific to cell therapy. This was undertaken in a workshop in July 2011 held by a newly established workgroup to develop international harmonization in the cell therapy arena. This workgroup is under the auspices of the Global Regulators Forum with WHO, Pan American Health Organization (PAHO), and Asia Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum.

To determine best practices in planning cell and gene therapy trials in pediatric populations and on informed consent review, CBER held a public workshop on Cell and Gene Therapy Clinical Trials in Pediatric Populations in November 2010, to gather information from Institutional Review Boards (IRBs), gene and cellular therapy clinical researchers, and other stakeholders. In February 2011, CBER also supported and participated in "The 14th U.S.-Japan Cellular and Gene Therapy Conference on Induced Pluripotent Stem Cells (iPS): Derivation and Characterization" conference. The goal of this conference was to exchange ideas on cutting-edge areas of biomedical research and to enhance opportunities for collaborations among scientists from the United States and Japan. CBER also issued "Final Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products" to clarify the potency information that could support an IND or a BLA. Additionally, CBER approved its first license application for a cord blood product, HEMACORD in November 2011, which is indicated for use in hematopoietic stem cell transplantation procedures in patients with disorders affecting the hematopoietic (blood forming) system, such as certain blood cancers and some inherited metabolic and immune system disorders.

Promoting Efficiency

Cell and gene therapy research and development in the United States continues to grow at a rapid pace and CBER is actively involved in overseeing this activity. CBER has been working closely with stakeholders to understand the causes and mechanisms that may underlie adverse events arising from these therapies. CBER is also working to address the regulatory and scientific challenges to ensure the safety and effectiveness

[2] CBER is showing its performance measures goal table by subprogram, but several of the measures are PDUFA goals that span several subprograms. Performance results for PDUFA measures contained in the subprogram performance tables will be stated in the subprogram narratives.

of gene therapies. In addition, CBER is working with stakeholders to address safety and effectiveness issues, and thereby defining pathways to approving new therapies. These interactions with industry and other stakeholders allow CBER to understand where guidance is needed to facilitate applications for therapies. These interactions also allow CBER to identify and address the research needed to evaluate scientific concerns in advance of receiving applications for new therapies.

As previously mentioned, the number of musculoskeletal tissue transplants has markedly increased from approximately 350,000 in 1990 to currently more than two million per year, which highlights the need for research to address the many gaps that exist in the scientific knowledge about risks of tissue transplantation. In addition to educational outreach and participation in HHS tissue safety initiatives, CBER has established a tissue microbiology laboratory to further enhance the safety and the availability of human tissues intended for transplantation. The activities of this research lab include 1) developing real-time Polymerase Chain Reaction (PCR) arrays for the rapid detection of relevant communicable disease agents and diseases (RCDADs) and high-grade pathogens, 2) establishing bioinformatics expertise using next generation sequencing for the detection and characterization of previously unknown adventitious agents that could threaten the safety of human tissues and 3) identifying "biomarkers" associated with the basic mechanisms of cell/tissue injuries and development of injury-associated microarrays. The added expertise should also provide a more robust scientific infrastructure, improve regulatory practices, and enhance the office's performance of regulatory reviews. Maintaining this expertise should allow product innovators to more efficiently develop new products and have greater certainty about the regulatory pathway that CBER will rely on to review and approve human tissue products.

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety – Field Activities
FY 2012 Enacted Amount: $11,938,000 (BA: $10,756,000 / UF: $1,182,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness of cells, tissues, and gene therapies for the treatment of human diseases, conditions, or injuries by conducting foreign and domestic inspections, performing entry review and import field exams on imported products, and by investigating and building compliance cases. For inspections of HCT/P establishments, the focus is on an establishment's ability to manufacture tissue in accordance with regulations to prevent the spread of communicable disease. Inspections are also conducted on clinical trials involving gene therapy and cellular therapies to ensure trials are conducted in accordance with FDA regulations, human subject rights are protected, all adverse events are reported and data demonstrating effectiveness of the therapy is generated and collected in a manner to protect its integrity.

Public Health Outcome

Inspections are conducted at manufacturing facilities and clinical study sites including clinical investigators and institutional review boards. These inspections are conducted prior to products being approved and/or once they are on the market. Inspections are conducted in part to assure:

- rights of human subjects participating in clinical trials are protected through proper oversight.

- data submitted to FDA and used in support of applications are valid and reliable.

- HCT/Ps do not contain communicable disease agents, they are not contaminated and they do not become contaminated during manufacturing.

- Gene Therapy and Cell Therapy Products are processed according to current good manufacturing practice requirements.

- laboratories are competent and adhere to applicable regulations.

ORA monitors recalls of human biological products and assures the adequacy of the firm's recall to effectively remove defective product from commerce. Through the classification process, CBER determines the level of public health risk that the product presents.

In some circumstances, ORA's findings necessitate further inquiries and action. During FY 2011, ORA's Office of Criminal Investigations (OCI) made six arrests, and secured four convictions with fines, restitutions and other monetary penalties in excess of $1 million. Some examples of OCI activities are:

- In July 2011, defendant pled guilty pursuant to a plea agreement to introducing an unapproved new drug into interstate commerce. The OCI investigation was initiated upon information received during a witness interview that identified an owner of a large laboratory in Phoenix, AZ was supplying stem cell material to a physician in the Brownsville, TX. The laboratory collected cord blood from a midwife on the Arizona/Mexico border; manufactured, sold, and delivered stem cells into interstate commerce without FDA approval. Final sentencing remains pending.

- In October 2011, a superseding indictment was filed in an ongoing investigation involving unapproved products. OCI investigation determined an individual was allegedly conducting a clinical trial without having obtained an IND. During an inspection, CBER discovered an individual in Las Vegas obtained human placentas from at least one Las Vegas area hospital and surgically implanted tissue from the placenta(s) into at least 16 patients suffering from multiple sclerosis and other serious conditions. CBER issued an untitled letter to the

individual who responded that he would move his experiments offshore. Websites associated with the individual remained on the Internet advertising placental implants for various conditions. CBER referred this matter to OCI in for criminal investigation. As a result of the FDA/OCI investigation, in October 2011, the individual was charged with 7 counts of mail fraud and 13 counts of wire fraud, as well as criminal forfeiture for his alleged role in a scheme to cause over 100 chronically ill patients to undergo experimental stem cell implant procedures. If convicted, the individual faces up to 20 years in prison and fines up to $250,000 fine on each count, and forfeiture of money or property up to $913,748.

In FY 2011, FDA again exceeded the human tissue goal of 533 inspections, accomplishing 605 inspections. These inspections focus on the safe manufacture of HCT/Ps. HCT/Ps recovered from unknown or high risk donors could present a significant risk to human health as transmissible diseases may be present. These inspections assess manufacturers to determine that appropriate procedures are in place and they have been followed to result in safe HCT/Ps including bone, skin, corneas, ligaments, tendons, dura mater, heart valves, and stem cells among others. Millions of patients receive these products each year and these inspections are conducted to ensure a safe supply is available.

Promoting Efficiency

ORA achieves program efficiencies by identifying tissue establishments through registration activities and collaboration with CBER. ORA inspects the establishments that present the most risk to ensure products of higher risk are manufactured in accordance with FDA regulations and are safe and effective for consumers in the United States. For cell and gene therapies, internal pre-inspectional collaboration efforts with CBER results in more efficient and thorough inspections that target human subject protection and ensure the integrity of clinical trial data. In addition, ORA works with CBER reviewers to conduct inspections of clinical trials involving gene and cellular therapies to ensure any concerns presented in the application are investigated during the inspection. This collaboration results in a more efficient process for FDA and for industry. These efforts not only allow for the timely marketing of safe products but also support efficient manufacturing of products through increased communications between regulated industry and FDA.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2011: 605 Target: 533 (Target Exceeded)	533	570	+37

Blood and Blood Products Premarket Review and Postmarket Safety – Center Activities

FY 2012 Enacted Amount: $ 94,918,070 (BA: $63,533,070 / UF: $31,385,000)

Public Health Focus

According to the most recent National Blood Collection and Utilization Survey Report (2009), over 17 million donations of Whole Blood and Red Blood Cells were collected in 2008 from almost 11 million donors. These donations were made into about 24 million blood components that were transfused into about 4.5 million patients. Additionally, about 20 million donations of Source Plasma were collected for further manufacture into life-saving plasma derivatives (e.g. clotting factors for hemophilia and immune globulins for patients with immune deficiencies). CBER currently regulates over 1,050 licensed and 355 registered only blood facilities. The public health focus of the Blood and Blood Products Premarket Review and Postmarket Safety subprogram is to ensure the safety, purity, potency and availability of blood and blood components used for transfusion and the safety and effectiveness of pharmaceutical products made from blood.

CBER is responsible for ensuring the safety of blood and blood products by regulating blood collection establishments and approving devices used in the preparation of blood, including blood typing reagents and donor screening tests for infectious agents. Based on the unique expertise of its scientists, CBER also regulates all Human Immunodeficiency Virus (HIV) and other retrovirus diagnostic assays used in the United States.

CBER reviews and approves a wide range of life saving plasma-derived and recombinant protein products such as clotting factors, albumin, and immune globulins. These biologic products impact the health of nearly one-half million recipients who use these products acutely and chronically.

For all blood-related biologics, CBER establishes product standards. For many of these products, CBER also conducts in-house release testing of individual manufacturing lots to ensure that the products reaching patients are safe and effective.

Public Health Outcome

In order to ensure blood safety, CBER issues guidance to blood establishments to progressively strengthen the overlapping blood safeguards and approves donor screening tests that protect patients from blood borne diseases. These safeguards, which are periodically updated, include:

- *Donor screening and deferral*- Donors are informed about potential risks to blood safety and are asked questions about factors that may affect the safety of their blood. Donors are deferred if they do not meet health criteria or have risk factors for infectious diseases.

- *Blood testing*- Each donation of blood for transfusion undergoes a series of tests for infectious diseases (e.g. HIV-1/2, HBV, HCV, HTLV-I/II, syphilis, WNV). A donor with a reactive test is deferred and their blood is not used. First time donors are tested for T. Cruzi, the agent that causes Chagas disease.

- *Donor lists*- Blood establishments must keep current list of deferred donors and use it to make sure that they do not collect or use blood from anyone on the list.

- *Quarantine*- Donated blood must be quarantined until it is tested and shown to be free of infectious agents and a determination is made that the donor met all eligibility criteria.

- *Problems and deficiencies*- Blood centers must investigate manufacturing problems, correct all deficiencies, and notify FDA when product deviations occur in distributed products.

CBER has worked actively with the blood community to streamline and standardize the donor history questionnaires for Whole Blood and Source Plasma collection. These questionnaires help to identify and prevent donations from donors who are at increased risk for transmissible infections. The outcome of this effort is an estimated 85 percent reduction of the risk of transmissible agents, such as HIV, in the blood donor population even before testing. The overlapping safeguards of CBER approved screening assays combined with donor history questionnaires and donor education has reduced the risk of transfusion transmission of HIV and HCV to approximately one in every two million donations.

Continuous vigilance is necessary to preserve the current high level of blood safety. For example, viral variants of HIV may emerge at any time and escape detection by current screening tests, CBER maintains an active program to acquire such variants to ensure that licensed donor screening tests can detect viral variants when they emerge.

To extend the availability of diagnostic tests critical to public health, CBER has approved HIV rapid tests for use in outreach settings and recently approved the Bio-Rad GS HIV Ag/Ab Combo which can be used to screen blood in emergency situations and as an aid in the diagnosis of HIV infection, including pediatric populations as young as two years old. CBER regulates blood grouping tests used to type donor and patient blood to prevent hemolytic reactions. Novel blood grouping reagents based on DNA are expected to be forthcoming.

CBER-approved plasma derivative products include clotting factors such as Factor VIII, Factor IX, and immune globulins which are used to treat infections or immunodeficiency. In February 2011, CBER approved Corifact, the first product indicated for prevention of bleeding in patients with the rare congenital deficiency of Factor XIII. Corifact is an Orphan Product, approved as a priority review under the accelerated approval mechanism. Also, in June 2011, CBER approved a plasma derived albumin product, Albumin (Human) 25 percent, which is used in numerous medical settings for the treatment of hypotension, burns, renal dialysis, and organ transplantation. It is anticipated that the availability of this marketed licensed albumin will enhance the nation's overall supply of medically-necessary albumin products. Additionally, in August 2011, CBER approved Anascorp, the first licensed treatment for poisonous stings of scorpions that are found mainly in Arizona. Severe symptoms and death, especially in children, can be prevented with use of this orphan product.

The interdisciplinary CBER Blood Safety Team continues to enhance safety through increased collaboration, coordination, evaluation, and communication in response to complex and emerging blood safety issues. Working with a private data partner, a strong correlation between Factor XIa and thromboembolic (blocking of a blood vessel by a blood clot) adverse events was discovered through a combination of epidemiologic investigation and laboratory research. In May 2011, CBER expanded this safety initiative through a workshop with the NIH and the plasma industry on risk mitigation strategies to address potential procoagulant activity in immune globulin products. CBER continues to work with international regulatory agencies to monitor and understand the cause of these events.

CBER is working to develop a final rule on post marketing reporting of adverse events in blood donors and is working to expand surveillance capacities with federal and private partners, including the CDC and the Center for Medicare and Medicaid Services to improve post-marketing surveillance strategies for monitoring blood and blood product safety. To enhance surveillance, CBER is developing the Mini-Sentinel pilot project, the Blood Safety Continuous Active-Surveillance Network (Blood SCAN), to create an active pharmacovigilance system for blood and blood products. This effort is being coordinated with other Department of Health and Human Services (DHHS) stakeholders

as part of a national biovigilance system. Data from these programs will be used to further evaluate and improve transfusion safety by early detection of new threats, enabling benchmarking of local performance to promote best practices and to permit evaluation of the effect of system interventions.

As part of a national initiative on biovigilance, CBER representatives have been active steering committee liaisons with the CDC/American Association of Blood Banks (AABB) blood recipient hemovigilance program, and the HHS/AABB donor hemovigilance program, both of which have now been piloted and activated nationally. These two programs constitute the first active components of a larger national biovigilance effort being coordinated by the Office of the Assistant Secretary for Health (OASH)/DHHS. The larger program will eventually encompass blood, tissues, and organs and will follow a framework of public-private partnerships designed to meet the needs of all stakeholders and minimize redundancy in outcome data collection.

Under the PDUFA program, FDA agreed to pursue a comprehensive set of application review performance goals. In FY 2010, the Biologics Program exceeded PDUFA goals for standard (ten months) and priority (six months) BLA/NDAs and efficacy supplements by reviewing and acting upon 100 percent of applications within the target timeframe. In FY 2010, CBER also exceeded target for review and action on blood bank and source plasma BLA submissions within 12 months receipt by reviewing and acting on 100 percent of submissions and 100 percent of 293 supplements. Other accomplishments achieved during FY 2010 include the finalization of guidance to provide revised preventive measures to reduce the possible risk of transmission of Creutzfeldt-Jakob disease (CJD) and vCJD.

FDA works closely with Public Health Service (PHS) operating divisions and OASH on blood safety and availability issues. CBER participates on the HHS Advisory Committee on Blood Safety and Availability (ACBSA). In June 2010, the ACBSA met to discuss possible changes to FDA's policy on blood donor deferral for men who have sex with men. CBER is participating with other PHS operating divisions to evaluate modifications to current blood donor eligibility criteria. Related to these efforts, CBER held a workshop in September 2011 on "Quarantine Release Errors in Blood Establishments."

CBER is sponsoring an Interagency Agreement with the National Heart Lung and Blood Institute (NHLBI) for Behavioral Studies on the perceptions of men who have sex with men (MSM) about current blood donation deferrals. The study will focus on reasons for non-compliance with the current blood deferral policies among MSM as well as possible behavioral responses to future deferral modifications.

CBER participated in a multi-institutional study led by NIH to test panels of specimens obtained from individuals with Chronic Fatigue Syndrome and blood donors. The study showed that xenotropic murine leukemia virus-related virus (XMRV) could not be reproducibly detected in specimens by any of the laboratories that participated in a multi-lab effort to analyze these specimens using PCR, serology and culture assays.

These data supported a conclusion that blood donor screening for XMRV is unlikely to be necessary.

CBER conducts blood-related outreach at many levels to consumers and to regulated industry. In FY 2011, a consumer webinar was conducted on the "Safety of the Blood Supply." Webinars for industry have also included presentations on IND basics, and preparing for sponsor meetings with FDA.

Promoting Efficiency

To provide blood and plasma establishments with an easier means to submit license applications and supplements in electronic format, CBER developed and piloted a web-based interactive application template known as e-Submitter for Blood and Plasma applications. This program is currently available for use by licensed blood establishments that collect Whole Blood and Blood components, including Source Plasma.

CBER improved the efficiency of reporting information related to biological product recalls by developing the Direct Recall Classification (DRC) program. This program provides blood and plasma establishments the opportunity to electronically report recall related information directly to CBER. The standardized reporting established for the submission of electronic Biological Product Deviation Reports (eBPDRs) has been expanded to collect additional information necessary for recall classification purposes. The DRC program allows CBER to work directly with recalling firms in the submission of information necessary to classify the recall without expenditure of resources from FDA District Offices.

Blood and Blood Products Premarket Review and Postmarket Safety – Field Activities

FY 2012 Enacted Amount: $27,452,000 (BA: $25,374,000 / UF: $2,078,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness blood and blood products, for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries and helps to defend the public against the threats of emerging infectious diseases and bioterrorism. ORA accomplishes this public health mission by conducting inspections both domestically and in foreign countries and by performing entry review and import field exams on imported products.

Public Health Outcome

Inspections are conducted at manufacturing facilities, clinical study sites including clinical investigators and institutional review boards, blood establishments, donor centers, and laboratories that perform testing on blood products and donors, and perform quality control testing for licensed blood establishments. These inspections are conducted prior to products being approved or licensed for use (premarket) and in the

postmarket arena after approval or licensing. Inspections are conducted in part to assure:

- rights of human subjects participating in clinical trials are protected through proper oversight.
- data submitted to FDA and used in support of applications are valid and reliable.
- blood and blood products are safe, effective, and adequately labeled as required by law and to determine the level of compliance and adherence with applicable Federal regulations.
- laboratories are competent and adhere to applicable regulations.

In FY 2011, ORA exceeded its goal of inspecting 1,000 of the highest risk registered blood bank and biological product manufacturers, conducting 1,112. ORA's Team Biologics completed its annual workplan, which includes manufacturers of plasma derivative biological drug products. Inspections of blood banks and plasma centers are conducted to ensure the safety of the nation's blood supply. Blood and blood products collected from high risk donors or not processed in accordance with current good manufacturing practice requirements could pose a significant threat to human health. Biological drug products are produced from blood and blood products, and other biological sources, to produce important drug products for treating many diseases. These products are on the forefront of new treatment therapies available to patients where no therapies may have existed previously.

Promoting Efficiency

In collaboration with CBER, ORA has provided basic and advanced training to all investigators conducting inspections in this program area. This training resulted in a cadre of investigators who consistently use the same approach to conduct inspections, communicate regulatory requirements and document violations, providing efficient uniform inspectional findings and guidance to industry. This consistency leads to greater program efficiency within this program.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)*	FY 2010: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2011: 1,112 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain

Information Technology Investments – Biologics Program Activities
(FY 2012 Enacted Amount displayed as a non-add item: $45,671,038)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities. This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In addition to the IT infrastructure, FDA-wide enterprise investments and the existing center-specific IT systems, additional automation of the Managed Review Process is planned. To support the continued move toward automation, CBER plans to implement the Health Level Seven, Regulated Product Submissions (RPS) message format. The RPS standard will support the PDUFA IT goal in two-ways. First, CBER will enhance the Electronic Technical Document and Electronic Document Room systems to include support for automatic receipt and processing of RPS messages. Second, CBER will enhance the capabilities of the Safety Reporting systems and consolidate safety reporting databases. The consolidation will enable a greater level of reporting and signal detection across product areas. These enhancements will increase CBER reviewer access to large datasets which will enhance their ability to analyze and monitor the

safety of biological products such as vaccines, which is crucial in the case of emerging infectious disease or possible pandemics.

Five-Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$233,508,000	$154,831,000	$78,677,000	1,066
FY 2009 Actual	$287,427,000	$194,534,000	$92,893,000	1,186
FY 2010 Actual	$291,430,000	$205,542,000	$85,888,000	1,250
FY 2011 Actual	$302,020,000	$211,790,000	$90,230,000	1,296
FY 2012 Enacted	$329,136,000	$212,224,000	$116,912,000	1,294

Summary of the Budget Request

The FY 2013 budget request for the Biologics Program is $332,756,000. This amount is an increase of $3,620,000 above the FY 2012 Enacted Level. The CBER amount in this request is $287,333,000, supporting 1,075 FTE. The Field amount is $45,422,000, supporting 242 FTE.

The FY 2012 Enacted funding for the Biologics program is $329,136,000, which includes $283,904,000 for CBER activities and $45,232,000 for the Biologics Field activities.

The Biologics Program is committed to advancing public health through innovative regulation that promotes the safety, effectiveness, and timely delivery of biological products to patients. With the FY 2012 Enacted funding, CBER will facilitate 1) the safety of the nation's blood supply and the products derived from blood, 2) the production and approval of safe and effective adult and childhood vaccines, and 3) the oversight of human tissues for transplantation, safe and effective gene therapies, and an adequate and safe supply of allergenic materials and anti-toxins. Field Biologics supports CBER's efforts to advance public health by conducting inspections, both domestically and abroad, and by performing entry review and import field exams of imported products.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to protect patients and advancing FDA's medical countermeasure initiative.

Budget Request

Pay Increase (Total Program: Commissioned Corps +$149,000)

The request for $209,827,000 in total budget authority for the Biologics Program reflects a pay increase for the Commissioned Corps. The Center's portion of this increase is +$120,000 and the Field's portion is +$28,000.

Data Consolidation and IT Savings (Total Program: -$1,875,000)

The budget request for $209,827,000 in total budget authority for the Biologics Program also reflects a data consolidation and IT savings reduction -$1,875,000 for FY 2013. The Center's portion of these savings is -$1,517,000 and the Field's portion is -$358,000.

The Biologics Program will achieve the savings by

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- Reducing expenditures by moving to a centralized data management model.
- Streamlining IT implementation of similar business processes and expediting the retirement of legacy systems.

The Office of Regulatory Affairs (ORA) will achieve savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.

- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.

- Streamlining user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance Services (MARCS) program, and providing the support architecture for other integrated systems.

- Economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems.

Rent Absorption (Total Program: -$923,000 / - 4 FTE)

The request for $209,827,000 in total budget authority for the Biologics Program also reflects rent absorptions of -$923,000 and -4 FTE for FY 2013. The Center's portion of these absorptions is -$685,000 and -4 FTE and the Field's portion is -$238,000.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

Vaccines Premarket Review and Postmarket Safety

Center Activities – (FY 2012 Enacted Amount: $135,148,740 (BA: $75,552,840 / UF: $59,595,900)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,541,170 / 8 FTE)
FY 2013 Increase for PDUFA: (+$1,270,270 / 7 FTE)

Protecting Patients Initiative: Biosimilars User Fee (+$270,900 / 1 FTE)

With the resources in this FY 2013 budget initiative, FDA will continue ongoing activities and begin additional activities to operate the 351(k) review program for approving biosimilars. FDA will also conduct the research required to develop biosimilar reference standards to assure the manufacturing quality of biosimilars.

CBER will review submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and INDs. FDA will develop regulations and guidance documents to facilitate the development of biosimilars.

Field Activities – (FY 2012 Enacted Amount: $5,842,000 (BA: $4,383,000 / UF: $1,459,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$92,000 / 0 FTE)
FY 2013 Increase for PDUFA: (+$31,000 / 0 FTE)
FY 2013 Increase for Proposed User Fees (Reinspection): (+$61,000 / 0 FTE)

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety

Center Activities – (FY 2012 Enacted Amount: $ 53,837,190 (BA: $32,625,090 / UF: $21,212,100)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$568,230 / 3 FTE)
FY 2013 Increase for PDUFA: (+$452,130 / 3 FTE)

Protecting Patients Initiative: Biosimilars User Fee (+$116,100 / 0 FTE)

With the resources in this FY 2013 budget initiative, FDA will continue ongoing activities and begin additional activities to operate the 351(k) review program for approving biosimilars. FDA will also conduct the research required to develop biosimilar reference standards to assure the manufacturing quality of biosimilars.

CBER will review submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and INDs. FDA will develop regulations and guidance documents to facilitate the development of biosimilars.

Field Activities – (FY 2012 Enacted Amount: $11,938,000 (BA: $10,756,000 / UF: $1,182,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$165,000 / 1 FTE)
FY 2013 Increase for PDUFA: (+$26,000 /0 FTE)
FY 2013 Increase for Proposed User Fees (Reinspection): (+$139,000 / 1 FTE)

Blood and Blood Products Premarket Review and Postmarket Safety

Center Activities – (FY 2012 Enacted Amount: $ 94,918,070 (BA: $63,533,070 / UF: $31,385,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$3,401,600 / 13 FTE)
FY 2013 Increase for PDUFA: (+$430,600 / 2 FTE)
FY 2013 Increase for MDUFA: (+$2,332,000 / 8 FTE)

Advancing Medical Countermeasures: (+$252,000 / 1 FTE)

FDA will continue to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. Specifically, FDA will continue to develop and qualify tools to assess efficacy such as animal models and developing methods to assess product quality and assays to support the release of Medical Countermeasures.

Protecting Patients Initiative: Biosimilars User Fee (+$387,000 / 2 FTE)

With the resources in this FY 2013 budget initiative, FDA will continue ongoing activities and begin additional activities to operate the 351(k) review program for approving biosimilars. FDA will also conduct the research required to develop biosimilar reference standards to assure the manufacturing quality of biosimilars.

CBER will review submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements. This would include activities related to biosimilar biological product development meetings and INDs FDA will develop regulations and guidance documents to facilitate the development of biosimilars.

Field Activities – (FY 2012 Enacted Amount: $27,452,000 (BA: $25,374,000 / UF: $2,078,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$501,000 / 2 FTE)
FY 2013 Increase for PDUFA: (+$33,000 / 0 FTE)
FY 2013 Increase for MDUFMA: (+$107,000 / 0 FTE)
FY 2013 Increase for Proposed User Fees (Reinspection): (+$361,000 / 2 FTE)

BIOLOGICS PROGRAM ACTIVITY DATA

Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
NDA/BLA Submissions			
Applications received Standard: Priority:	 14 0	 13 1	 13 1
Applications completed [1/] Standard: Priority:	 13 0	 14 1	 14 1
Applications approved [2/] Standard: Priority:	 8 2	 10 3	 10 3
Applications pending [3/] Standard: Priority:	 29 3	 31 4	 31 4
Efficacy Supplements			
Applications received Standard: Priority:	 23 0	 25 1	 25 1
Applications completed [1/] Standard: Priority:	 9 0	 9 3	 9 3
Application approved [2/] Standard: Priority:	 22 1	 16 1	 16 1
Applications pending [3/] Standard: Priority:	 28 0	 31 1	 31 1
Original Manufacturing Supplement			
Applications received	1,249	1,354	1,354
Applications completed [1/]	332	360	360
Applications approved [2/]	1,059	1,147	1,147
Applications pending [3/]	853	924	924

Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
Device Premarket Applications - PMAs			
Applications received Supplements received	2 40	1 43	1 43
Applications completed [1/] Supplements completed [1/]	2 10	2 11	2 11
Applications approved [2/] Supplements approved [2/]	2 33	1 35	1 35
Applications pending [3/] Supplements pending [3/]	1 13	2 14	2 14
Device 510(k)s			
Applications received	44	48	48
Applications completed [1/]	65	67	67
Applications approved [2/]	21	23	23
Applications pending [3/]	31	33	33
Investigational Applications			
Commercial IND/IDE Receipts [4/]	130	141	141
IND/IDE Amendment Receipts [4/]	10,172	11,020	11,020
Active INDs/IDEs [4/]	2,535	2,746	2,746
Other Activities			
Patient Safety			
Adverse Event Report Received [5/]	39,032	40,000	40,000
Biological Product Deviation Report Received	51,993	52,000	52,000
Sponsor Assistance/Outreach			
Meetings	394	427	427
Final Guidance Documents [6/]	15	19	19
Admin/Management Support			
Advisory Committee meetings held	21	19	19
FOI requests processed	354	380	380

1/ Complete action letter was sent to sponsor. Includes withdrawn, denied, NSE, and exempts.

2/ Includes all applications approved during the fiscal year, regardless of year of receipt.

3/ Includes applications for which complete action has not been achieved at the end of the fiscal year. It does not mean the application is overdue.

4/ Includes IND, IDE, Master File and license master file receipts.

5/ Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports or Medical Device Reports for CBER-regulated medical devices.

6/ Includes all FDA final guidances issued by CBER and other FDA centers that pertain to biological products.

Combined Field Activities – ORA
Program Activity Data

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2011 Actual	FY 2012 Actual	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,012***	***2,045***	***2,112***
Bioresearch Monitoring Program Inspections	98	151	151
Blood Bank Inspections	1,087	1,080	1,080
Source Plasma Inspections	190	196	196
Pre-License, Pre-Market Inspections	11	7	7
GMP Inspections	40	28	28
GMP (Device) Inspections	4	7	7
Human Tissue Inspections	606	600	668 [1]
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***58***	***55***	***55***
Bioresearch Monitoring Program Inspections	15	15	15
Foreign Human Tissue Inspections	0	0	0
Blood Bank Inspections	8	7	7
Pre-License Inspections	5	6	6
GMP Inspections	30	27	27
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***2,070***	***2,100***	***2,167***
IMPORTS			
Import Field Exams/Tests	84	84	84
Import Line Decisions	53,731	56,270	58,928
Percent of Import Lines Physically Examined	0.16%	0.15%	0.14%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,070***	***2,100***	***2,167***

[1] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013 for domestic human tissue inspections. During the full performance year (FY 2013), the FY 2011 BA enacted funding increases for inspections will allow ORA to conduct an additional 68 domestic human tissue inspections.

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

ANIMAL DRUGS AND FEEDS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$161,451**	**$158,771**	**$166,365**	**$183,899**	**$17,534**
Center	$107,244	$104,817	$109,379	$123,352	$13,973
FTE	461	510	508	519	11
Field	$54,207	$53,954	$56,986	$60,547	$3,561
FTE	281	296	313	324	11
Program Level FTE	**742**	**806**	**821**	**843**	**22**
Budget Authority	**$139,178**	**$139,025**	**$138,021**	**$136,175**	**($1,846)**
Center	$85,403	$85,499	$84,699	$83,582	($1,117)
Field	$53,775	$53,526	$53,322	$52,593	($729)
Budget Authority FTE	**654**	**713**	**710**	**710**	**0**
Center	375	420	420	420	0
Field	279	293	290	290	0
User Fees	**$22,273**	**$19,746**	**$28,344**	**$47,724**	**$19,380**
Center ADUFA	**$17,209**	**$14,992**	**$19,261**	**$26,996**	**$7,735**
FTE	66	67	66	66	0
Field ADUFA	**$281**	**$277**	**$315**	**$464**	**$149**
FTE	1	2	2	2	0
Center AGDUFA	**$4,632**	**$4,326**	**$4,898**	**$6,527**	**$1,629**
FTE	20	23	20	20	0
Field AGDUFA	**$151**	**$151**	**$160**	**$211**	**$51**
FTE	1	1	1	1	0
Field Food Reinspection			**$2,550**	**$2,666**	**$116**
FTE			18	18	0
Recall User Fee			**1,160**	**1,213**	**53**
Center			521	545	24
FTE			2	2	0
Field			639	668	29
FTE			2	2	0
Field Medical Products Reinspection [1]			**0**	**140**	**140**
FTE			0	1	1
Food Establishment Registration Fee [1]			**$0**	**$9,507**	**$9,507**
Center				$5,702	$5,702
FTE				11	11
Field				$3,805	$3,805
FTE				10	10
User Fees FTE	**88**	**93**	**111**	**133**	**22**

[1] Proposed User fee; the amount includes associated rent activity

FDA Animal Drugs and Feeds Program operate under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act (1944) (42 U.S.C. 264, 271)
Animal Drug Amendments (1968) (21 U.S.C. 360b)
Generic Animal Drug and Patent Term Restoration Act (1988)*
Animal Medicinal Drug Use Clarification Act of 1994*

Animal Drug Availability Act of 1996*
Food and Drug Administration Modernization Act of 1997*
Public Health Security and Bioterrorism Preparedness Response Act of 2002*
Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12)
Minor Use and Minor Species Animal Health Act of 2004*
Food and Drug Administration Amendments Act of 2007 (FDAAA)*
Animal Drug User Fee Amendments of 2008 (P.L. 110-316)
Animal Generic Drug User Fee Act of 2008 (P.L. 110-316)
FDA Food Safety Modernization Act (P.L. 111-353)
Protecting Patients and Affordable Care Act of 2010*

Allocation Method: Direct Federal/intramural; Contract; Competitive grant

Program Description and Accomplishments

The Center for Veterinary Medicine (CVM) is a consumer protection organization that fosters public and animal health by approving safe and effective products for animals and enforcing applicable provisions of the Federal Food, Drug and Cosmetic (FD&C) Act and other authorities. CVM is responsible for regulating drugs, devices and food additives used in animals — approximately 9.2 billion chickens and turkeys, 159 million cattle and pigs, 8.7 million sheep and goats, 78 million dogs, 86 million cats, 7 million horses and minor animal species that include all animals other than cattle, swine, chickens, turkeys, horses, dogs and cats.

The Animal Drugs and Feeds Program is responsible for ensuring that animal drugs and feeds used for food-producing animals do not result in unsafe residues in the food supply and that food from treated animals is safe. FDA accomplishes this through a comprehensive, science-based, prevention-oriented approach to safeguard the American food supply. This approach focuses on the most important food safety issues in the life cycle of foods – from farm-to-table – and is structured to implement the requirements of the FDA Food Safety Modernization Act of 2011 (FSMA) signed into law in December 2010. FSMA requires FDA to establish science-based standards and gives FDA the power to focus on prevention and enforcement. With FDA's food and feed safety and nutrition and animal health activities becoming more challenging each year, the 2012-2016 Food and Veterinary Medicine (FVM) Program Strategic Plan was published for comment, charting the direction for the future of FSMA.

The Animal Drugs and Feeds Program also protects the health of companion animals and addresses zoonotic diseases — animal diseases that can be transmitted to humans. The Program is able to accomplish its responsibilities through premarket review of animal drug submissions, surveillance and compliance activities to prevent marketing of unsafe products, enforcement actions against unsafe products and scientific research to support these pre- and post-market activities.

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The FD&C Act gives FDA the authority to regulate animal drugs and medicated feeds. In 1968, the act was amended by Congress to include new authorities for animal drugs. The Animal Drugs and Feeds Program is funded through appropriations and user fees. In FY 2003, the Animal Drug User Fee Act (ADUFA) was enacted for five years (FY 2004 – FY 2008) and reauthorized in FY 2008 as the Animal Drug User Fee Amendments of 2008 for an additional five years (FY 2009 - FY 2013). In addition, the Animal Generic Drug User Fee Act (AGDUFA) was enacted for five years (FY 2009 – FY 2013). The new Minor Use and Minor Species Grant Program initiated in FY 2009 provides CVM funding for grants for the development of new animal drugs intended for minor species or minor uses in major species. This funding reduces the costs of qualified safety and effectiveness testing expenses incurred in connection with the development of designated new animal drugs.

CVM conducts the activities of the Animal Drugs and Feeds program with assistance from the Office of Regulatory Affairs (ORA). ORA supports the Animal Drugs and Feeds Program activities by assessing industry compliance with the applicable regulations to protect the public health. ORA achieves this assessment by conducting pre- and post-market risk-based inspections of domestic and foreign establishments to determine the safety of manufactured products. ORA monitors and samples imports to ensure the:

- safety of the animal drug supply
- safety and food defense related security of the feeds supply
- compliance with recalls of violative products.

In instances of criminal activity, ORA's Office of Criminal Investigations complements the enforcement activities of the regular Field force. The Field Animal Drugs and Feeds Program is funded by appropriated dollars and user fee revenues from ADUFA, AGDUFA, Reinspection and Recall user fees.

The Animal Drugs and Feeds Program carries out its public health responsibilities in two major areas: food safety and medical product safety.

Food safety focuses on four strategic areas to ensure the pre- and post- market safety of the human and animal food supply:

- prioritizing prevention
- strengthening surveillance
- strengthening enforcement
- improving response and recovery.

Medical product safety focuses on pre- and post-market safety and compliance for companion and exotic animals that can transmit disease to humans.

Prioritizing Prevention - Center Activities
FY 2012 Enacted Amount: $39,659,000 (BA: $25,164,000 / UF: $14,495,000)

Public Health Focus

Prevention is the cornerstone of an effective and proactive food safety strategy. FDA is able to protect consumers and animal populations with the use of scientific and analytical tools to better identify food safety risks, effective control measures and food safety standards.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks that FDA articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf.

In the case of Prioritizing Prevention, CVM contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than reacting to problems after they occur. CVM is implementing the provisions of FSMA through the development of regulations, standards and guidance documents. These activities are documented in the draft FDA FVM Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, identifies the most significant food-borne contaminants and evaluates the effectiveness of existing controls for those contaminants.

Public Health Outcome

CVM reviews animal drug applications, establishes standards for feed contaminants, approves safe food additives and directs FDA's medicated feed and pet food programs. CVM works with all stakeholders to promote responsibility through the identification, development and implementation of new regulations to further support the production of safe feed for all animals.

Currently, FDA has regulations governing the controls for manufacturing, processing, packing and holding of drug premixes and medicated feeds. However, a broader regulatory approach is required that addresses animal food safety issues associated with the manufacturing, processing, packing and holding of animal food, including pet food, animal feed, raw materials and ingredients. FSMA modified the FD&C Act to provide FDA with the authority to develop regulations for a risk-based, preventive controls food safety system. The regulations are intended to prevent animal food containing hazards, which may cause illness or injury to animals or humans, from entering the food supply. CVM is working to have final animal food preventive control regulations in place by the end of September 2012. These regulations will require

written food safety plans for facilities that are required to register with FDA under the FD&C Act. FDA published a notice in the Federal Register (FR) in May 2011 seeking public comment on preventive control measures in order to help develop guidance for food facilities.

In March 2011, FDA published draft guidance for industry entitled ‘‘Testing for *Salmonella* Species in Human Foods and Direct-Human-Contact Animal Foods.’’ The draft guidance is intended for firms that manufacture, process, pack or hold human foods or direct-human-contact animal foods (e.g., pet food or animal feeds) intended for distribution to consumers, institutions or food processors. The draft guidance addresses testing procedures for *Salmonella* species (spp.) in human foods (except shell eggs), direct human-contact animal foods and the interpretation of test results when the presence of *Salmonella* spp. may render the food harmful to human health.

CVM has developed a comprehensive system for regulating animal feed in the interest of protecting animal and human health. Most recently, this regulation has been accomplished within the context of the Animal Feed Safety System (AFSS) that covers regulation of the labeling, producing and distributing of all feed ingredients and mixed feeds at all stages of manufacture, distribution and use. An integral part of a safe animal feed system effort is the development of a relative-risk ranking model for potentially toxic or deleterious biological, chemical and physical hazards. However, planning for future execution of CVM’s regulation of pet food and animal feed safety is being influenced greatly by the implementation of FSMA. AFSS is a comprehensive, risk-based, preventive system that minimizes or eliminates the risks to animal and human health that can come from animal feed

CVM reviews new and generic animal drug applications for the effect on the targeted animal users and human users who may consume food produced from the animal. CVM works to minimize delays in bringing animal drugs to market, including products developed using new technologies such as biotechnology — genetically engineered animals and cloning. Bringing animal drugs to the market quickly helps to ensure the public has access to safe and effective drugs on a timely basis. This access protects public health by reducing the use of unapproved animal drugs, including illegally compounded animal drugs and improperly labeled drugs used to treat animal diseases and for growth promotion.

In July 2011, FDA made available a Public Master File containing safety and effectiveness data to support a new animal drug application (NADA), or supplemental NADA for use of lincomycin hydrochloride water soluble powder, for the control of American foulbrood in honey bees. Foulbrood is caused by spore-forming *Paenibacillus larvae ssp. larve.* The data may be used by pharmaceutical sponsors at no cost to support the approval of this product. Sponsors need to supply the additional manufacturing, labeling and other required information to constitute a complete NADA.

In December 2010, FDA began a new initiative to address unapproved animal drugs by publishing a notice in the Federal Register (FR) requesting comments from the public

on ways to increase the availability of legally marketed animal drugs. FDA expects drug companies to legally market animal drugs, in compliance with the requirements of the FD&C Act. However, FDA is open to using both existing authority and new approaches to make more drugs legally available to veterinarians, animal producers and pet owners. CVM received approximately 300 comments to the FR notice from a wide range of stakeholders including veterinarians, pet owners, pharmacists, industry representatives and professional organizations. In addition to the FR notice, FDA launched the Unapproved Animal Drugs Web page which explains what illegally marketed unapproved animal drugs are and why FDA is concerned about these drugs.

CVM faces a revolution at the intersection of agriculture, biomedical sciences and other cross-disciplinary public health initiatives that challenge our current veterinary, biomedical and food safety capacities. The revolution centers on biotechnology — genetically engineered (GE) animals that provide the potential for new or improved versions of human and animal drugs to treat human and animal diseases. In FY 2011, the Center's Animal Biotechnology Interdisciplinary Group (ABIG) became a permanent program, having been initiated in 2010 as a pilot project to address the new and challenging set of regulatory issues posed by animal biotechnology including GE animals. The ABIG program follows GE animals over the lifecycle of the product and leverages expertise from across the Center in a matrix-managed environment to ensure the entire life cycle is covered, from early research to post-market surveillance. ABIG has spent much of FY 2011 working on adapting and developing regulatory documents to address the specific needs of products of animal biotechnology. In addition, ABIG continued to develop and refine its review process and worked in concert with the Office of Research (OR) and sponsors to validate regulatory analytical methods that can be used to identify the GE animal or its edible products. ABIG members were invited to speak, attend or lead discussions at almost 30 scientific conferences, inter-agency meetings or international meetings on various scientific and regulatory topics during the fiscal year. ABIG members have also been very active in international outreach activities

In an effort to improve the public awareness of animal and human health issues, CVM continues to enhance the Animal Health Literacy Campaign. The campaign is geared towards using social media, such as a Pet Health and Safety Widget for websites and an Animal Health Twitter account, to connect with consumers, veterinarians and industry to facilitate the sharing of important animal health and safety tips, public health updates and product recalls. Information is also disseminated to consumers through a variety of methods such as articles, brochures and posters. CVM also publishes a free online newsletter every four months dedicated to promoting human and animal health.

Promoting Efficiency

CVM continues to exceed all user fee performance goals under ADUFA. Sustaining this performance protects the American public as they consume products from food-producing animals and gives manufacturers a reliable review process and timeline for animal drug applications. It also accelerates the recovery of companies' investments in

new products, thereby encouraging companies to invest in innovation. The following enhancements to the review process are efficiencies that CVM will sustain.

- In March 2011, CVM released an electronic submission tool, eSubmitter, for use in submitting Investigational New Animal Drug (INAD) file submissions and NADA submissions. Electronic submissions eliminate the need for paper, reduce printing and mailing costs for industry and allow CVM scientists to review the submissions electronically. eSubmitter provides a structured online system allowing for a more efficient and effective drug approval process than with paper submissions. The development and release of eSubmitter meets ADUFA II goals for creating a tool for INAD and NADA electronic submissions. CVM expanded the development of the tool to include all submission types.

- A process to improve the timeliness, scheduling and predictability of foreign preapproval inspections. This improvement supports the timely approval of animal drug applications submitted by manufacturers**.** FDA completed 19 foreign inspections in FY 2010, with an average time of 106 days to complete the inspections. FDA also completed 19 foreign inspections in FY 2011, with an average time of 142 days to complete the inspections.
- A process to address End-Review Amendments (ERA). This process allows CVM to reduce the number of review cycles which reduces the time to market for approved products. CVM used the ERA process to request additional information on 167 submissions associated with the FY 2010 and FY 2011 cohort. Virtually all (166 of 167) of the requests were related to INAD submissions. In response, ERAs were submitted to 96 percent (160 of 167) of the requests, and 91 percent (146 of 160) of the submissions with ERAs had their reviews end with a favorable outcome in only one review cycle.

CVM implemented the first generic animal drug user fee program and achieved performance goals for review of generic animal drugs. CVM reengineered its business process for the review of generic animal drugs and eliminated a backlog of more than 150 generic new animal drug submissions. This process improvement continues to support the review of current generic animal drug applications bringing safe and effective products to the market more quickly and more efficiently.

Prioritizing Prevention - Field Activities
FY 2012 Enacted Amount: $12,288,000 (All BA)

Public Health Focus

ORA focuses on prevention through outreach coordination and technical assistance to advance public health and protect consumers, Internal and external training remains a top priority of the Field to gain expertise and encourage collaboration with external stakeholders.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks that FDA articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link:

In the case of Prioritizing Prevention, ORA contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than reacting to problems after they occur. Implementing the provisions of FSMA is done through the development of regulations, standards and guidance documents. These activities are reflected within the draft FDA Foods and Veterinary Medicine (FVM) Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant food-borne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

ORA views state-based grant programs such as the Small Scientific Conference (SSC) and Food Protection Task Force grants (FPTF) as important mechanisms for providing feed safety and feed defense program coordination. SSC and FPTP grants support an enhanced focus on topics of intervention and prevention by reviewing feed supply vulnerabilities, performing risk-based inspections, sampling, and surveillance as a means of enhancing an integrated feed safety system.

ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advance FDA policies and initiatives to internal and external stakeholders. In FY 2011, ORA outreach efforts included participation at a variety of public meetings, symposiums, webinars and conferences attended by regulated industry, other government agencies and foreign regulatory bodies.

In FY 2011, ORA awarded contracts to states under the Feed Safety BSE Contract program. These contracts aid FDA in establishing an expanded level of inspection coverage, surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those facilities subject to the BSE rule.

ORA's focus on prevention includes non-research international harmonization activities. ORA's work with FDA's Office of International Programs (OIP) Global Offices in China, India and Latin America enables cooperation between FDA and its counterpart regulatory authorities. This cooperation improves the safety and quality of animal feed and other FDA regulated products exported to the United States and enhances the level of feed safety and public health protection provided to consumers in the United States.

Working in collaboration with CVM/Office of Research, ORA's Denver Laboratory and the Animal Drugs Research Center (ADRC) developed, validated, implemented and published a total of twelve analytical methods. Several multiclass screening methods were developed for drug residues in food products such as milk, shrimp, finfish, and frog legs. In addition, a study in the bioaccumulation of cyanuric acid in the edible tissue of shrimp was completed.

FDA developed and is currently implementing a new strategy, in collaboration with the CBP and Immigration and Customs Enforcement (ICE), to better prevent the entry of smuggled food/feed into the U.S., fulfilling the requirement of FSMA Section 309(a). FDA is working closely with Customs and Border Protection (CBP) to target and examine import shipments that could conceal undeclared foods/feeds, focusing on high risk parties and imported foods/feeds that pose a significant public health risk.

The enactment of FSMA in FY 2011 shifts the regulatory paradigm from response to prevention. During FY 2011, ORA awarded seven grants to enhance the agility and capacity of the organization to design, develop and deliver food safety training and personnel certification programs by leveraging the collaborative efforts and expertise of prestigious academic institutions, professional trade associations and non-profit organizations. By working with federal, state, territorial and local regulatory and public health partners, FDA aims to establish a fully integrated food safety system (IFSS) that will place priority on preventing foodborne illness, in both food for humans and animals, through the adoption and uniform application of model programs, such as Manufactured Food and Retail Food Regulatory Program Standards and other appropriate program standards.

Promoting Efficiency

The use of grant and contract programs allows ORA to increase its focus on prevention. Grants such as the SSC and FPTF enhance evaluation of feed supply vulnerabilities, risk-based inspections, sampling and surveillance bolster an integrated feed safety system and U.S. feed defense efforts. These efforts aid in the support of more efficient manufacturing and product development.

ORA was recently accepted into the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The PIC/S will make more efficient use of inspection resources through the sharing of Good Manufacturing Practices (GMP) inspection reports with the 37 participating global authorities. It will also develop and promote harmonized GMP standards and guidance documents and training of competent authorities.

ORA's outreach events provide FDA with the opportunity to ensure transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. ORA is able to identify areas where regulated industry can work as partners to more efficiently protect the public health and serve to address safety issues related to products on the market and in development. These efforts also

create a sense of ownership of the important role the import trade community and regulated industry play in ensuring safe and secure products for U.S consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2010: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	0%
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	NA	90% w/in 380 days	90% w/in 270 days	-110 days

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities
FY 2012 Enacted Amount: $14,303,000 (All BA)

Public Health Focus

New animal drug products are carefully tested before they are marketed. However, wider use of the drug products may result in the discovery of problems not evident during pre-marketing research and review. Therefore, the assessment of the safety of a new animal drug is a continuing process that takes place throughout the development and marketing of a drug. Animal drugs are used to treat and prevent illnesses in food producing animals. As a result, post-marketing surveillance is critical to ensure the safety of our food supply. If public health warrants, FDA may recommend withdrawal of an approved drug if it is found to be unsafe or ineffective.

FDA Food Safety Strategy

In the case of Strengthening Surveillance, CVM contributes to achieving the overall FDA strategy by implementing the development of risk-based systems**.** This includes establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting and developing a model for evidence-based resource planning. In addition, these activities are reflected in the FVM goals of

strengthening scientific leadership, capacity and partnership to support public health and animal health decision making. These goals include maintaining and strengthening mission-critical science capabilities, improving centralized planning, performance measurement and improving information sharing internally and externally including effective communication of research plans and knowledge gaps. These goals help evaluate risk, surveillance of effectiveness of the food and feed safety system and regulatory science to inform risk evaluation and standard setting activities across the farm-to-table continuum.

Public Health Outcome

FDA reviews and analyzes information from adverse experience reporting to protect consumers and animals and ensure the safety of products throughout their life cycle. CVM, in cooperation with FDA Field Offices, monitors the safety and effectiveness of approved drugs, feeds, food additives and veterinary devices to protect public and animal health after they enter the market. In addition, CVM works with the U.S. Department of Agriculture (USDA) and state agencies to monitor drug residues in meat, dairy and poultry products and to conduct educational and enforcement activities. CVM also conducts surveillance to protect animal feed from contamination by mycotoxins, pesticides, heavy metals, industrial chemicals and other toxic materials.

CVM utilizes the existing Pet Food Early Warning Surveillance System as a mechanism for detecting issues with animal feeds, including pet foods. With this system, CVM can quickly and effectively identify animal food product problems and outbreaks of illness and provide notice to veterinarians and stakeholders during recalls. The early warning surveillance system continues to be refined and is used in addition to the Rational Questionnaire launched in 2010 for pet food that is a component of FDA's Safety Reporting Portal. As a component of the early warning surveillance system, the Partnership for Food Protection and CVM launched the Pet Event Tracking Network (PETNet) in August 2011. The PETNet is a voluntary, secure, web based information exchange, surveillance and alert system that allow Federal and State Agencies to share information about emerging pet-food related incidents, such as illness associated with the consumption of pet food or pet food product defects. PETNet is currently made up of over 200 representatives from four Federal agencies, all 50 states, Puerto Rico and the District of Columbia.

Basic and applied research is being conducted using animals and animal systems that focus on veterinary compounds as well as veterinary pathogens that pose potential health risks to both animal health and human food safety. In response to increase regulatory surveillance needs from a growing U.S. aquaculture industry, CVM scientists conduct research designed to assist the FDA in assuring that fish derived from aquaculture production environments (domestic and international) are safe for human consumption. Approximately 80 percent of U.S. seafood is being imported, approximately half of which is aquaculture. CVM is developing analytical methods to detect antibiotic resistant aquatic bacteria as well as to detect drug residues. Research also explores the effectiveness of drugs on fish disease pathogens and how fish

distribute, metabolize and eliminate drugs and other chemicals, including feed contaminants, using aquaculture.

CVM protects public health by monitoring antimicrobial drugs used in food-producing animals to identify the development of resistance among bacterial foodborne pathogens. CVM, in collaboration with the Centers for Disease Control (CDC) and USDA, leads the National Antimicrobial Resistance Monitoring System program (NARMS). NARMS monitors changes in susceptibility or resistance of select zoonotic bacterial organisms recovered from animals, humans and retail meats. NARMS helps provide important information on antimicrobial resistance in humans due to consuming food producing animals that are given antimicrobial drugs. CVM is expanding NARMS to develop a database to provide data analysis and reporting tools needed for animal drug application reviewers. The database will enable similar research analytics to be conducted by the scientists at CDC and USDA, using a secure website hosted on FDA's Extranet, as well as automated flagging of resistance patterns among animal, human and retail meat isolates.

In May and September 2011, the NARMS 2008 and 2009 Executive Reports were published which summarize data on non-typhoidal *Salmonella* and Campylobacter isolates recovered in 2008/2009 from food animals at federally inspected plants, retail meats and humans. The report also includes susceptibility data on *Escherichia coli* isolates recovered from retail meats and chicken. Summary data from prior years are also included. In addition, the 2009 NARMS Retail Meat Report was published in FY 2011 providing a comprehensive analysis of antimicrobial-resistant bacteria from ground beef, ground turkey, chicken breast and pork chops collected in 10 states throughout the year. In January 2011, CVM announced the availability of the NARMS five-year strategic plan (2011-2015), a dynamic roadmap which outlines the program's commitment to sustained food safety through monitoring and research. Public comments were requested and received.

In FY 2011, CVM provided funding to USDA to conduct on-farm pilot studies to measure antimicrobial resistance in foodborne bacteria and collect antimicrobial use information on sampled animals. In addition, CVM provided funding to CDC to develop tools that will enable linkage of outbreak strains and antimicrobial resistance information with the PulseNet database. CVM lead epidemiological investigations, conducted detailed statistical and trend analysis developed and implemented new software tools, for data analysis and sharing, and generated reports for stakeholders and Agency officials.

In June 2010, CVM published draft guidance on the judicious use of medically important antimicrobials in food-producing animals. The draft guidance provides information reducing the development of resistance to medically-important antimicrobial drugs used in food-producing animals. CVM has completed the review and analysis of the public comments received and is continuing a dialogue with all interested stakeholders to discuss recommendations. This input will support the CVM's effort to develop practical strategies to assure that public health is protected and the health needs of animals are addressed.

In December 2010 and October 2011, as mandated by ADUFA II, CVM published its second annual report summarizing sales and distribution data for 2009 and 2010 of antimicrobial drugs approved for food-producing animals. The collection of data on antimicrobial drugs assists FDA's evaluation of antimicrobial resistance trends as well as its analysis of other issues that may arise relating to the safety and effectiveness of antimicrobial drugs approved for use in food-producing animals.

FDA, along with the National Institutes of Health (NIH) and the CDC, co-chairs the Interagency Task Force on Antimicrobial Resistance. In March 2011, a draft revised Public Health Action Plan (PHAP) to Combat Antimicrobial Resistance was published for public comment. This plan revised the 2001 version of PHAP to identify actions needed to address the emerging threat of antibiotic resistance and highlight the need to improve federal agencies' ongoing monitoring of antibiotic use and of antibiotic-resistant infections.

CVM is working closely with the World Health Organization (WHO) Advisory Group for Integrated Surveillance of Antimicrobial Resistance and the WHO Global Foodborne Infections Network to build laboratory capacity for detection of foodborne pathogens and disease and antimicrobial resistance patterns. This partnership will provide FDA access to the data necessary to inform and prioritize science-based approaches to assuring food safety. It will also help to minimize public health concerns related to antimicrobial use in food producing animals.

Promoting Efficiency

CVM has recently incorporated the use of social science, the study of human society and of individual relationships in and to society, into some of its key program areas. Introducing the field of social science helps CVM better target its communications with various stakeholders and design more effective outreach strategies. For example, CVM is conducting a "mental modeling" study to identify decision factors that influence dairy farmers' ability to avoid tissue residues. Dairy cattle represent approximately seven percent of the U.S. beef sold, yet contribute approximately 80 percent of the drug tissue residues identified by the USDA. When farmers try to sell dairy cows that are found to have unacceptable drug residue levels, they lose the potential income from the sale of those animals. This effort will bolster dairy farmers' income by helping them better understand how to avoid drug residues in their cows before trying to sell them. To the extent that fines are imposed in such cases, a better understanding of how to avoid unacceptable drug residues will enable farmers to avoid incurring those fines as well.

PETNet's voluntary information exchange, surveillance and alert system is designed to provide a real-time mechanism for sharing information about emerging pet food related illnesses and product defects between and among FDA, other Federal agencies, and the States. Utilizing PETNet increases efficient communication between Federal and State agencies for identifying and potentially responding to concerns associated with pet food. PETNet members can use the data entered into PETNet to track the emergence of illness association with pet food products and pet food product defects and to evaluate the need for action within individual jurisdictions. PETNet will be

evaluated in FY 2012 with potential expansion of the system to include food-producing animals in FY 2013.

CVM conducts studies with food-producing animals in a production-like environment to provide other regulatory scientists, reviewers and regulators to address drug residue and withdrawal-time issues for animal drugs. Developing new methods through these studies has generated efficiencies for industry by making available additional tools that industry uses in surveillance of its own products. These new methods also support the development of methods that benefit regulated industry during the pre-approval or post-market phases of the product lifecycle. In turn, governmental agencies have been able to implement better and more cost-efficient surveillance programs for veterinary drug residues in foods. The methods also give FDA the means to rapidly respond and assess specific food-related hazards.

The information generated through NARMS -- supporting the judicious use of antimicrobials by industry -- helps deliver scarce government resources to areas of high interest. It also reduces the threat and health care costs associated with antimicrobial resistance among the American public. CVM and its partners have automated NARMS data processing to speed the preparation of large data blocks for uploading into the NARMS database. CVM is analyzing improvements in the NARMS laboratory to streamline processes and shorten the time from data acquisition to reporting.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Field Activities
FY 2012 Enacted Amount: $13,774,000 (All BA)

Public Health Focus

To strengthen animal food and feed defense/safety surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses.

Laboratory analysis activities include sample analysis, product testing and methods development to enable FDA to develop solutions for specific regulatory problems. ORA applies risk-based principles to the life cycle of ORA scientific operations—including sample collection, sample analysis, data reporting and data analysis.

FDA Food Safety Strategy

In the case of Strengthening Surveillance, ORA contributes to achieving the overall FDA strategy by implementing the development of risk-based systems. This includes establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and a model for evidence-based

resource planning. It also includes maintaining and strengthening mission-critical science capabilities, improving centralized planning and performance measurement and improving information sharing internally and externally.

Public Health Outcome

ORA utilizes a combination of techniques to perform import surveillance, including:

- electronic information technology for risk-based screening
- intensive ORA staff surveillance
- physical exams
- laboratory analysis.

Because the number and complexity of FDA-regulated imported products is increasing exponentially, ORA increased its efforts to strengthen surveillance and risk analysis.such as:

- continued to staff the Commercial Targeting and Analytical Center (CTAC)
- issued 21 notices identifying modifications to animal feed and animal drug program related Import Alerts
- developed and implemented a multi-residue regulatory method designed to increase the scope of analysis for feed products in the “Distiller’s Grain” surveillance program.
- conducted routine surveillance examinations, sampling, and analysis
- conducted targeted inspection and or sample collection and analysis assignments
- established a committee in collaboration with the Association of American Feed Control Officials, consisting of state and FDA officials to develop Animal Feed Regulatory Program Standards (AFRPS).

In 2011, ORA awarded contracts and grants to the states to increase collaborative efforts, leverage existing resources and to bolster an integrated feed safety system. These types of ORA-awarded contracts include:

- tissue residue program contracts to states to provide for completion of tissue residue inspections by state inspectors
- Food Protection Task Force grants to state and local groups
- Small Scientific Conference grants to associations that allow for increased interactions at operational levels to assure uniformity and consistency in enforcement activities
- contracts awarded to states under the Feed Safety BSE Contract program. These contracts aid FDA in establishing an expanded level of inspection coverage as well as surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

ORAs Prior Notice Center (PNC) was established in response to the requirements of the Public Health Security and Bioterrorism Preparedness Act (BPA) of 2002, which required FDA to take additional steps to protect the public from a threatened or actual

terrorist attack on the U.S. human food and animal feed supply and other food and feed-related emergencies. In FY 2011, the PNC continued to improve its targeting and vetting processes, increase intelligence-related food and feed shipment data mining and contribute to ORA's response to emerging global incidents to more effectively target high risk food/feed shipments prior to their arrival.

Promoting Efficiency

ORA is increasing efficiencies by reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). PREDICT allows ORA to target its resources in a more strategic manner. PREDICT expedites clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk animal feed and drug products.

ORA implemented the Analytical Tools Initiative (ATI) to assess tools for the investigator toolbox to provide greater capabilities to field staff to identify and address safety issues. This includes the evaluation of field deployable kits and instruments to enhance an investigator's ability to quickly test and assess products in the field for potential public health risks as well as the evaluation of additional instrumentation for laboratory use that will enhance laboratory capacity and capability.

ORA continues to resource violative findings during inspections of foreign facilities to establish pre-emptive import controls to address safety issues related to products that are destined for the U.S. market. ORA increases examination and sampling of products manufactured under violative conditions for a higher level of scrutiny for products destined for import into the United States.

ORA's expansion of prior notice bio-security targeting capabilities and intelligence data mining have allowed ORA to provide an increased focus on imported animal food and feed shipments that pose the highest risk of an intentional act of bio-terrorism. These advances have increased bio-security review efficiency and increase FDA's ability to detect and prevent high risk feed shipments that pose a bio-security threat from reaching domestic distribution chains.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2011: 43% Target: 22% (Target Exceeded)	55%	69%	+14%

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities FY 2012 Enacted Amount: $8,804,000 (All BA)

Public Health Focus

Appropriate enforcement strategies and regulatory decisions, such as inspections, need to be in place to ensure the compliance of marketed products. Working with our state counterparts, the Animal Drugs and Feeds Program conducts targeted, risk-based interventions with emphasis on the points of manufacture and distribution in order to prevent contaminated food and feed from entering the food supply.

FDA Food Safety Strategy

In the case of Strengthening Enforcement, CVM contributes to achieving the overall FDA strategy by implementing new enforcement authorities designed to achieve higher rates of compliance with prevention-based and risk-based food and feed safety standards. These activities are reflected within the draft FDA FVM Program Strategic Plan goal of achieving high rates of compliance with preventive controls standards domestically and internationally. This includes accomplishing domestic and foreign inspections, implementation of new enforcement tools (e.g., mandatory recall authority) and improving mechanisms for assuring that imported foods and feeds meet preventive controls standards. CVM is able to accomplish this through enforcement and inspections at farms, processing, transportation and retail outlets.

Public Health Outcome

In July 2010, FDA released a draft Compliance Policy Guide that explains the conditions under which FDA would consider taking regulatory action concerning Salmonella in animal feeds, including pet food. It was released to the general public to show the direction FDA is taking in its policies. The draft guidance on "*Salmonella* in Animal Feed" will apply in cases in which feed is likely to come in contact with humans, contains *Salmonella*, and is not going to be further treated to eliminate the *Salmonella*. The draft guidance describes when FDA will take action to protect the health of animals that might be at risk. CVM is completing a review of the public comments received and developing strategies for implementing the recommendations outlined in the draft guidance.

CVM is responsible for programs and regulatory actions aimed at preventing illegal drug residues in human food products derived from animals improperly treated with drugs. Illegal drug residues in edible products are a hazard to the health of persons consuming such food. Poor animal husbandry practices are the principal causes of illegal drug residues in meat and milk. CVM is concerned that the same poor practices that have led to illegal drug residues in dairy cattle tissues may also be resulting in illegal drug residues in milk. CVM has engaged in extensive outreach to facilitate the cooperation of the states and the milk industry and to seek input on approaches for conducting a sampling assignment that minimizes disruption to the milk industry.

CVM conducts a wide range of compliance activities designed to assure post-approval safety of new animal drugs that receive CVM approval and safety of all other products that are within CVM's regulatory sphere. During FY 2011, there were 410 recalls, involving 60 firms/manufacturers of products regulated by CVM. These included recalls of pet food, animal feed, animal drugs and animal devices. This is more than twice the number in FY 2010. Also during the year, CVM processed 69 warning letters, 11 injunction actions, two seizure actions and 10 untitled letters.

CVM continues to use risk-based inspection criteria for the bovine spongiform encephalopathy (BSE), tissue residue, medicated feeds and animal drug inspection programs. These criteria allow CVM, in collaboration with ORA, to prioritize inspection workload based on risk. As a result of these risk-based inspections, CVM effectively and efficiently manages compliance programs to protect animal feed from contamination by mycotoxins, pesticides, heavy metals, industrial chemicals and other toxic materials. The risk-based inspections also prevent the establishment and amplification of BSE through feed. CVM continues to gain experience with the new real-time Polymerase Chain Reaction method as the primary analytical method of testing imported and domestic animal feed and feed ingredients for the presence of BSE-related prohibited material.

Promoting Efficiency

CVM has drafted a Compliance Policy Guide to focus the regulatory response on those classes of feeds and Salmonella serotypes that have shown the highest risk of causing human or animal illness. This guide will promote efficiency and improve public health. Previously, without a policy to prioritize Salmonella serotypes by significance, all Salmonella events were treated equally. This risk-based decision tool allows FDA and others to achieve maximum benefit from resources devoted to addressing Salmonella serotypes of human and animal health concern for the prevention of and response to Salmonella events. CVM is able to protect animal and human health more efficiently by targeting those serotypes that have a higher risk of causing damage to public health.

CVM is also promoting efficiency by continuously working with the feed and food industries to ensure safe uses of products that would otherwise be considered adulterated. These efficiency efforts maximize the availability of feed ingredients while still protecting animal and human health. Examples include reconditioning of Salmonella-contaminated feeds and diverting mycotoxin-contaminated feeds from use in highly sensitive animal species to use in species that would not be negatively impacted. Additionally, CVM has established safeguards to identify the conditions for the safe use of otherwise-compromised products, such as sugarcane which was contaminated by an oil well blowout. This information will assist the feed and food industry in utilizing raw materials in a manner that is consistent with the protection of animal and human health. Without such information, these raw materials would have to be discarded, causing the industry to suffer unnecessary economic loss.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
FY 2012 Enacted Amount: $15,787,000 (BA: $12,598,000 / UF: $3,189,000)

Public Health Focus

One of ORA's main feed protection duties is to conduct risk-based inspections and enforcement activities. ORA investigators conduct physical inspections of regulated domestic and foreign feed establishments and conduct follow-up investigations on reports of tissue residues.

FDA Food Safety Strategy

In the case of Strengthening Enforcement, ORA contributes to achieving the overall FDA strategy by implementing new enforcement authorities designed to achieve higher rates of compliance with prevention-based and risk-based food safety standards, conducting risk-based domestic and foreign food safety inspections, implementing new enforcement tools (for example mandatory recall authority), improving mechanisms for assuring that imported foods and feeds meet preventive controls standards, and improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts. By adopting risk-based approaches to conducting inspections, ORA is able to more efficiently utilize scarce resources and maximize the public health benefit to consumers by ensuring high rates of compliance.

Public Health Outcome

Currently, the best approach to improving the safety and security of feed is to utilize resources to expand targeting and follow through in potentially high-risk areas such as:

- reviewing risk-based scenarios of bioterrorism and develop criteria that target animal feed and feed ingredients that pose an increased risk for intentional contamination
- working in conjunction with CVM compliance to take steps to reinstate the milk monitoring program including developing methods
- creating and launching a searchable FDA webpage and database for recalls to include a process and tracking system
- implementing a new streamlined enforcement process for seizures and injunctions
- issuing 69 warning letters to prevent the continued distribution of adulterated animal products in US commerce
- drafting a new Compliance Policy Guide (currently in final clearance status with the Department) describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection
- supporting the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs, assuring a broader regulatory framework for the U.S. feed supply.

During FY 2011, there were 410 recalls, involving 60 firms/manufacturers of products regulated by FDA. These included recalls of pet food, animal feed, animal drugs and animal devices. This is more than twice the number in FY 2010. In FY2011, the agency's MARCS-Compliance Management System has indicated 11 approved CVM injunction actions, two seizure actions and 10 untitled letters.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. In FY 2011, ORA made more than 1,170 informed compliance calls to regulated trade due to incomplete or inaccurate prior notice data submissions. In addition, ORA initiated more than 1,050 compliance enforcement cases, taken in conjunction with CBP, where BTA registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These actions require resubmission of accurate prior notice data before the imported food and feed shipments are allowed to enter the U.S.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011, and included data for FY2009 and FY2010 inspections. The Agency is committed to updating the data periodically, but at least twice per year and has already updated the data to include the first six months of FY2011. This action will provide the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

In May 2011, FDA implemented two new enforcement authorities under FSMA, both effective in July 2011. The first allows FDA to administratively detain food/feed that FDA has reason to believe is adulterated or misbranded. The products will be kept out of the marketplace while FDA determines whether an enforcement action, such as seizure or injunction against distribution of the product in commerce, is necessary. Before this new rule, FDA would often work with state agencies to embargo a food product under the state's legal authority until federal enforcement action could be initiated in federal court. In keeping with other provisions in FSMA, FDA will continue to work with state agencies on food safety and build stronger ties with those agencies.

The second authority provides FDA with more information about imports and allows for risk-based targeted examinations by requiring importers of food and feed into the United States to inform FDA if any country has refused entry to the same product. This new reporting requirement will be administered through the prior notice submission for incoming shipments of imported food/feed established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. With prior notice, in the event of a credible threat for a specific product linked to a specific manufacturer or processor, FDA will mobilize and assist in assuring products that may pose a serious health threat to humans or animals do not enter the U.S. food/feed supply. This new data requirement also allows FDA to make better informed bio-security decisions in

managing the potential risks of imported food/feed. During FY 2011, ORA's OCI opened 16 investigations that are still active.

In FY2011, ORA worked with CVM to develop a milk sampling assignment to determine whether illegal drug residues are in the nation's milk supply. Illegal drug residues are sometimes found in the tissue of animals offered for slaughter. Many of these animals originated at dairies. To determine if the dairy industry is complying with regulations governing the treatment of cows with veterinary drugs including observing withhold times that apply to reintroducing the animal to the milking herd. This sampling assignment targets dairy that have had positive tissue residue samples in the past, but the samples will be blinded so as not to negatively impact the milk industry. This sampling assignment will be issued and is expected to be completed in FY 2012.

Promoting Efficiency

The FDA Regulatory Procedures Manual (RPM) was revised to provide a process for issuing Warning or Untitled Letters based on evidence obtained by state personnel. The process allows FDA to issue Warning or Untitled Letters if the standards and criteria used by state personnel provide reliable support for regulatory action consistent with FDA's guidance on regulatory actions and laboratory procedures. This process increases the number of enforcement actions and decreases the time and resources required to prevent the continued distribution of adulterated products in US commerce, resulting in greater efficiency. These leveraged activities allow for greater efficiency of FDA resources, allowing for the release of safe products into the US market.

Informing the import trade community of the importance of submitting accurate prior notice data via informed compliance calls, compliance actions and joint cases with CBP serves to increase the reliability and specificity of ORA bio-security assessments and targeting. These enforcement efforts have added operational efficiency to both the animal food/feed import trade community and FDA while continuing to ensure the U.S. animal feed supply is not impacted by an act of bio-terrorism. These activities continue to assist in facilitating the release of foreign sourced products into the US market.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2011: 275 Target: 250 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2011: 572 Target: 490 (Target Exceeded)	500	500	Maintain
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2011: 50% w/in 15 working days Target: 80% w/in 15 working days (Target Not Met)	50% w/in 15 working days	60% w/in 15 working days	+10%

Improving Response and Recovery - Center Activities

FY 2012 Enacted Amount: $2,746,000 (BA: $2,225,000 / UF: $521,000))

Public Health Focus

Early detection of illnesses associated with food, tracing the source of the outbreak and removing the contaminated product from the market are critical to containing potential risks to the public.

FDA Food Safety Strategy:

In the case of Improving Response and Recovery, CVM contributes to achieving the overall FDA strategy by better responding to and containing problems when they occur. These activities are reflected within the draft FDA Foods FVM Program Strategic Plan goal to improve detection of, and response to, foodborne outbreaks and contamination incidents. This would include investigation and adoption of innovative technologies and processes to detect and investigate such events, enhancement of the Reportable Food Registry and effective risk communications related to outbreaks and contamination incidents. CVM is able to do this by responding to issues that occur across farm-to-table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

CVM is improving on how to communicate with consumers about food related emergencies and ensuring that communications relating to food safety better meet the health and information needs of consumers. Improving safety through better risk

communication ensures consumers understand what to do – and not do – in response to safety problems.

CVM has established coordination and communication with the Coordinated Outbreak Response and Evaluation (CORE) Team, established in August 2011 and located within CFSAN. The agency created CORE to manage outbreak response and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products. The goal is to strengthen FDA's efforts to prevent, detect, investigate, respond to, and learn from incidents and outbreaks.

CVM, in collaboration with CFSAN and other FDA Offices, developed the Reportable Food Registry to provide a reliable mechanism to track patterns of adulteration in food. This Registry supports FDA's efforts to target limited inspection resources in a manner that best protects public health.

In FY 2011, CVM established Vet-LRN, the Veterinary-Laboratory Response Network, which integrates state and federal laboratories resources and expertise for timely and accurate reporting, identification, and analysis of animal feed chemical and microbiological contamination events. The system operates by examining animal tissues and diagnostic specimens for microbiological agents, toxins, and other causes of disease. CVM provides early detection of foodborne disease outbreaks in animals with rapid notification to stakeholders in order to minimize animal illness, death and economic losses. These efforts contribute to overall food safety as animal feed events could signal potential issues in the human food system.

In March 2011, Vet-LRN held its first developmental meeting with veterinary laboratory directors from around the U.S. and Canada to establish contact and coordination with various laboratories that are interested in joining the network. Comments and ideas were provided by the laboratory directors to help Vet-LRN plan its activities and coordinate with other existing networks such as the Food Emergency Response Network (FERN) and other animal disease health networks in the United States such as USDA's National Animal Health Laboratory Network. As a result of recruiting and networking efforts, Vet-LRN had 21 member veterinary diagnostic laboratories at the end of the year.

In advance of foodborne illness events, CVM reviews and improves the protocol and roles and responsibilities for emergency coordination. CVM has full-time emergency and complaint response coordinators and other staff members dedicated solely to monitoring and responding, in real-time, to situations involving contaminated food and feed. CVM is able to initiate a rapid Agency response upon detection and identification of an animal disease outbreak associated with pet food products.

Promoting Efficiency

CVM continues to develop the Vet-LRN, a system that is "proactive" in a "reactive" situation. This network provides the means to rapidly identify, analyze and report human or animal adverse events associated with CVM-regulated products. This system of university, state and federal veterinary diagnostic laboratories leverages expertise and integrates resources to obtain needed veterinary diagnostic information, which is outside the usual scope of FDA sources. Protocols are being established for timely and accurate reporting, diagnosis, and analysis of national and international chemical and microbial animal feed or drug contamination events. Working with partners in the FERN, CVM is leveraging pre-existing electronic reporting technology, facilities and expertise to reduce duplication between laboratories and to save costs to both consumers and government investigators. Additionally, Vet-LRN partnerships provide the opportunity for new method development, proficiency testing for accreditation and increased national surge capacity from veterinary diagnostic laboratories. These enhanced capabilities contribute to overall food safety through more-timely responses to animal feed or drug contamination events, which could signal potential issues in the human food system.

Coordinating intra-Agency efforts between NCTR, CFSAN and CVM has saved government resources by complementing each center's efforts through the leveraging of equipment and manpower. As an example, CVM conducted pioneering melamine toxicity studies that were vital during FDA and WHO risk assessments for melamine during the pet food recall and infant formula events of 2007 and 2008. CVM scientists have worked with WHO and CFSAN risk assessors to provide critical data regarding melamine toxicity. Data obtained from collaborative work by CVM and industry resulted in one of the most-cited papers on melamine toxicity (Dobson et al 2008). CVM studies have provided valuable insight into the mechanism of renal failure caused by melamine related compounds. This information was extremely important during the infant formula recall and subsequent contamination events. CVM's method development work has helped industry develop new methods to detect melamine and related compounds. Recent collaborations in this area include evaluation of melamine effects in fetal and neonatal rats with CFSAN and expanded studies with the National Toxicology Program and NCTR evaluating threshold dosages for renal crystal formation which cause kidney failure.

Improving Response and Recovery - Field Activities
FY 2012 Enacted Amount: $9,851,000 (All BA)

Public Health Focus

With the integrated food supply chain, it is more important than ever for ORA to work with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners, in order to protect the nation's food supply.

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating and responding to foodborne illnesses. In FY 2011, ORA continued to work with the states on establishing new and develop further existing rapid response teams (RRTs), comprised of both ORA and state inspectors.

Another tool, in FDA's response and recovery efforts is the Reportable Food Registry (RFR). The RFR is an electronic portal to which industry, public health officials and consumers can report when there is a reasonable probability that an article of animal food and feed will cause serious adverse health consequences or death to animals. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

FDA Food Safety Strategy

In the case of Improving Response and Recovery, ORA contributes to achieving the overall FDA strategy by better responding to and containing problems when they occur, investigating and adopting of innovative technologies and processes to detect and investigate such events, enhancing the Reportable Food Registry and effective risk communications related to outbreaks and contamination incidents. ORA is able to respond to issues that occur across farm-to-table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

ORA leverages its regulatory partnerships to rapidly respond to outbreaks and facility recovery. Examples of these partnerships include State contracts, Food Emergency Response Network laboratories, rapid response and state lab cooperative agreements, BSE contracts and 50-State Meetings. ORA develops and supports FERN, a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. FERN laboratories provide critical analytical surge capacity during food emergency events. The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination.

ORA developed nine RRTs through the use of cooperative agreements and continues to develop the existing teams while working to enroll remaining states in the program. The established teams continue to work with Federal and local partners (including 10 ORA districts) to explore, develop, implement and share best practices. This enables Federal and state partners to improve their systems to more quickly and effectively stop an outbreak, mitigate the concern, and identify sources of contamination and contributing factors for the outbreak when possible. The teams also reach conclusions and possible interventions for the prevention of future cases. The RRTs have developed tools and guidance to share and facilitate improvement on key capabilities that are essential for effective responses to emergencies.

ORA continues to respond to numerous incidents reported through pet foods and animal feed RFRs in FY2012.

Promoting Efficiency

Improving the coordinated, rapid response of federal, state and local partners to feed related emergencies through the use of RRTs helps to minimize the public health consequences of an incident while diminishing unnecessary costs at the federal, state and local levels resulting from poor response coordination or communication.

The RFR is an example of how FDA uses technology to prevent animal feed safety threats from resulting in consumer illness or injury, providing a reliable mechanism to track patterns of adulteration in feeds. Pre-emptive investigations into reports received assured ORA investigations were comprehensive and affected products were contained and recalled before illness or injury could occur. In addition, these efforts provide information to FDA in a manner which allows FDA to follow up with regulated industry in a timely fashion, ensuring continued production of un-safe products does not continue, resulting in savings for manufacturers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. *(Outcome)*	FY 2011: 21 (Historical Actual)	23	25	+2

Animal Drug Review - Center Activities

FY 2012 Enacted Amount: $26,008,000 (BA: $16,344,000 / UF: $9,664,000)

Public Health Focus

The increasing companion animal population in the U.S,, along with the growing affinity pet owners have for their pets — evidenced by the rising expenditures for pet care and aggressive marketing of pet products — illustrates the need for more safe and effective drugs for disease prevention, treatment, and control in companion animals. CVM meets this public interest need by increasing the availability and diversity of approved, safe and effective veterinary products which relieve the pain and suffering of pets.

Public Health Outcome

Timely review for safety and effectiveness of new animal drug products is critical to bringing innovative, high quality and safe medical products to market for companion animals. CVM reviews safety and effectiveness data submitted in premarket applications for pioneer and generic new animal drugs. In addition, under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, CVM reviews conditional drug approval requests, index requests, and designation requests to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species. MUMS-designated drugs may obtain exclusive marketing rights for a period of seven years after approval or conditional approval preventing CVM from approving or conditionally approving, during those seven years, the same drug in the same dosage form for the same intended use as a designated product. The purpose of an index request is to allow a sponsor to legally market a product that is unlikely to be approved because the numbers of animals in the species group are too few or too precious to use in field trials. In addition, CVM administers a grant program to support the development of new animal drugs intended for minor species or minor uses in major species.

The reauthorized Animal Drug User Fee Amendments (ADUFA) of 2008 and the Animal Generic Drug User Fee Act (AGDUFA) of 2008 have provided resources for sustained performance, making it possible for safe and effective drug products to reach the market sooner.

CVM employs a phased-in approach to minimize the likelihood that drug makers will make critical and costly mistakes that delay the review of new animal drugs, thus bringing safe and effective products to the market more efficiently. This approach encourages sponsors to submit information to support approval as it becomes available, rather than waiting until they have collected all needed information and to maintain ongoing consultations with CVM about requirements for approval.

CVM continues to work with drug sponsors who are pursuing approval of currently marketed unapproved drugs. Four approvals, since the start of the unapproved drugs initiative, are particularly significant because there were only unapproved products available to veterinarians. Two of these products, approved in FY 2011, are phenyl-propanolamine and pergolide. The approved phenylpropanolamine product, marketed under the trade name ‘Proin’, is indicated for the control of urinary incontinence due to urethral sphincter hypotonus in dogs. The approved pergolide product, marketed under the trade name ‘Prascend’, is indicated for the control of clinical signs associated with Pituitary Pars intermedia Dysfunction (equine Cushing’s disease) in horses. Prascend is the first drug approved for use in horses to treat Cushing’s disease, a common disease where the gland that produces hormones, the pituitary gland, malfunctions as a horse ages that results in significant morbidity and mortality if left untreated.

Promoting Efficiency

CVM began a plan in FY 2010 to encourage the development of innovative and novel new animal drugs to meet public and animal health needs. A working group of CVM scientists, the InnoVation Exploration Team (IVET), was assembled as a think tank to introduce innovative products and processes to FDA, and to increase the certainty of the regulatory pathway for innovative products. IVET works with pharmaceutical companies, engaging their leadership in discussions to better understand pressures facing the industry that impact the development of innovative products. IVET draws upon the broad expertise across CVM and FDA to further these goals.

The MUMS Designation program for animal drugs provides incentives to the pharmaceutical industry to pursue drug approval for species and diseases that represent small markets. This program assists drug approval through grants to support safety and effectiveness testing and through exclusive marketing rights. In addition, this program defrays the costs of some required studies, thus lowering the direct cost of drug approval. It also protects the sponsor from competition following approval to further offset the company's drug development costs. These products also qualify for waivers from user fees which provide an additional incentive to the industry to seek approval. Absent approved drugs or indications, veterinarians and consumers treating minor species or minor uses have no choice but to turn to unapproved, and therefore potentially unsafe or ineffective, drugs. The MUMS Designation program therefore reduces the likelihood of unapproved drug use.

The MUMS Indexing program benefits the regulated industry by providing a reasonable and less expensive path to legal marketing of drug products for non-food-producing minor species. Indexing takes much less time than drug approval thus allowing companies to recoup their investments sooner. The cost is a fraction of that of a drug approval. Inclusion in the Index is based on the evaluation of the target animal safety and effectiveness of each specific product by a panel of qualified experts. A Small Entity Compliance Guide was published to assist the regulated industry -- especially small businesses – in using both the designation and indexing options. CVM carries out research with aquatic species in support of CVM, FDA and other governmental entities to increase efficiency in approval and surveillance of products used in aquatic health and production programs.

Animal Drug Review - Field Activities
FY 2012 Enacted Amount: $2,600,000 (BA: $2,125,000 / UF: $475,000)

Public Health Focus

The ORA Field supports the Animal Drugs Program by advising FDA leadership on enforcement, import, inspection and laboratory policies. Through its Field offices nationwide, ORA supports the Animal Drugs Program by conducting premarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

Public Health Outcome

ORA's Field force conducts preapproval inspections to support CVM's review of New Animal Drug Applications and Abbreviated New Animal Drug Applications. The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA perform inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed. Accurate data is essential to the review and approval of new animal drugs. Inspections also help ensure that the rights and welfare of animals are protected.

Promoting Efficiency

ORA provides training on how to conduct inspections of animal drug manufacturers and non-clinical laboratories, increasing the consistency of these inspections. When significant violations are observed during inspections, ORA works collaboratively with CVM to determine and implement the appropriate follow-up regulatory actions to assure the safety of U.S. public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2010: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	NA	90% w/in 380 days	90% w/in 270 days	-110 days

Post-market Safety and Compliance - Center Activities

FY 2012 Enacted Amount: $17,859,000 (All BA)

Public Health Focus

Monitoring the safety and effectiveness of marketed animal drugs, food additives and veterinary devices is paramount in ensuring the health and safety of our pets. Wider use of products often results in the discovery of problems not evident during the pre-market

review stage. Consequently, surveillance efforts enable the identification of potential harm prior to an adverse event. In addition, CVM is responsible for controlling the spread of zoonotic diseases that can be transmitted from animals to humans by pets and exotic animals.

Public Health Outcome

As in the foods area, FDA has a public health objective of ensuring the safety of companion animal related products throughout the life cycle. CVM utilizes and maintains an Adverse Drug Experience (ADE) database to identify drug safety signals and effectiveness issues of concern that were not detected during pre-market testing. CVM scientists use the ADE database to make decisions about product safety, which may include changes to the label or other regulatory action. Early identification of unsafe and ineffective drugs through a robust surveillance system helps foster public assurance that FDA is working for their benefit by promoting confidence in the nation's foods and drugs.

In January 2011, CVM began receiving gateway-to-gateway submissions allowing thousands of adverse event reports to immediately enter the adverse drug experience database for real-time processing and analysis. In July 2011, CVM announced it would provide the "number of times reported" along with the "signs associated with an animal drug" currently being reported in its Cumulative ADE Summaries Report. The public can use the database to search for the active ingredient of a drug to see if particular signs associated with adverse reactions have been reported with the drug's use.

CVM has the ability to address regulatory issues designed to prevent and control the spread of zoonotic diseases in both animal and human populations. The constant interactions of humans, animals and the environment have a tremendous impact on public health. There are over 200 infectious zoonotic diseases that are an important public health concern because they cause significant morbidity and mortality in the U.S. and worldwide. The most commonly heard of zoonotic diseases are variant Creutzfeldt-Jakob disease, West Nile virus, avian influenza, H1N1, rabies, monkeypox and salmonellosis. Approximately 75 percent of emerging human diseases seen in the past 25 years have been zoonotic with animals being the major source of the pathogens involved in zoonoses.

CVM's international activities have continued to grow in response to the increased globalization of the markets for the products that CVM regulates. The Center's International Programs Team (IPT) leads, coordinates and manages CVM's international activities in collaboration with relevant FDA Centers and Offices. IPT has adopted a strategic plan to enable CVM to better meet that challenge to better advance the overall mission of CVM and FDA in an international context,. The CVM International Programs Strategic Plan is designed for the enhancement of global outreach through leadership, coordination and management. As part of its work, IPT will seek the establishment of programs that promote and protect animals and humans who are exposed to them. This will occur through the use of One Health strategies that

decrease the spread of zoonotic diseases and enhance the societal importance of the human-animal bond globally. The IPT will accomplish its mission by working with various strategic partners within and outside of FDA.

In the area of regulatory research, genomic and proteomic methods are being developed to identify specific biomarkers that can be used to verify specific label claims and identify possible adverse reactions. These efforts should result in more safe veterinary products and decrease the extra-label use of many drugs. Genetic and proteomic markers of inflammation have been identified, which, following validation, should result in a method for substantiating anti-inflammatory claims in companion and food animal drugs. In addition, a genetically-modified mouse model, in which mice express canine genes, has been developed. The establishment of the model may replace the use of dogs during pre-clinical safety assessments of certain veterinary drugs and save time and costs during pre-clinical risk and target-species safety assessments.

Promoting Efficiency

CVM is applying lessons learned in the human drug arena and incorporating applicable methods to improve animal patient safety. Reducing and preventing medication errors has become a top priority in improving patient safety with other FDA Centers. In 2008, CVM began a patient safety initiative to prevent medication errors in animals. While early in the process, CVM has already identified reports of preventable medication errors in animals that are similar to the medication errors in humans, which may cause unnecessary harm and injury to animals.

CVM developed and implemented a pharmacovigilance program that accepts reports electronically and pre-populates an adverse drug experience database. The program provides significant administrative savings to industry reducing the burden on drug sponsors of having to create and mail voluminous paper submissions and allows CVM to provide more real-time surveillance of adverse drug event reports so that safety signals can be identified immediately and communicated to veterinarians and animal owners without any down time for data entry. Electronic submission of adverse event information was made possible through either the electronic submissions gateway or the safety reporting portal to allow adverse drug event reports to be transmitted directly from industry to CVM gateway-to-gateway submission. This provides financial savings to those companies and ensures they provide the appropriate adverse event safety information needed to protect animals and humans.

Over the last several years, there has been increasing concern with the rising number of animal drug shortages. CVM has established procedures for evaluating shortages of approved animal drugs to determine whether the approved animal drug is a medically necessary veterinary product, so that appropriate action can be taken to prevent or mitigate, whenever possible, a supply disruption. CVM has developed a table that provides a quick reference list of current animal drug shortages and those that have been resolved. This information is provided in our new Animal Drug Information

webpage to inform the public of CVM's activities in managing animal drug shortages. Another table that CVM manages in order to be proactive in averting animal drug shortages involves the identification of animal drug products that are solely manufactured at a single manufacturing site. While activities to manage animal drug shortages have been performed by CVM reviewers in past years, the newly developed reference tables provide a quick reference to efficiently address animal drug shortages and provide data to the public on the Animal Drug Information webpage.

Post-market Safety and Compliance (medical) - Field Activities
FY 2012 Enacted Amount: $2,686,000 (All BA)

Public Health Focus

ORA supports the Animal Drugs Program by evaluating manufacturing practices to determine the safety and effectiveness of manufactured products. ORA also supports the Animal Drugs Program by advising FDA leadership on enforcement, import, inspection and laboratory policies.

Public Health Outcome

Through its Field offices nationwide, ORA supports the Animal Drugs Program by conducting post-market inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

ORA monitors and samples imports to ensure the safety of the animal drug supply. In instances of criminal activity, ORA's Office of Criminal Investigations and the Forensic Chemistry Center complement the regular Field force activities.

ORA supports the Center's evaluation of adverse event reports. The Field offices conduct follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. In addition, ORA reviews adverse event and complaint files during inspections for compliance with FDA reporting regulations. In the event of a public health incident concerning a disease from an animal, for example salmonella from pet turtles, ORA will assist CVM by conducting any appropriate investigations. Targeted inspections allow for efficient use of FDA resources while focusing our efforts on products of concern that are destined for or may already be in the US market.

Promoting Efficiency

ORA evaluates adverse event reports in consultation with CVM and uses this information to perform targeted inspections to determine potential root causes. Targeted inspections allow for efficient use of FDA resources while focusing our efforts on products of concern that are destined for or may already be in the US market.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2011: 43% Target: 22% (Target Exceeded)	55%	69%	+14%

Information Technology Investments – Animal Drugs and Feeds Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $19,364,563)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities. This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency and HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts related to the regulation of our nation's veterinary products and feeds. FDA is committed to moving to an all-electronic work environment to support CVM's business processes. CVM is leveraging its pre-market Electronic Document Submission and Review (EDSR) system for pre-market Food Additive Petitions, Investigational Food Additive files, and Generally Recognized as Safe (GRAS) notifications, post-market Drug Experience Reports and Minor Use Minor Species Drug Index Files. CVM intends to continue expanding this technology for all its business processes involving regulated products. In addition, CVM is converting its paper archives into an electronic archive.

CVM is expanding and enhancing the National Antimicrobial Resistance Monitoring System (NARMS) with its external stakeholders including Centers for Disease Control and Prevention, the U.S. Department of Agriculture, and state agencies. This expansion includes providing data entry points for state reporting laboratories, developing analytical tools for regulators and researchers, and expanding the user community to include states, academia, and research organizations. CVM continues to expand and enhance the electronic processing of adverse event reports, product problem reports, and both adverse event and product problem reports submitted by the regulatory

industry and the public to include the reporting of voluntary animal drug events, the reporting for medicated feeds, and the reporting of reportable foods (both pet food and animal feed), which allows FDA to access and review the information in an efficient and timely manner to protect and promote the public health. CVM intends to create an animal and pet food database that supports the Food Safety Modernization Act.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$109,625,000	$97,365,000	$12,260,000	589
FY 2009 Actual	$135,359,000	$121,519,000	$13,840,000	680
FY 2010 Actual	$153,919,000	$134,360,000	$19,559,000	767
FY 2011 Actual	$158,771,000	$139,025,000	$19,746,000	806
FY 2012 Enacted	$166,365,000	$138,021,000	$28,344,000	821

Summary of the Budget Request

The FY 2013 budget request for the Animal Drugs and Feeds Program is $183,889,000. This amount is an increase of $17,534,000 above the FY 2012 Enacted Level. The CVM amount in this request is $123,352,000, supporting 519 FTE. The Field amount is $60,547,000, supporting 324 FTE.

The FY 2012 enacted funding for the Animal Drugs and Feeds Program is $166,365,000 which includes $109,379,000 for the CVM activities and $56,986,000 for the Field activities.

The Animal Drugs and Feeds Program is committed to meeting its mission of protecting human and animal health. With the FY 2012 enacted funding, CVM will fulfill its responsibilities for the evaluation, approval and post-approval monitoring of:

- animal drugs
- food additives
- feed ingredients
- animal devices.

CVM's mission is to increase the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, improve food-producing animal productivity, and do not compromise human health.
The FY 2012 enacted funding requested in this budget will satisfy the trigger requirements for user fee collections under the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). These user fees supplement the appropriated portion of the new animal drug review program and will enable the Program to continue improving the quality and timeliness of the new animal drug and animal generic drug review processes.

The initiatives proposed under the FY 2013 president's budget request support mission critical program activities and Presidential, HHS and FDA public health priorities such as the Transforming Food Safety and Nutrition initiative, which aims to protect patients by implementing the Food Safety Modernization Act (FSMA).

Budget Request

Pay Increase (Total Program: Commissioned Corps: $98,000)

The request for $98,000 in total BA for the Center for the Animal Drugs and Feeds program reflects a pay increase for the Commissioned Corps. The Center's portion of this increase is $60,000, and the Field's portion is $38,000.
.

Data Consolidation and IT Savings (Total Program: -$1,219,000)

The request for $136,175,000 in total budget authority for the Animal Drugs and Feeds Program also reflects a data consolidation and IT savings reduction of -$1,219,000 for FY 2013. The Center's portion of these savings is -$748,000 and the Field's portion is -$471,000.

The Animal Drugs and Feeds Program will achieve savings by:

- reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams and achieve economies of scale in the 24/7/365 network and server operations.
- reengineering business processes to maximize the efficiency of supporting processes, including the systems development process..
- reducing user enhancements and completing the build out of the Mission Accomplishment and Regulatory Compliance Services (MARCS) program. The

completion of the final phase of MARCS development is scheduled to occur in FY 2013.
- reducing maintenance costs of the MARCS program through the use of state-of-the-art technology and the retirement of costly legacy systems. In FY 2012, FDA will recompete the MARCS software development contract, which will achieve maintenance cost savings in FY 2013.

Rent Absorption: (Total Program: -$725,000 / -0 FTE)

The Animal Drugs and Feeds Program will be absorbing the cost of rent inflation, which will result in the loss of operating costs in the Animal Drugs and Feeds Program public health activities. The Center's portion of these savings is -$429,000 and the Field's portion is -$296,000.

Changes in the Pay Increase (Commissioned Corps), Data Consolidation of IT programs, Rent Absorption and affect all subprograms.

Prioritizing Prevention

Center Activities – (FY Enacted Amount: $39,659,000 (BA: $25,164,000 / UF: $14,495,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+9,297,000 / 7 FTE)
FY 2013 Increase for Current Law User Fees (ADUFA): +$4,641,000; 0 FTE
FY 2013 Increase for Current Law User Fees (AGDUFA): +$977,000; 0 FTE
FY 2013 Increase for Prior Proposed User Fees (Food Establishment Registration Fee): +$3,679,000; 7 FTE

FY 2013 Initiatives:

Transforming Food Safety Initiative: Regulations and Guidance – FSMA Sections 103-104 (UF +$3,679,000 / 7 FTE)

The budget authority funding in this request will enable CVM to develop and implement a preventive, risk-based system that fully addresses all aspects of manufacturing, packing and storing animal feed. CVM will develop regulations to encourage the animal feed industry to take necessary steps in preventing, eliminating or reducing to acceptable levels, potential risks to human and animal health, including steps to:
- eliminate or control risks from feed hazards
- establish regulatory limits for feed hazards
- develop guidance documents
- provide training and outreach to regulatory partners and industry.

CVM will develop guidance and standards to address the safe production of animal feed and to develop uniform hazard analysis standards, risk-based controls for food, feed and dietary ingredients, and food safety plans for food and feed facilities. Regulation

and guidance are important prevention-focused tools in FDA's efforts to improve food and feed safety. The more successful the system is in safely producing, processing, transporting and preparing foods and feeds, the safer the nation's food supply will be.

Field Activities – (FY 2012 Enacted Amount: $12,288,000 (BA: $12,288,000 / UF: $0))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$2,440,000 / 6 FTE)

2013 Initiatives:

Transforming Food Safety: Regulations and Guidance - FSMA Section 110 (UF $1,000,000 / 0 FTE)

Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources:

- support the implementation and enforcement of preventive controls in feed processing facilities
- continue to train some 400 inspection personnel -- consisting of ORA inspection personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners -- in preventive controls inspections and enforcement methods.

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$1,440,000 / 6 FTE)

With this investment, FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the animal food and feed supply, and sustainable multi-year infrastructure investments. This will provide more uniform coverage and safety oversight of the animal food and feed supply. ORA will conduct the following activities with the resources in this subprogram:

- fund two FTE to develop and validate certification testing instruments
- fund four FTE for program oversight through ORA audits of regulatory and public health partners to measure performance against FDA program standards.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Center Activities – (FY 2012 Enacted Amount: $14,303,000 (All BA))

FY 2013 Total Increase above FY 2012 Enacted Level: (+847,000 / 2 FTE)
FY 2013 Increase for Prior Proposed User Fees (Food Establishment Registration Fee): (+$847,000; 2 FTE)

FY 2013 Initiatives:

Transforming Food Safety: Science for Food Safety – FSMA Section 110
(UF +$847,000 / 2 FTE)

FDA will establish food and feed safety standards to address hazards from farm-to-table and based on the latest scientific developments. These standards will include:

- developing next generation methods for detecting high-priority contaminants in animal feeds and feed components
- evaluating and customizing commercially available systems for detecting illegal drug residues in animal feed and animal derived human food products
- developing metabolism studies to identify marker residues to be used to develop and validate analytical methods for detection of residues in imported and domestic animal feed products
- expanding technical capacity of laboratory surveillance networks to analyze animal feed commodities for contamination.

Scientific research and analysis provide the basis for prevention and the development of appropriate regulations and guidance.

Field Activities – (FY 2012 Enacted Amount: $13,774,000 (BA: $13,774,000 / UF: $0))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$480,000 / 2 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$480,000; 2 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply. and sustainable multi-year infrastructure investments. This will provide more uniform coverage and safety oversight of the food supply. In this subprogram, ORA will hire:

- one FTE to serve as an Official Establishment Inventory (OEI) Coordinator for the field
- one FTE to serve as a Scientific Coordinator to support the states as FDA moves to national standards for laboratories.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Center Activities – (FY 2012 Enacted Amount: $8,804,000 (All BA))
FY 2013 Total Increase above FY 2012 Enacted Level: (+$24,000 / 0 FTE)
FY 2013 Increase for Current Law User Fees (Recall): (+$24,000; 0 FTE)

Field Activities – (FY 2012 Enacted Amount: $15,787,000 (BA: $ 12,598,000 / UF: $3,189,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,030,000 / 2 FTE)
FY 2013 Increase for Current Law User Fees (Reinspection): (+$116,000; 0 FTE)
FY 2013 Increase for Current Law User Fees (Recall): (+$29,000; 0 FTE)

2013 Initiatives:

Transforming Food Safety: Inspections and Technology for Greater Efficiency – FSMA Section 201 (UF +$645,000 / 1 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance and respond effectively when problems emerge. Inspections are essential to hold industry accountable for their responsibility to produce safe products.

The resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs and improve FDA food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. This is essential in order to achieve the most public health value from FDA inspection and compliance programs and successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote Access Devices will allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, complete collection reports and all necessary documentation. In addition, expedited review, examination and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$240,000 / 1 FTE)

Investment supports a comprehensive prevention-focused import feed safety program that will rely more heavily on entities in the feed supply chain – feed manufacturers, processors, packers, distributors and importers – to provide assurances that the feed imported to the United States are safe and meet regulatory requirements. With these resources, ORA will:

- hire one FTE to conduct import verification inspections in support of the Foreign Supplier Verification Program.

Improving Response and Recovery

Center Activities – (FY 2012 Enacted Amount: $2,746,000 (BA: $2,225,000; UF: $521,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,176,000 / 2 FTE)
FY 2013 Increase for Prior Proposed User Fees (Food Establishment Registration Fee): (+$1,176,000; 2 FTE)

FY 2013 Initiatives:

Transforming Food Safety: Planning and Response – FSMA Section 202
(UF +$1,176,000 / 2 FTE)

FDA will develop a network of shared state and federal laboratory data, working with regulatory partners to identify and close current gaps in the oversight of the feed industry. FDA will determine viable laboratory accreditation options best suited to ensure that participating laboratories perform post-response testing and provide consistent and meaningful data that will enable compliance with the FDA and make surveillance possible in partnership with the Veterinary Laboratory Response Network (*Vet-LRN*). Planning and responding effectively, when food safety problems emerge, will minimize negative public health impacts. This network of shared data will also help ensure effective responses.

Field Activities – (FY 2012 Enacted Amount: $9,851,000 (BA: $9,851,000 / UF: $0))

Animal Drug Review

Center Activities – (FY 2012 Enacted Amount: $26,008,000 (BA: $16,344,000 / UF: $9,664,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$3,746,000 / 0 FTE)
FY 2013 Increase for Current Law User Fees (ADUFA): (+$3,094,000; 0 FTE)
FY 2013 Increase for Current Law User Fees (AGDUFA): (+$652,000; 0 FTE)

Field Activities – (FY 2012 Enacted Amount: $2,600,000 (BA: $2,125,000 / UF: $475,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$200,000 / 0 FTE)
FY 2013 Increase for Current Law User Fees (ADUFA): (+$149,000; 0 FTE)
FY 2013 Increase for Current Law User Fees (AGDUFA): (+$51,000; 0 FTE)

Post Market Safety and Compliance

Center Activities – (FY 2012 Enacted Amount: $17,859,000 (All BA))

Field Activities – (FY 2012 Enacted Amount: $2,686,000 (All BA))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$140,000 / 1 FTE)
FY 2013 Increase for Proposed User Fees (Medical Products Reinspection): (+$140,000; 1 FTE)

Center Animal Drugs & Feeds Program Activity Data (PAD)				
Animal Drugs & Feeds Workload and Outputs	**FY 2010 Actuals**	**FY 2011 Actuals**	**FY 2012 Estimate**	**FY 2013 Estimate**
New Animal Drug Applications (NADAs) [1]				
Received	12	11	13	14
Completed	13	13	14	14
Approved	11	12	11	12
Pending [2]	3	1	1	1
New Animal Drug Application Supplements [1, 3]				
Received	552	538	552	552
Completed	493	606	552	552
Approved	344	497	344	344
Pending [2]	212	142	241	241
Abbreviated New Animal Drug Applications (ANADAs) [1]				
Received	21	23	21	30
Completed	32	30	32	32
Approved	10	6	12	14
Pending [2]	25	18	3	1
Abbreviated New Animal Drug Application Supplements [1, 3]				
Received	187	199	187	187
Completed	196	238	196	196
Approved	112	154	112	112
Pending [2]	166	126	148	139
Investigational New Animal Drug (INAD) Files [4]				
Received	3,377	2,720	3,377	3,377
Completed	3,088	3,050	3,379	3,381
Pending [2]	702	361	700	696
Generic Investigational New Animal Drug (JINAD) Files [4]				
Received	271	219	271	271
Completed	269	214	271	271
Pending [2]	67	57	67	67
Food (Animal) Additive Petitions Completed	39	38	39	45
Investigational Food Additive Petitions Completed	89	92	92	95
Adverse Experience Reports (AERs) [5]				
Received	52,926	54,017	58,000	61,000
Reviewed	11,562	23,273	31,900	42,000

[1]Includes originals applications and reactivations. If the application is not approvable, the sponsor may submit additional information until FDA is able to approve the application.

[2]Reflects submissions received during the fiscal year that still require review.

[3]A supplemental application is a sponsor request to change the conditions of the existing approval. Supplemental applications can be significant (such as a new species or indication), or routine (such as product manufacturing changes). The estimates do not include invited labeling change supplement applications because it is not possible to accurately project sponsor or CVM requests for this type of application.

[4]An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including requests for interstate shipment of an unapproved drug for study, protocls, technical sections, data sets, meeting requests, memos of conference, and other information.

[5]Received and reviewed in the current fiscal year.

Combined Field Activities – ORA
Program Activity Data

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,051***	***1,723***	***1,764***
Pre-Approval /BIMO Inspections	50	79	79
Drug Process and New ADF Program Inspections	248	205	222 [3]
BSE Inspections	1,571	1,205	1,205 [2]
Feed Contaminant Inspections	29	25	25
Illegal Residue Program Inspections	405	440	473 [1]
Feed Manufacturing Program Inspections	191	141	141
Domestic Laboratory Samples Analyzed	1,674	2,458	2,458
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***53*** [4]	***68***	***68***
Foreign Pre-Approval/Bioresearch Monitoring Program	26	45	45
Foreign Drug Processing and New ADF Program Inspections	33	33	33
Foreign Feed Inspections	7	7	7
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,104***	***1,791***	***1,832***
IMPORTS			
Import Field Exams/Tests	6,254	3,600	3,600
Import Laboratory Samples Analyzed	747	750	750
Import Physical Exam Subtotal	**7,001**	**4,350**	**4,350**
Import Line Decisions	284,973	342,600	411,881
Percent of Import Lines Physically Examined	2.46%	1.27%	1.06%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,651***	***5,949***	***5,949***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***151***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,630	5,850	5,850
State Contract Inspections: Feed Manufacturers	444	321	321
State Contract Inspections: Illegal Tissue Residue	204	412	412
State Partnership Inspections: BSE and Other	151	151	151
State Contract Animal Drugs/Feeds Funding	$2,552,632	2,750,000	3,000,000
BSE Cooperative Agreement Funding	$2,766,282	2,702,830	2,572,920
State Contract Tissue Residue Funding	$663,018	665,610	712,200
Total State Funding	**$5,981,932**	**$6,118,440**	**$6,285,120**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,906***	***8,040***	***8,081***

[1] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013. During the full performance year (FY 2013), the FY 2011 BA enacted funding increase for inspections will allow ORA to conduct and additional 33 domestic tissue residue inspections. Resources are being shifted from the BSE program into the Tissue Residue program area, which is why the number of BSE inspections decreases and the number of Tissue Residue inspections increases from the FY 2011 level (the change in inspections is not equivalent for both categories because the time it takes to conduct a tissue residue inspection is longer than the time required to conduct a BSE inspection with the same level of resources, thus resulting in fewer inspections conducted by comparison).

[2] The decrease in inspections (366) from FY 2011 is due to program resources being shifted to the Tissue Residue program.

[3] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013. During the full performance year (FY 2013), the FY 2011 BA enacted funding increase for inspections will allow ORA to conduct and additional 17 domestic animal drug inspections.

[4] The FY 2011 actual unique count of foreign inspections includes 2 OIP inspections (both in China). One was for Animal Drugs and the other was for Animal Feeds.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

Devices and Radiological Health

The following table displays the funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
Devices
(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$378,215**	**$378,509**	**$375,989**	**$386,766**	**$10,777**
Center	$282,116	$285,977	$280,655	$285,168	$4,513
FTE	1,319	1,406	1,374	1,413	39
Field	$96,099	$92,532	$95,334	$101,598	$6,264
FTE	473	496	492	531	39
Program Level FTE	**1,792**	**1,902**	**1,865**	**1,944**	**78**
Budget Authority	**$322,370**	**$322,182**	**$322,672**	**$319,127**	**-$3,545**
Center	$240,486	$240,695	$241,475	$239,072	-$2,403
Field	$81,884	$81,487	$81,197	$80,055	-$1,142
Budget Authority FTE	**1,519**	**1,603**	**1,611**	**1,606**	**(5)**
Center	1,066	1,127	1,139	1,134	(5)
Field	453	476	472	472	0
User Fees	**$55,845**	**$56,327**	**$53,317**	**$67,639**	**$11,312**
Center MDUFMA	$35,627	$40,370	$33,177	$40,093	$6,916
FTE	230	248	209	248	39
Field MDUFMA	$1,138	$1,586	$1,060	$1,281	$221
FTE	12	12	12	12	0
Center MQSA	$6,003	$4,912	$6,003	$6,003	$0
FTE	23	31	26	31	5
Field MQSA	$13,077	$9,459	$13,077	$13,077	$0
FTE	8	8	8	8	0
Field Reinspection [1]				$3,579	$3,579
FTE				24	24
International Courier User Fee [1]				$3,606	$3,606
FTE				15	15
User Fees FTE	**273**	**299**	**255**	**338**	**39**

[1] Proposed User fee; the amount includes associated rent activity

The FDA Devices and Radiological Health Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act[1] (21 U.S.C. 321-399)
Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss)
Medical Device Amendments of 1976[1]
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Safe Medical Devices Act of 1990[1]
Mammography Quality Standards Act of 1992 (42 U.S.C. 263b)
Medical Device Amendments of 1992[1]
Food and Drug Administration Modernization Act[1]
Medical Device User Fee and Modernization Act of 2002[1]

Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Medical Device User Fee Stabilization Act of 2005[1]
Food and Drug Administration Amendments Act of 2007 (FDAAA)[1]
Patient Protection and Affordable Care Act, 2010

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Devices and Radiological Health Program (the Devices Program) began in 1976 with the passage of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (the Act). Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness.

- Class I, General Controls, is the lowest risk category of devices and includes items such as adhesive bandages. These devices are subject to the general controls of the Act, which include establishment registration and device listing and compliance with current Good Manufacturing Practice (cGMP), labeling, record-keeping, and reporting requirements.
- Class II, Special Controls, is a medium-risk category of devices and includes devices such as intravenous catheters and powered wheelchairs. Class II devices typically require that FDA review a premarket notification (510(k)) [2] prior to marketing. These devices are subject to the general controls of the Act as well as Special Controls, which may include special labeling requirements, mandatory performance standards, and postmarket surveillance, in order to ensure device safety and effectiveness.
- Class III is the highest risk category of devices and includes devices such as heart valves and coronary stents. These devices are subject to the general controls of the Act, plus require approval of a premarket approval application (PMA) prior to marketing. PMAs are the most rigorous premarket submission type, and contain substantial scientific evidence to support the device's safety and effectiveness.

Under the Devices Program, the Center for Devices and Radiological Health (CDRH) and the Office of Regulatory Affairs (ORA) protect and promote public health by ensuring the safety, effectiveness and quality of all medical devices. The Devices Program also protects the public from unnecessary exposure to radiation from radiation-emitting products, such as microwave ovens, x-ray equipment, medical ultrasound and MRI machines, and many other consumer, industrial, and medical products. In addition, the Program monitors mammography facilities to make sure their equipment is safe and properly run.

[1] Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified in scattered sections of 21 U.S.C.
[2] A 510(k) is a premarket submission to demonstrate that the device to be marketed is "substantially equivalent" to another legally marketed (predicate) device.

ORA Field offices support Devices Program activities by assessing industry compliance with applicable regulations. To provide this support ORA:

- conducts premarket and postmarket inspections of domestic and foreign manufacturers
- investigates medical device reports (MDR) and consumer complaints
- monitors and evaluates compliance with recalls of violative products
- performs laboratory analysis to support inspections
- reviews and evaluates imports of medical devices and radiological products to ensure products meet FDA quality standards
- conducts enforcement activities.

A combination of appropriations and user fee programs funds the regulatory process to assure product safety and effectiveness. The Program's user fees are authorized under the Mammography Quality Standards Act (MQSA), enacted in 1992, and the Medical Device User Fee and Modernization Act (MDUFMA), enacted in FY 2002, and reauthorized in FY 2007 as the Medical Device User Fee Act (MDUFA). The current legislative authority for MDUFA expires in September 2012 and FDA anticipates new legislation to reauthorize user fee collections for the medical device program for FY 2013 to FY 2017. The Centers for Medicare and Medicaid Services (CMS) user fee program, authorized by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), also provides support for the Devices Program.

The Devices Program executes its regulatory responsibilities in five areas:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA).

Premarket Device Review – Center Activities

FY 2012 Enacted Amount: $133,382,559 (BA: $110,820,346 / UF: $22,562,213)

CDRH's Premarket Device Review activities focus on ensuring the safety and effectiveness of new devices and radiological products before they can be marketed in the United States. By increasing the predictability, consistency, and transparency of its premarket review programs, CDRH works to provide new treatments and diagnostic tests to patients more quickly and to stimulate investment in and development of promising new technologies to meet critical public health needs.

Through Premarket Device Review activities, CDRH is able to achieve important FDA, HHS, and Administration priorities including:

- applying the least burdensome principle
- proactively facilitating innovation and addressing unmet public health needs

- improving health care quality and patient safety
- reducing health care costs
- protecting Americans in public health emergencies
- accelerating scientific advances in lifesaving cures and quality health outcomes.

Public Health Outcome

CDRH evaluates the safety and effectiveness of new devices and approves or clears thousands of products annually, many of which are critical to the delivery of health care in the United States. Recent examples of device approvals include:

- A device that uses an innovative technique to correct a heart arrhythmia condition that cannot be treated with medication. The process freezes and destroys abnormal heart tissue responsible for producing irregular beats and restores normal electrical activity.
- A novel device to treat adults with the most common form of primary brain cancer, glioblastoma multiforme (GBM). This device is at least as effective as chemotherapy and provides end-stage patients with a better quality of life.
- A pacemaker system designed to deliver standard pacing therapy in patients who have slow heart rates (bradycardia). This system was the first specifically designed and tested to permit patients implanted with the device to receive magnetic resonance imaging (MRI) scans in certain circumstances where the imaging may be critical to diagnosis and treatment.

Nearly two years ago, CDRH recognized that, given the growing complexities of medical product development, the Center needed to re-evaluate and modernize its regulatory review processes in order to ensure that patients had timely access to safe and effective medical devices. At that time, CDRH began to undertake a new systematic approach to device regulation, moving away from the traditional misperception that safety and effectiveness and innovation are incompatible. Rather than focus on *more* regulation or *less* regulation, CDRH began to focus on smart regulation.

In August 2010, following extensive public input, CDRH released two reports that identified problems with our premarket programs and potential actions to address their root causes. After considering extensive public input, CDRH announced 25 specific actions that the Center would take to improve the predictability, consistency, and transparency of our premarket programs. Since then, CDRH announced additional efforts to improve premarket review, including actions to improve clinical trials and the Investigational Device Exemption (IDE) program. Collectively, these actions can be grouped into three main areas of emphasis that seek to:

- create a culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks
- ensure more predictable and consistent recommendations, decision-making, and application of the least-burdensome principle

- implement more efficient processes and use of resources.

On October 19, 2011, CDRH released a detailed report that supports FDA's Transparency Initiative and informs constituents of the many actions and activities CDRH is undertaking to improve its premarket device review programs. (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm276272.htm).

The improvements CDRH is undertaking include developing a range of updated and new guidance documents to clarify FDA requirements for timely and consistent product review. These efforts include:

- On August 15, 2011, CDRH issued draft guidance clarifying the criteria used to make benefit-risk determinations a part of device premarket decisions. With these criteria, CDRH will provide greater predictability and consistency and apply a more patient-centric approach by considering patients' tolerance for risk in appropriate cases.
- On October 3, 2011, CDRH issued draft guidance streamlining the de novo review process, the pathway by which novel, lower-risk devices without a predicate can come to market. The guidance makes clear which devices are eligible for the de novo process and what data are necessary to support de novo classification of suitable devices.
- On November 10, 2011, CDRH issued guidance streamlining the clinical trial – investigational device exemption (IDE) processes by providing industry with guidance to clarify the criteria for approving clinical trials, and the criteria for when a first-in-human study can be conducted earlier during device development.

These actions help balance patient safety with innovation by providing manufacturers and developers with clear and predictable outlines of CDRH expectations while at the same time creating incentives to bring new technologies to the United States.

Other improvements include launching a Reviewer Certification Program in September 2011 – a combination of required courses and auditing of work product – which all new reviewers must complete. The purpose of the program is to give reviewers the type of training that can help accelerate their learning curve and help them develop the skills and experience necessary to perform high-quality reviews.

In FY 2011, CDRH also announced its Innovation Initiative, which includes several proposals to help maintain the position of the U.S. as the world's leader in medical device innovation. The initiative includes the creation of a new approach for important, new technologies called the Innovation Pathway. In FY 2012, CDRH is expanding the Innovation Pathway and broadening its mandate. The effort is designed to take a fresh look at how we assess risks in the context of probable benefits, how we engage early on with innovators, and how we create a program that is adaptable, sustainable, and value-adding. To achieve this goal, CDRH assembled a team of entrepreneurs in residence – made up of external experts in medical device development, business

process improvement, and information technology – who will work day-to-day with FDA staff and leadership to use innovative approaches that can rapidly build an improved Innovation Pathway.

CDRH is also in the process of completing the classification of the remaining Class III medical device types that were in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law. In FY 2011, CDRH published five proposed rules and four final rules pertaining to the Class III pre-amendment devices. CDRH is completing the final classification process for the remaining Class III pre-amendment devices.. This resource intensive effort requires a risk-based evaluation of each of the remaining Class III pre-amendment devices and a rule-making process, as required by statute.

To accelerate the development of medical products to treat Americans in the event of a chemical, biological, radiological or nuclear (CBRN) attack or an infectious disease outbreak, CDRH is engaged actively in the Department-wide Medical Countermeasures Initiative (MCMi). CDRH evaluates the safety and effectiveness of diagnostic and detection devices, personal protective equipment, and emergency devices such as ventilators – and addresses gaps in these critical areas. The CDRH MCM Program is working on dozens of projects designed to enhance MCM regulatory science innovation and infrastructure capacity. Some of these projects look at emergency usage of existing medical devices to identify and overcome challenges, while others seek to understand what types of devices may be needed in the future.

CDRH works to provide scientific and regulatory guidance to sponsors of MCM devices during the product development phase, and CDRH conducts interactive premarket reviews of these products. An essential component of these efforts includes accelerating regulatory pathways for emerging technologies critical to speeding diagnosis and treatment in response to a CBRN threat. In FY 2011 and the first quarter of FY 2012, CDRH held public workshops on whole genome sequencing and multiplex diagnostic devices to obtain important input from stakeholders on the evaluation of these vital, new technologies.

Through the Bioresearch Monitoring Program (BIMO), CDRH continues to prevent unnecessary harm to human research subjects and to assure the integrity of data collected. In FY 2011, CDRH issued over 370 clinical and non-clinical inspections of medical device research, and provided outreach programs to foster understanding of clinical-study data integrity and human research subject protections. As a result of these BIMO inspections, CDRH issued 13 warning letters in FY 2011 for clinical investigators, Institutional Review Boards, nonclinical laboratories, and sponsors who revealed human subject protection violations and premarket data integrity issues.

Promoting Efficiency

CDRH continually works to stretch its limited Premarket Device Review Program resources to keep U.S.-based companies leading the roughly $350 billion global

medical device industry while ensuring the highest return of service to American patients and consumers.

On December 1, 2011, CDRH issued draft guidance to facilitate the development and marketing of Artificial Pancreas Device Systems (APDS) and to provide maximum flexibility to manufacturers seeking to bring this device to U.S. patients. The draft guidance provides for flexibility in the choice of study endpoints, number of patients to be studied and the length of the clinical trial. The approach outlined in the draft guidance allows sponsors to take the least burdensome approach to showing safety and efficacy of APDS.

Other key efforts include CDRH's streamlining of the path to market for full field digital mammography systems to permit less costly and more rapid review and clearance of submissions. This effort included issuing guidance for industry and FDA staff that down regulated full field digital mammography systems from class III devices to class II devices. As a result, the number of commercially available, FDA cleared, full field digital mammography systems increased in FY 2011 by 120 percent. Down regulating well-validated and understood devices promotes U.S. economic and job growth by reducing unnecessary regulatory burdens on device makers without compromising patient safety. CDRH also took steps to effectively down regulate 30 other medical devices in FY 2011.

Premarket Device Review – Field Activities
FY 2012 Enacted Amount: $8,465,000 (BA: $7,457,000 / UF: $1,008,000)

Public Health Focus

The ORA Field force supports the Devices Program in the initial phases of the total product life cycle by conducting preapproval inspections of domestic and foreign establishments to determine if the facility is able to manufacture products according to the specifications stated in their application. ORA also conducts bioresearch monitoring inspections of clinical research studies—including the clinical investigators, sponsors and monitors, and Institutional Review Boards—to safeguard patients and to validate laboratory methods for device premarket application decisions.

Public Health Outcome

ORA conducts inspections to ensure that medical device establishments are able to manufacture products according to the specifications outlined in an application and that concerns or issues raised during review of the application are accounted for. ORA efforts help to assure that medical products are cleared or approved based on reliable data and evidence of manufacturing capability, and once manufactured, become a viable supply of safe commodities for U.S. consumers.

Promoting Efficiency

ORA collaborates with CDRH to ensure that ORA field staff conduct the most efficient bioresearch monitoring inspections possible. This collaboration provides ORA investigators with information on the use of the device being studied, previous clinical trials, and concerns raised during review of preapproval inspections. These Field activities allow FDA to efficiently focus its available inspection resources on significant issues related to data integrity and human subject protection. By doing so, FDA helps ensure that sponsors collect data that can support a device application rather than conducting clinical trials that yield data that cannot support device approval.

In 2011, ORA worked with CDRH to develop a pilot program designed to increase the review efficiency of inspectional findings related to pre-clearance 510(k) violations. This pilot encourages early collaboration between the field and center to more quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and more efficient and quicker issuance of Warning Letters, if appropriate. This will result in more rapid decision-making and communication with manufacturers, which should result in industry taking swifter action to comply, and improved public health protection.

Performance Measures

The Premarket Device Review program is supported by the MDUFA user fee program. Under MDUFMA and MDUFA, FDA agreed to pursue a comprehensive set of device review performance goals.

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. *(Outcome)*	FY 2009 1/: 77% of 37 in 180 days and 85% of 37 in 295 days Target: 60% in 180 days and 90% in 295 days (Target Not Met)	50% in 180 days and 60% in 295 days	50% in 180 days and 60% in 295 days	Maintain

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. *(Outcome)*	FY 2009 1/: 85% of 162 in 180 days and 91% of 162 in 210 days Target: 85% in 180 days and 95% in 210 days (Target Not Met)	75% in 180 days and 85% in 210 days	75% in 180 days and 85% in 210 days	Maintain
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. *(Outcome)*	FY 2009 1/: 90% in 90 days and 98% in 150 days Target: 90% in 90 days and 98% in 150 days (Target Met)	75% in 90 days and 80% in 150 days	75% in 90 days and 80% in 150 days	Maintain
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2011: 322 Target: 300 (Target Exceeded)	300	300	Maintain

1/ FY 2009 Premarket performance data are accurate as of October 21, 2011, Industry Stakeholder meeting. FY 2009 cohort remains open.

Postmarket Safety – Center Activities

FY 2012 Enacted Amount: $50,032,538 (BA: $44,307,671 / UF: $5,724,867)

Public Health Focus

CDRH Postmarket Safety activities focus on monitoring medical device and radiological product performance, including adverse events, once the products reach the market. CDRH analyzes safety signals with potential clinical impact and – when an issue surfaces – strives to respond quickly to identify and limit potential public health problems. These efforts are critical to ensuring that devices and radiological products remain safe and effective for patients and consumers.

Through Postmarket Safety activities, CDRH is able to achieve important FDA, HHS, and Administration priorities including:

- improving health care quality and patient safety
- promoting the adoption and meaningful use of health information technology
- fully implementing a total product life cycle approach that enables well-supported regulatory decisions at any stage of a device's cycle.

Public Health Outcome

CDRH uses two principle systems to capture device-related adverse event and product problem reports: the Medical Device Reporting regulation (MDR) and the Medical Product Safety Network (MedSun).

MDR is the mechanism by which FDA receives over 300,000 significant medical device adverse events from manufacturers, importers, and user facilities annually. Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to CDRH under the MDR program. CDRH carefully evaluates the reports received to identify safety concerns of public health importance.

MedSun is an “active” adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. Over 350 health care facilities, primarily hospitals, participate in the MedSun Network. In FY 2011, improved MedSun reporting and analysis resulted in over 40 MedSun-based recalls and 115 manufacturers’ actions, which is an increase of over 60 percent and 20 percent respectively from FY 2010 levels. MedSun provides better understanding of how certain devices are used in the clinical environment, how regulatory actions against manufacturers will affect the patient care in hospitals, and if manufacturer recalls and other actions successfully solved the reported device problems.
CDRH utilizes postmarket surveillance data to detect and respond to device-related public health issues as they arise. and to provide the public with important information about the risk-benefit profiles of medical devices. CDRH addressed issues with transvaginal placement of surgical mesh devices for pelvic organ prolapse (POP).This condition occurs when tissues that hold the pelvic organs in place become weak or stretched. Based on an updated analysis of adverse events, CDRH identified that serious complications associated with this form of POP treatment are not rare and are a serious public safety concern. As a result, CDRH provided updated safety recommendations and warned the public, clinical community and manufacturers of the risks associated with the transvaginal placement of mesh to repair POP.

CDRH proactively works with multiple stakeholders to advance the development of device registries. In FY 2011, CDRH worked with Cornell University and Kaiser Permanente to develop a strategic plan for establishing a large-scale scientific infrastructure, in the form of a distributed consortium, of U.S. and internationally-based orthopedic registries. In May 2011, CDRH held the first meeting of the International Consortium of Orthopedic Registries (ICOR) with 29 registries, which collectively represented 14 nations and 3.5 million hip/knee replacement patients. This ground-breaking consortium enables harmonized collaborations and approaches to answer key research questions and fill important gaps in knowledge concerning safety and effectiveness of devices.

CDRH is also leading an effort to develop and implement a national strategy for the best public health use of health-related electronic data that incorporates a Unique Device

Identification (UDI) system and leverages existing device and procedure registries. The purpose of UDI is to allow all stakeholders to unambiguously and consistently identify medical devices throughout the supply chain up to the point of patient use and throughout the device's life cycle. In September 2011, CDRH held a public workshop to discuss the adoption, implementation, and use of UDIs in electronic healthcare data sources and its incorporation into a National Medical Device Registry. During FY 2011, CDRH completed the proposed rule to require medical device manufacturers to place a UDI on a label or the device itself. The proposed rule is currently under OMB review. Investments in UDI will provide significant benefits to industry by supporting more efficient and effective recalls, creating supply chain efficiencies, and reducing costs to distribute products internationally by using a single device identification framework.

Consistent with FDA's transparency initiative, CDRH is enhancing its efforts to disseminate valuable postmarket device information to the public and industry. In calendar year (CY) 2011, CDRH had over 220 post-approval studies (PAS) publicly available on FDA's website, an increase of more than 15 percent from CY 2010. Information is now available on products' study designs, including the size, population, data collection methods and follow-up visits. Completed studies include final results, safety and effectiveness findings, strengths and weaknesses of the study, and any recommended labeling changes. Greater access to information about the scope, progress and results of PAS studies will provide healthcare professionals, patients and the public with an improved understanding of the performance of high risk devices after they have been marketed.

Promoting Efficiency

CDRH strategically invests in cost-saving, postmarket safety activities to enhance FDA's capability to efficiently monitor the safety and effectiveness of medical devices. These efforts include converting from a paper-based, adverse event reporting system to electronic reporting. Electronic medical device reporting (eMDR) provides significant cost savings to taxpayers and industry by replacing a far less efficient paper-based reporting system that requires manual database entry. It also encourages more rapid reporting of vital postmarket information from industry. As a result of CDRH's active industry engagement and outreach, the percentage of electronic submissions in FY 2011 doubled (56%) compared to electronic submissions in FY 2010 (28%). Electronic reporting reduces document control costs for FDA and industry and enablesquicker analysis and identification of emerging public health issues.

Postmarket Safety – Field Activities
FY 2012 Enacted Amount: $791,000 (BA: $739,000 / UF: $52,000)

Public Health Focus

The ORA Field force supports the Devices Program in postmarket safety by conducting follow-up investigations of MDRs. These inspections of reporting medical facilities or manufacturers identify significant problems by analyzing recurring problems and

performing trend analysis. ORA also collects data on complaints, significant problems and potential hazards so corrective actions can be initiated. ORA conducts bioresearch monitoring inspections of post-approval studies, which monitor the postmarket safety of products already available for public use.

Public Health Outcome

ORA conducts inspections of both domestic and foreign medical device firms where issues or concerns have been identified. These inspections ensure the marketplace is safe from defective or hazardous products.

Promoting Efficiency

In 2011, FDA issued press releases, guidance to industry and alerts providing industry, health care professionals and consumers with FDA recommendations, guidance or warnings on specific medical devices. Examples include infusion pumps, infusion set needles, and counterfeit surgical mesh. These notices provided industry with guidance on the FDA's current initiatives and provided up-to-date information to consumers and medical professionals about device safety concerns. These FDA communications raised industry and consumer awareness, ensured efficient and timely public health response, and minimized negative pubic health outcomes and the financial and personal costs associated with them.

ORA worked with CDRH to develop a pilot program designed to increase the efficiency of the review of inspectional findings related to MDR violations. This pilot encourages early collaboration between the field and center to more quickly determine whether regulatory action is required to correct deficiencies observed during inspections. The expected outcome of the pilot is speedier review of inspectional findings and more efficient and quicker issuance of Warning Letters, if appropriate. This will result in more rapid decision making and communication with the manufacturer, which should result in industry taking swifter action to comply and improved public health protection.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
252202: Enroll the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. *(Outcome)*	FY 2011: 80% Target: 67% (Target Exceeded)	87%	93%	+6%

Compliance, Enforcement, and Radiation Safety – Center Activities
FY 2012 Enacted Amount: $37,212,387 (BA: $37,212,387 / UF: $0)

Public Health Focus

CDRH's Compliance, Enforcement, and Radiation Safety activities focus on protecting patient safety by assuring that manufacturers comply with laws and regulations. These efforts enable CDRH to achieve important FDA, HHS, and Administration priorities of:

- improving health care quality and patient safety
- protecting patients by strengthening the safety and integrity of the global supply chain
- strengthening compliance and enforcement activities to improve patient safety and support public health.

Public Health Outcome

Compliance, Enforcement, and Radiation Safety activities are designed to quickly identify major violations and take prompt, clear, and appropriate actions to resolve issues. Examples of recent enforcement efforts include:

- obtaining a consent decree in early 2011 to protect patients from unsafe cardiac and vascular surgical devices marketed by Terumo Cardiovascular Systems (Terumo CVS). This action was the result of a finding of systemic and procedural deficiencies identified during FDA inspections.
- seizing Rite-Dent, Inc.'s adulterated and misbranded dental devices in January 2011. The devices were seized because the company failed to comply with quality system regulations. These violations included using expired raw materials to manufacture devices.
- identifying serious health risks associated with the King International Shoulderflex Massager, which led to the recall of 11,934 devices on August 30, 2011. CDRH informed the public that use of the device could result in strangulation and death, and advised patients and consumers to immediately stop using the device.

In FY 2011, CDRH began its Recall Process Improvement project to advance the clarity and timeliness of regulatory actions against medical device firms in which violations of the Food, Drug and Cosmetic (FD&C) Act are found. As a result of the process improvements, CDRH classified 45 percent more recalls in FY 2011, while simultaneously increasing the number of recalls classified within current timeframe goals by 9 percent. By streamlining the recall classification process and improving recall notice timeframes, CDRH is able to more rapidly resolve public health risks and better protect patients from devices that are defective, could be a risk to public health, or both.

Obstacles to business-wide integration of best quality practices exist within the industry that FDA regulates, and they have grown dramatically over the past decade. To better define high-impact quality manufacturing practices and engage industry, CDRH initiated

the Business Case for Quality Initiative and released the "Understanding Barriers to Medical Device Quality" report on October 31, 2011. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM277323.pdf The report describes many of the barriers that device manufacturers face in integrating best-quality manufacturing practices across their organizations, details several reasons for the barriers, and recommends steps to overcome them. By closely collaborating with industry to identify and better define high-impact quality practices, CDRH is working to enhance quality manufacturing and better protect American patients and consumers.

CDRH's strategic and targeted compliance efforts are essential to maximizing the value of limited resources. CDRH recently conducted an in-depth examination of three device categories that historically have been responsible for a disproportionate share of adverse events and recalls. The evaluation of external infusion pumps, external defibrillators, and ventilators included analysis of adverse events and recalls along with data from manufacturers, users and patients. Systemic deficiencies were identified in the design, manufacture, and review of these products. As a result, nearly one million unsafe devices were removed from the market and seven firms were requested to improve manufacturing processes of these products to ensure the safety of American patients.

To address current public health needs related to electronic product radiation, CDRH administers— through its Radiological Health Program—the Electronic Product Radiation Control provisions of the FD&C Act. CDRH monitors industry for compliance with required performance standards, monitors radiation dose to the public, and balances public health safety benefits and risks. These activities identify and correct unnecessary and hazardous radiation exposure and reduce the incidence and severity of acute and chronic radiation injury. In FY 2011, CDRH reduced its average timeframe for review of field establishment inspection reports to less than 30 days, an improvement of over 50 percent from the 64 day average timeframe in FY 2010 and over 75 percent from previous years. This accomplishment permitted more timely communication and rapid correction of deficiencies in radiation emitting electronic products and devices.

Through the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, CDRH collaborates with partners in the Federal government and the healthcare professional community to promote safe use of medical imaging devices, support informed clinical decision making, and increase patient awareness. Examples of recent CDRH activities include:

- developing, in collaboration with manufacturers and the National Electrical Manufacturers Association, a new device safety standard that safeguards computed tomography (CT) scanners from delivering excessive radiation
- producing, in collaboration with Image Wisely, a medical imaging professional group, a Patient Medical Imaging Record for tracking the date, type, and location of radiology exams

- developing, in collaboration with the National Council on Radiation Protection and Measurements, Diagnostic Reference Levels for common CT procedures.

The goal of the initiative is to support the benefits associated with medical imaging while minimizing the risks. Through a balanced public health approach, CDRH seeks to ensure each patient will receive the right imaging exam at the right time with the right radiation dose. CDRH's actions are based on the principles of optimizing the dose of radiation administered and performing medical imaging that uses ionizing radiation only when justified.

Promoting Efficiency

The U.S. medical device industry is one of the few sectors, in these challenging economic times, with a positive trade balance. In 2000, the U.S. medical device industry ranked 13th in venture capital investment – a decade later, it is our country's fourth largest sector for venture capital investment. In fact, in the third quarter of 2011, more than 62 percent of the $631.4 million that venture capital invested in the life sciences went to medical device companies. CDRH compliance activities protect capital investments in the device sector and the jobs they create by:

- ensuring manufacturers comply with laws and regulations that maintain or enhance public confidence in their product by minimizing public safety concerns
- helping to rapidly remove defective products from the market before they have wide spread impacts on consumer confidence.

To more effectively leverage limited compliance resources and lower costs to industry and taxpayers, CDRH is working with Health Canada to establish the Single Audit Program (SAP). As part of this effort CDRH will access and review reports of inspections conducted by trusted foreign authorities that use U.S.-recognized inspection standards. SAP can provide significant cost savings to American taxpayers and industry by eliminating duplicate inspections by trusted regulatory counterparts and enabling a single, shared audit under one uniform regulatory standard.

In FY 2011, CDRH expanded its efforts to educate and empower foreign and domestic regulatory partners and help industry become more efficient. These efforts include CDRH Learn, a comprehensive, interactive, and easily accessible online training resource available in multiple languages. In FY 2011, CDRH Learn training modules were utilized over half a million times, a 400% increase from FY 2010 levels. In FY 2011, CDRH also responded to over 36,000 inquiries from industry via phone, email, and fax. CDRH proactively assists the medical device sector to more efficiently deploy resources by providing interactive, high quality responses to thousands of industry questions concerning device and radiological health regulatory issues.

Compliance, Enforcement, & Radiation Safety – Field Activities
FY 2012 Enacted Amount: $68,474,000 (BA: $68,474,000/ UF: $0)

Public Health Focus

The ORA Field force supports the Devices Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its nationwide field offices, ORA supports Compliance, Enforcement and Radiation Safety activities by conducting risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. The work includes conducting inspections of reprocessors of single-use devices and manufacturers of radiological health products. ORA's radiological health activities include inspecting radiation emitting products such as lasers, sunlamps and x-ray equipment to ensure that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated products.

ORA works with state contractors through the inspection contract program to support the mission of assuring the safety, quality, and effectiveness of medical devices. Inspections ensure that Class I (low risk) and Class II medical device manufactures are in compliance with the Quality Systems Inspection Technique (QSIT)/Good Manufacturing Practices (GMP) regulations.

ORA conducts import entry reviews, import field exams, and import sample collections to determine if import entries comply with the medical device registration and listing requirements and other general controls. These reviews assure that import entries declared as import for export are CDRH approved. ORA detains all import entries that do not comply with applicable regulations.

As part of the recall program, CDRH determines the level or classification of public health risk a product presents and makes appropriate public notification of a recall. ORA monitors recalls of medical devices that have been found to present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce.

ORA field offices investigate and build enforcement cases, which are initiated by CDRH or ORA. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serves to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

Public Health Outcome

In FY 2010, ORA established a dedicated foreign device cadre consisting of ten experienced medical device investigators to augment the existing foreign inspection program. The cadre performs foreign device firm inspections, which provide greater assurance that products manufactured abroad are safe for use in the United States. In FY 2011, the dedicated foreign device cadre conducted approximately 170 inspections. In follow-up to objectionable conditions noted during these inspections, FDA has issued twenty-five Warning Letters, nine of which included placing the firm on Import Alert with automatic detention. In addition, in FY 2011 FDA established a new import alert for foreign medical device firms that refuse ORA surveillance inspection, and ORA added one firm to that Import Alert.

In FY 2011, ORA continued to staff the Commercial Trade Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once risks are identified, the appropriate agencies work together to minimize the risk. ORA is working closely with other government agencies on several ongoing cases including Devices Program products such as lasers. In FY 2011, ORA, in conjunction with CDRH, U.S. Customs and Border Protection Service (CBP), and other government agencies, worked to stop importations of “Wicked Lasers,” which are dangerously high powered laser products marketed to US consumers via the internet. Although marketed as FDA compliant laser pointers, these products are considered a significant public health hazard because of the risk they pose to the public in causing severe eye damage or blinding, skins burns, and flash blinding. Some of the products have power levels at 250 times the regulatory power. FDA subjected the product to detention without physical examination and also issued a warning to consumers not to use the product.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections. Also available is a searchable database of inspected facilities with FDA inspection classifications. The website premiered May 2011 and includes inspection data for FY 2009, FY 2010, and the first six months of FY 2011. The Agency is committed to updating the data periodically, but at least twice per year. This action provides the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

In FY 2011, FDA classified and issued recalls for 427 Class I; 2,665 Class II; and 119 Class III recalls of medical device products to protect consumers from violative or unsafe products. Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death. As part of the recall program, CDRH determines the level or classification of public health risk a product presents and makes appropriate public notification of a recall. ORA monitors recalls of medical devices that

present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce.

ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure that FDA posts firm recall notices on the intranet within 24 hours of receipt.

ORA continues to provide FDA with greater assurance that imported commodities comply with FDA requirements by:

- conducting import entry reviews and import field examinations to ensure imported medical devices and their components are in compliance with FDA requirements
- collecting surveillance samples of imported medical devices and their components to assure industry conformance with FDA regulations and standards
- collecting "for cause" sample collections when concerns or issues arise that indicate possible non-conformances with FDA regulations.

When it is determined, either through review, examination or sampling that an imported commodity does not comply with applicable regulations, ORA works to detain those products to ensure they do not reach U.S. consumers.

In FY 2011, ORA issued 91 notices for numerous medical device products and medical device firms that were found to be manufacturing or shipping violative medical device products. These actions were a result of ORA import surveillance collections and testing of regulated products at the time they were offered for import into the U.S., as well as "for cause" sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These actions serve to provide ORA with a mechanism for automatic detention of violative products, and the notices provide increased communication of those actions, resulting in increased coverage at the border to assure that these products are not available to the U.S. consumer.

In FY 2011, ORA issued 175 warning letters to prevent the continued distribution of adulterated medical device products in U.S. commerce. In addition, there was one seizure for medical device products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

ORA field offices investigate and build enforcement cases, which are initiated by CDRH or ORA. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serve to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

In May, 2011 ORA implemented a new streamlined enforcement process for seizures and injunctions. The new process

- increases collaboration at an early state in the process of case development
- reduces paperwork by removing redundant and unnecessary documentation
- removes a bias toward inaction by making the process less daunting and more collaborative
- provides a mechanism for continuous improvement in case development
- shortens approval times.

ORA drafted a new Compliance Policy Guide (CPG) (currently in final clearance status with the Department) describing the policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection. This CPG will facilitate the Agency's ability to prevent the introduction of medical devices in U.S. commerce from facilities that have delayed, denied, or moved to avoid an FDA inspection.

The ORA Office of Criminal Investigation (OCI) is responsible for criminal investigation activities in cases involving significant FDA violations. During FY 2011, ORA's OCI made 20 arrests and secured 18 convictions with fines, restitutions and other monetary penalties in excess of $278 million. The successful investigative efforts of OCI resulted in several actions during FY 2011, including these examples:

- In January 2011, sentencing was handed down on Guidant LLC for failure to report defibrillator problems. OCI initiated an investigation based on a New York Times article alleging that Guidant made unreported changes to the Prizm 2 Implantable Cardioverter Defibrillator (ICD), which led to the death of a patient in March 2005. The investigation revealed that Guidant made numerous changes to the Prizm to mitigate an arcing problem, but did not properly report the changes to FDA. The investigation also determined that Guidant experienced a similar arcing problem in the Renewal Cardiac Resynchronization Therapy Device (CRT-D) in 2004. The device failures resulted in the display of a warning screen which did not properly identify the problem. Guidant disguised the purpose of a communication of this information to the physicians and did not correct the device labeling to instruct for proper analysis when the screen was encountered. In 2011, Guidant LLC was sentenced and ordered to pay a fine of $253,962,251, and was also sentenced to a term of 36 months probation and ordered to forfeit $42,079,675 in assets.

- In September 2011, Lake County Indiana Sheriff's Department (LCSD) personnel were charged with conspiring to defraud the FDA by knowingly submitting fictitious police department purchase orders and related forms and knowingly selling lasers to the general public via the Internet, circumventing the authority of the FDA. This OCI investigation case was initiated upon a request

by the United States Attorney's office in the Northern District of Indiana who sought OCI assistance in a joint investigation with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and Defense Criminal Investigative Service (DCIS). Federal Agents identified one of the laser sights (Class IIIb) for sale on eBay and conducted a test purchase. The laser was traced back to equipment received by =LCSDpersonnel and signed for by a LCSD Deputy Chief. LCSD personnel submitted fictitious police department purchase orders and signed product disclosure agreements, indicating these items were being purchased for police department use, but were subsequently being sold via the internet. Final sentencing remains pending.

- In April 2011, a clinic owner and others associated with the clinic were federally indicted for twenty-five (25) counts of Health Care Fraud, one (1) count of Conspiracy, and one (1) count of Forfeiture for $8,100,000. This OCI investigation case originated from a request for assistance by the Nevada State Health Department regarding the Endoscopy Center of Southern Nevada, Las Vegas, NV. The investigation revealed several individuals infected with Hepatitis C were patients of the Endoscopy Center. A state inspection documented the unsafe medical practice of reusing single use vials and syringes resulting in the adulteration of an anesthetic. The State sent letters to more than 39,000 former and current patients of the Center, informing them that they should immediately be tested for Hepatitis C, Hepatitis B, and HIV. Final sentencing remains pending.

- In May 2011, the president and sole shareholder of two corporations in Florida was charged with engaging in a scheme to sell approximately 6,000 boxes of counterfeit LifeScan One Touch diabetic test strips. The owner purchased the test strips from China and England and sold them to wholesale customers in the U.S. and Canada, who in turn, sold the counterfeit products for purchase in pharmacies and other stores throughout the U.S. The indictment charged the individual with mail fraud, trafficking in counterfeit goods, entry of goods into the U.S. through a false statement on a customs form, and making a false statement to a federal agency. If convicted, the defendant faces a maximum possible sentence of 57 years' imprisonment and fines up to $3,000,000.

- During FY 2011, OCI continued the coordination and communication between criminal investigators, regulatory components of FDA, and the United States Attorney's Offices investigating health care fraud-related investigations. As a result of the investigative efforts during FY 2011, OCI secured two indictments against a physician and clinical research coordinator for falsifying study data in a clinical trial. The indictment alleges the defendants falsely stated physical examinations had been conducted on two unqualified test subjects, signed false statements to FDA indicating the clinical study was being conducted in accordance with proper protocol, and arranged for the unqualified subjects to have office visits while the executive director was at lunch to conceal the fact

the test subjects were ineligible as they were employees of the research institute and under the required age to participate.

OCI regularly conducts criminal investigations involving the internet, where some of the most egregious examples of the threats to the public health can be found. OCI investigates a wide variety of alleged violations, including illegal Internet pharmacies and any other websites engaged in the illegal marketing or sale of any FDA-regulated products. These products include prescription drugs, supplements, biologics, medical devices, and tobacco products.

The investigations are often complex and resource-intensive, as they have become increasingly global in nature. Criminals are regularly based in foreign countries and attempt to masquerade behind the anonymity of the Internet while offering counterfeit, stolen, and unapproved FDA-regulated products to U.S. consumers. These criminals manufacturer, sell and distribute substandard (and potentially deadly) products solely for monetary profit, with total disregard for consumer health and safety.

OCI has been identified by our domestic and foreign law enforcement peers as an expert and global leader in Internet investigations. Violative websites are proactively identified, researched, and investigated by OCI. Field offices receive criminal investigative assignments, which often include undercover test purchases and other resource-intensive activities, such as: subpoena and search warrant service; reviews of thousands of emails; the identification of subjects, witnesses, and victims; and the analysis of voluminous financial data associated with the illicit profits.

. In FY 2011, OCI provided multiple Internet investigation training courses (both domestic and foreign) to our regulatory counterparts from many countries, including Canada, Italy, United Kingdom, Ireland, Israel, Romania, Estonia, Poland, Czech Republic, and others. OCI continues to build and foster strong working relationships with other law enforcement agencies in the U.S. as well as in countries throughout the world to identify and prosecute violators who use the Internet to sell FDA-regulated products that threaten the health and safety of the American public.

In FY 2011, OCI received special funding from the Department of Justice to apply toward completion of the recently established OCI National Document Center. The support provided by the center helps OCI criminal investigations obtain substantive data relating to fraudulent activity which maximizes monetary recoveries related to illicit proceeds. Many OCI investigations are complex and very document intensive, requiring a scanning and optical character resolution (OCR) solution in order to search, identify, extract and analyze key information. This information is often required by the U.S. Attorney's Offices who are accepting the cases for federal prosecution. The OCI Document Center is being used for, but not limited to, OCI criminal investigations including the off-label promotion of FDA approved drugs and medical devices, application fraud, clinical investigator fraud, healthcare fraud involving FDA regulated

products, import investigations involving any criminal investigations national in scope, and document-intensive cases involving FDA regulated products.

Promoting Efficiency

ORA and CDRH recently developed a set of automated database lookup procedures for the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system. FDA is using these automated PREDICT procedures to determine the admissibility of imports of medical devices and radiological health products. With appropriate data submitted by import entry filers, the system can electronically determine the marketing status of a product during import review. This enhancement to PREDICT allows FDA to expedite the clearance of firms' low risk products, while allowing ORA to focus resources on higher risk device products. PREDICT provides both Industry benefits and greater assurance that imported products are safe and effective for use by U.S. consumers. As of December 2011, PREDICT is fully implemented and in use within all import districts within ORA.

The universe of FDA regulated medical devices and radiation-emitting products is diverse. Many of these devices and products have unique regulatory and performance requirements. ORA and CDRH continue to implement a joint initiative to create and issue a series of field advisories to assist ORA investigators. This effort to establish and implement nationwide guidance resulted in uniform national procedures that increase the efficiency of admissibility decisions while minimizing delays in processing import shipments. These efforts allow ORA to efficiently allow medical devices to enter U.S commerce in a timely manner, ensuring that safe and effective products are available to U.S. consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
254202: Increase percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. *(Output)*	FY 2011: 54% Target: 75% (Target Not Met)	60%	60%	Maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2011: 1,799 Target: 1,445 (Target Exceeded)	1,515	1,600	+85

Device Innovation and Regulatory Science – Center Activities
FY 2012 Enacted Amount: $50,896,397 (BA: $46,006,476 / UF: $4,889,921)

Public Health Focus

CDRH's Device Innovation and Regulatory Science investments focus on strengthening the U.S. research infrastructure and promoting high-quality regulatory science, facilitating the development and evaluation of transformative innovative technologies and scientific breakthroughs, and developing and sharing scientific information and tools to assess the safety and effectiveness of medical devices for American patients.

Through Device Innovation and Regulatory Science activities, CDRH is able to achieve important FDA, HHS, and Administration priorities:

- transforming health care by improving health care quality and patient safety
- proactively facilitating innovation and addressing unmet public health needs
- accelerating the process of scientific discovery to improve patient care.

Public Health Outcome

CDRH's Device Innovation and Regulatory Science activities are essential to assure that advances in science and technology translate into improvements in human health. These activities include researching how new devices interact with the body, developing test methods for new technologies, testing products to identify root causes of failure, and developing epidemiological methods to help conduct postmarket studies of devices.

As a medical device is developed and evaluated, regulatory science plays an important role in evaluating its benefit-risk profile. It provides a vehicle through which CDRH collaborates with other stakeholders in developing tools that help manufacturers develop innovative products, and it helps manufacturers and FDA assess those products. The result is a more effective, efficient, and timely approach to device development, assessment, and manufacturing.

In the premarket design stage, new regulatory science advances mirror the emergence of new types of products, such as those used in modern minimally-invasive diagnosis and therapy. For example, one important category of minimally-invasive medicine is optical diagnosis — a suite of techniques that shine light onto tissue to make diagnoses rather than taking invasive surgical tissue biopsies. CDRH scientists designed new test methods for evaluating and comparing benefit-risk profiles of optical technologies such as optical coherence tomography (OCT). These methods help industry evaluate new devices and provide CDRH reviewers a better foundation to assess safety and effectiveness for new device technologies.

CDRH regulatory science investments also help manufactures redesign and evaluate existing devices with systematic safety problems. For instance, when device failures cause injuries, CDRH scientists conduct and share scientific investigations that provide in-depth analyses of the underlying causes. In one recent case, blindness-inducing infections occurred in two independent outbreaks in association with contact lens solutions. These incidents led to substantial product recalls. CDRH lab investigations

revealed the cause to be a previously unrecognized incompatibility between some contact lenses and contact lens solutions. CDRH scientists then developed new, more effective tests to identify potentially problematic combinations of lens materials and solutions. This method was provided to industry and academia to aid in their testing of new lens and cleaning solution products.

As technology advances, medical devices are becoming increasingly complex. CDRH must be able to anticipate these advances, creating the scientific tools that will assist the industry in developing new products and assessing their safety, effectiveness, quality, and performance. In FY 2011, CDRH enhanced its personalized medicine (PM) staff to prepare for and address the new generation of medical products that provide patients with targeted medical treatment based on individual patient genetic attributes. The PM staff is tracking inter-center reviews for personalized medicine products, assuring consistent regulatory and policy advice to sponsors, and taking the lead on developing validation requirements for novel in vitro diagnostic (IVD) products, such as devices that employ whole genome testing. Additionally, in July 2011, CDRH released draft guidance intended to increase predictability for industry on the requirements for companion diagnostics – tests used to help health care professionals determine whether a patient with a particular disease or condition should receive a particular drug therapy or how much of the drug to give.

CDRH is working to provide regulatory clarity on FDA's approach to nanotechnology, an emerging technology that has the potential to revolutionize medical devices and the delivery of medical care. To help understand possible toxicity of nanoparticles and how to measure their size, CDRH is investigating ways to determine the biological effects of nanoparticles and whether current methods can predict these properties effectively. These investigations have already yielded development of accurate methods of measuring nanoparticle size and uniformity. CDRH's nanotechnology efforts are strengthening FDA's scientific capacity to evaluate potential safety problems of this emerging technology and supporting the responsible development of nanotechnology devices for American patients.

In FY 2011, CDRH established a Center Science Council (the Council) to help assure consistency and predictability in our scientific decision making and to monitor the quality and performance of the scientific programs. Important scientific issues that warrant senior level review are now brought to the Council for consideration. The Council now reviews device review team recommendations for an increase in clinical data requirements for all manufacturers of a type of device. Implementation of this process improvement helps ensure decisions are made consistently and efficiently, at the appropriate level, and apply the least-burdensome principle. Consistent with the transparency initiative, the Council's draft charter is available on FDA's website: (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm249248.htm).

Promoting Efficiency

CDRH's Device Innovation and Regulatory Science activities help foster a robust medical device industry by reducing the time and resources needed to develop and assess new products. CDRH scientists identify the underlying mechanisms of device actions on the body and develop the science-based questions, test methods, and tools necessary to assess the safety and effectiveness of medical products. These tests and tools are then designed, validated, and provided to consensus standards organizations and industry.
Magnetic Resonance Imaging (MRI) is an important and widely-used diagnostic tool. However, MRI machines can significantly heat or move certain types of implantable devices and can disrupt implant function. Implanted devices may also distort the MRI images. For these reasons, patients with some types of implanted devices (e.g., implanted defibrillators and brain stimulators) have not been able to undergo MRI testing, which puts their physicians at a diagnostic disadvantage. To facilitate the development of innovative MRI-compatible implanted devices, CDRH scientists, in collaboration with academia and industry, performed electromagnetic testing of novel device designs, developed physical and computer models to evaluate them, and established standards for new MRI-compatible devices. This has helped open a scientifically sound pathway for the development of new products, and in FY 2011 led to approval of the first MRI-compatible implantable device—a pacemaker.

CDRH's development of well-validated and reliable tests, methods, and tools are essential to maintain the growth of the U.S. medical device industry and the jobs it creates. These investments can reduce the cost of device development, assessment, and review for U.S. device manufacturers, reduce ambiguity as industry develops and submits data for review, and provide FDA the means to assess the safety and effectiveness of transformative innovative technologies and scientific breakthroughs. In CY 2011, CDRH signed a Memorandum of Understanding with Minnesota's LifeScience Alley to advance the development of critical test methods.

Device Innovation and Regulatory Science –Field Activities

FY 2012 Enacted Amount: $1,784,000 (BA: $1,784,000 / UF: $0)

Public Health Focus

ORA's Winchester Engineering and Analytical Center (WEAC) conducts analyses and develops new analytical test methods for medical devices and radiation emitting electronic products in support of regulatory actions to ensure safe and effective medical devices.

Public Health Outcome

ORA continues to make advancements in device safety for consumers by leveraging internal and external stakeholders, by conducting postmarket analytical methods

development activities on pressing public health risks, and by developing a proactive FDA approach for post-market device testing. WEAC continues to:

- develop new and improved methodology to support regulatory analysis
- validate analytical methods to support enforcement activities
- conduct product evaluation study projections to provide comprehensive postmarket surveillance information about devices.

The focused efforts of ORA's laboratories, in collaboration with academia, federal and state partners, continue to ensure that suspect medical devices are removed from U.S. commerce. In FY 2011, new methods, analyses and expert scientific testimony in federal court by ORA supported criminal convictions by US Attorneys in New York and California.

In FY 2011, efforts made by ORA led to several medical device product recalls including billions of Huber-style needles used for chemotherapy delivery, counterfeit surgical mesh distributed to hospitals and surgical centers, and tainted contact eye solution distributed to retail establishments throughout the U.S. In addition, ORA laboratory analyses iresultedin numerous refusals of unsafe foreign sourced medical devices as well as facilitating commerce by removing compliant firms from previous Import Alerts.

ORA's laboratories support the Devices Program through analysis and surveillance of samples for the Condoms and Gloves programs to assure they are safe and effective. These analyses help reduce the risk to the public and health care community of unnecessary exposure and transmission of blood-borne pathogens, particularly human immunodeficiency virus (HIV), hepatitis B, and hepatitis C infections by increasing the number of medical gloves analyzed at an expedited rate utilizing a high throughput model previously adopted for food borne outbreaks.

ORA conducted 1,513 medical device laboratory analyses in FY 2011 using a risk-based approach focusing on device categories that historically have been responsible for a disproportionate share of adverse events and recalls. Some of these laboratory analyses led to medical device product recalls including infant and neonatal filter line sets used by emergency medical services and hospitals during ventilation of newborn infant patients; blood tubing sets used during hemodialysis; and automatic external defibrillators (AEDs) distributed to fire departments, EMS, health clubs and schools.

In addition, ORA laboratories developed new and innovative test methods for AEDs, infusion pumps, ventilators, endotracheal tubes, and hemodialysis blood tubing sets to evaluate imports of medical devices ensuring products meet FDA quality standards. Test results of many devices led to the addition of firms/products to Import Alerts calling for automatic detention of potentially unsafe products offered for import into the United States.

In FY 2011, ORA scientists, in conjunction with CDRH partners, revealed the cause of blindness-inducing infections which occurred in two previous independent outbreaks associated with contact lens solutions. These methods were provided to industry to aid in their redesign and testing of new lens and cleaning solution products.

Promoting Efficiency

Increased efficiencies and capacity allow ORA to analyze a higher volume of basic yet essential products, such as medical gloves, in reduced timeframes. These efforts support the timely release of industry products into U.S. commerce and also ensure that reliable medical products are available to the health care community, thus safeguarding medical practitioners and patients from ineffective medical devices.

ORA scientists also foster communication between the public and private sectors to develop solutions that meet both the requirements of business and the broader needs of protecting the public from harmful medical devices. One outcome of these activities is to allow manufacturers to more efficiently conduct product development and manufacturing of billions of syringes, which will lead to savings for manufacturers while ensuring the safety of patients.

ORA scientists leveraged ongoing research with federal partners and academia to develop new analytical methods using advances in technology. One specific scientific collaboration between ORA labs and MIT/Harvard on the fracture of stents was cited by the Science Board to the FDA as a model federal government-academia collaboration.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2011: 148 Target: 125 (Target Exceeded)	131	131	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2011: 1,697 Target: 1,175 (Target Exceeded)	1,300	1,300	Maintain

Mammography Quality Standards Act (MQSA) – Center Activities
FY 2012 Enacted Amount: $9,131,120 (BA: $3,128,120 / UF: $6,003,000)

Public Health Focus

CDRH administers the Mammography Quality Standards Act (MQSA) to ensure the quality of mammography services. MQSA provides national quality standards for mammography and assures that mammography facilities meet these standards. These activities, combined with new and improved treatment methods, led to a decline in breast cancer morbidity and mortality in the United States.

Through MQSA activities, CDRH is able to achieve the important FDA, HHS, and Administration priorities of:

- improving health care quality and patient safety
- strengthening compliance and enforcement activities to support public health
- transforming health care by reducing the growth of healthcare costs while promoting high-value, effective care.

Public Health Outcome

MQSA requires FDA-approved accreditation bodies to evaluate and accredit mammography facilities based on quality standards. Once accredited, FDA or an FDA-approved State certifying agency grants the facility a certificate so that it can legally operate. FDA, along with its State contract partners, annually inspects each of the approximately 8,650 certified mammography facilities in the United States. As a result of the MQSA program, over 83 percent of the facilities are free of violations at the time of inspection, and less than half of one percent of facilities are cited with the most serious Level I violations. CDRH works with facilities that are not in compliance to bring them into compliance. If these efforts fail, MQSA allows a variety of sanctions to be imposed, including certificate revocation and suspension.

Promoting Efficiency

CDRH continually strives to improve its MQSA program, streamline its efficiency, and reduce costs. These efforts include stretching resources to develop and publish online training for state inspection partners and regulated industry. In FY 2011, CDRH provided two-thirds of MQSA training online for inspectors, thereby reducing access time and travel expenses for FDA and State partners. In addition, mammography facilities, manufacturers, inspectors, and the general public can easily obtain up-to-date information on MQSA program regulations and guidance at FDA's mammography webpage: (http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm).

Mammography Quality Standards Act – Field Activities
FY 2012 Enacted Amount: $15,820,000 (BA: $2,743,000/ UF: $13,077,000)

Public Health Focus

To protect consumers and advance public health for women, ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the states, which includes an annual audit of state inspections and FDA-provided training for state inspectors.

Public Health Outcome

The ORA Field force supports the MQSA program by managing state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries. The Field:

- inspects certified mammography facilities
- conducts follow-up inspections to determine compliance with terms of corrective action plans based on non-compliances found during prior inspections
- performs on-site quality assurance audits of FDA and State MQSA inspectors to ensure their proficiency in conducting mammography facility inspections.

To ensure high quality facility inspections conducted by the states, ORA coordinated with CDRH to offer annual MQSA training courses to new state inspectors as well as to provide continuing education for certified state inspectors.

Promoting Efficiency

ORA works with the states to maintain MQSA contract program quality standards, which ensure that women receive high quality mammography for early breast cancer detection. Maintaining the contract program through collaboration with qualified state partners maximizes resources dedicated to MQSA and ensures that a greater number of mammography facilities are inspected each year than could be accomplished by an individual program alone.

Performance Measures

The following table lists the performance measure associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	FY 2010: 97% FY 2010 Target: 97% (Target Met)	97%	97%	Maintain

Information Technology Investments – Devices and Radiological Health Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $61,052,843)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state-of-the-art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities. This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In addition to investments in IT infrastructure and enterprise-wide systems, CDRH-specific IT planning and development efforts support the Center's strategic priorities. CDRH adheres to the concept of managing the total product life cycle of medical and radiological products, including premarket evaluation and review, oversight of production practices, and tracking and evaluation of products in the marketplace. The IT systems that CDRH develops are tailored to enhance or expand the total product life cycle and continue the movement away from a paper environment to an electronic environment. CDRH builds externally facing systems that help the public and regulated industry to address information requirements and interact with the Agency, and inward facing systems that provide the data and information necessary for CDRH to perform its mission efficiently.

To achieve its strategic priorities, CDRH depends heavily on modernized IT, informatics standards, and the continued migration from paper to standardized electronic submissions and communications. In addition to maintaining and/or enhancing existing IT systems, CDRH leverages commercial off the shelf (COTS) software and services, government off the shelf (GOTS) and FDA technologies and initiatives to help achieve those objectives. Two examples for FY 2013 are the Unique Device Identification (UDI) database and the adverse event reporting system (CDRH FAERS).

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2008 through FY 2012 for the Devices and Radiological Health Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$275,284,000	$237,734,000	$37,550,000	1,564
FY 2009 Actual	$345,311,000	$298,536,000	$46,775,000	1,707
FY 2010 Actual	$369,971,000	$313,452,000	$56,519,000	1,801
FY 2011 Actual	$378,509,000	$322,182,000	$56,327,000	1,902
FY 2012 Enacted	$375,989,000	$322,672,000	$53,317,000	1,866

Summary of the Budget Request

The FY 2013 budget request for the Devices and Radiological Health Program is $386,766,000. This amount is an increase of $10,777,000 above the FY 2012 Enacted Level. The Center for Devices and Radiological Health amount in this request is $285,168,000 supporting 1,413 FTE. The Field amount is $101,598,000 supporting 531 FTE.

The FY 2012 Enacted funding for the Devices and Radiological Health Program is $375,989,000, which includes $280,655,000 for the Center for Devices and Radiological Health Center activities and $95,334,000 for the Devices and Radiological Health Program Field activities.

The FY 2012 Enacted funding allows the Devices and Radiological Health Program to protect and promote public health by ensuring the safety and effectiveness of medical devices that Americans rely on every day while facilitating scientific innovations that extend and improve lives. To accomplish its regulatory responsibilities, the Devices and Radiological Health Program executes the activities of the following mission-essential subprograms:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement, and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA)

The initiative proposed under the FY 2013 budget request supports HHS, FDA and Presidential public health priorities to advance medical countermeasures. This investment fosters the rapid and reliable development of medical countermeasures to respond to public health threats and ensure Americans have access to the medical devices needed to counter a deliberate chemical, biological, radiological or nuclear (CBRN) attack or a naturally occurring epidemic.

Budget Request

Pay Increase (Commissioned Corps): (Total Program: +$227,000)

The request for $319,127,000 in total BA for the Devices and Radiological Health Program reflects a pay increase for the Commissioned Corps. The Center's portion of this increase is $169,000, and the Field's portion is $57,000.

Data Consolidation and IT Savings (Total Program: -$2,851,000)

The request for $319,127,000 in total budget authority for the Devices and Radiological Health Program also reflects data consolidation and IT savings reduction of -$2,851,000 for FY 2013. The Center's portion of these savings is -$2,133,000, and the Field's portion is -$717,000.

The Devices and Radiological Health Program will achieve the savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.

- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.

- Implementing strategic reductions of process submission enhancements to CDRH e-submission systems

- Implementing strategic reductions of support and planned improvements to CDRH systems

- Streamlining user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance

Services (MARCS) program, and providing the support architecture for other integrated systems

- Economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems

Rent Absorption (-$1,644,000 / -8 FTE)

The Devices and Radiological Health Program will absorb part of the cost of the FY 2013 inflationary rent increase, resulting in the loss of eight FTE for CDRH public health activities.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

Premarket Device Review

Center Activities – (FY 2012 Enacted Amount: $133,382,559 (BA: $110,820,346 / UF: $22,562,213)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$5,185,266 / 31 FTE)
FY 2013 Increase for MDUFA: (+$4,703,266 / 29 FTE)

2013 Initiatives

Advancing Medical Countermeasures (MCM) Initiative: (+$482,000 / 2 FTE)

> **Objective 1 –** Optimizing the Review Process for MCM by Establishing Public Health and Security Action Teams (PHSATs): (+$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to operationalize its Public Health and Security Action Team to support pediatric, pregnancy, and special population issues and next-generation assessment of MCM safety and efficacy during public health emergencies. In addition, FDA will implement authorities to foster the development and deployment of MCMs including: (1) strengthening its program to provide technical assistance to the developers of the highest-priority MCMs; and (2) establishing a program to issue pre-event EUAs.

> **Objective 3 –** Optimizing the Legal, Regulatory and Policy Framework for Effective Public Health Response: (+$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to continue to work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM

development and availability to ensure these adequately support emergency preparedness and response. These efforts include strengthening its program to implement authorities to enhance rapid deployment and pre-event planning and positioning of MCMs.

Field Activities – (FY 2012 Enacted Amount: $8,465,000 (BA: $7,457,000 / UF: $1,008,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$221,000 / 0 FTE)
FY 2013 Increase for MDUFA: (+$221,000 / 0 FTE)

Postmarket Safety

Center Activities – (FY 2012 Enacted Amount: $50,032,538 (BA: $44,307,671 / UF: $5,724,867)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,193,392 / 5 FTE)
FY 2013 Increase for MDUFA: (+$1,193,392 / 5 FTE)

Field Activities – (FY 2012 Enacted Amount: $791,000 (BA: $739,000/ UF: $52,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$0 / 0 FTE)

Compliance, Enforcement, and Radiation Safety

Center Activities – (FY 2012 Enacted Amount: $37,212,387 (BA: $37,212,387 / UF: $0)

FY 2013 Total Change from FY 2012 Enacted Level: ($0 / 0FTE)

Field Activities – (FY 2012 Enacted Amount: $68,474,000 (BA: $68,474,000/ UF: $0)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$7,185,000 / 39 FTE)
FY 2013 Proposed User Fees (Medical Product Reinspection): (+$3,579,000 / 24 FTE)
FY 2013 Proposed User Fees (International Courier): (+$3,606,000 / 15FTE)

Device Innovation and Regulatory Science

Center Activities – (FY 2012 Enacted Amount: $50,896,397 (BA: $46,006,476 / UF: $4,889,921)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,260,341 / 6 FTE)
FY 2013 Increase for MDUFA: (+$1,019,341 / 5 FTE)

2013 Initiatives

Advancing Medical Countermeasures (MCM) Initiative: (+$241,000 / 1 FTE)

> **Objective 2 –** Advancing Regulatory Science for MCM Development and Evaluation: (+$241,000 / 1 FTE)

FDA will use FY 2013 proposed increases to sustain extramural MCM regulatory science partnerships with industry, academia and U.S. government partners to enable FDA to harness cutting-edge science and apply innovative approaches to the regulatory process to improve MCM development timelines and success rates. Focus areas for FDA investments in regulatory science include: 1) developing methods to assess product quality and assays to support the release of MCMs; 2) developing and assessing advanced diagnostic tests; and 3) novel manufacturing platforms.

Field Activities – (FY 2012 Enacted Amount: $1,784,000 (BA: $1,784,000 / UF: $0)
FY 2013 Total Increase above FY 2012 Enacted Level: (+$0/ 0 FTE)

Mammography Quality Standards Act (MQSA)

Center Activities – (FY 2012 Enacted Amount: $9,131,120 (BA: $3,128,120 / UF: $6,003,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$0 / 5 FTE)

Field Activities – (FY 2012 Enacted Amount: $15,820,000 (BA: $2,743,000 / UF: $13,077,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$0 / 0 FTE)

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 President's Budget
Expedited PMA Received	7 [1/]	6	6
Expedited PMA Approved	3 [2/]	4	4
Expedited PMA – Performance	90% [3/]	60%	60%
PMAs Received (PDP and PMA)	45	45	45
PMAs Approved (PDP and expedited)	30	30	30
Original PMA performance	90% [3/]	60%	60%
PMA Supplement Panel Tracks Received	8	12	12
PMA Supplement Panel Track Approved	9	10	10
Panel Track PMA Supplement Performance	90% [3/]	60%	60%
Humanitarian Device Exemptions Received	8	6	6
Humanitarian Device Exemptions Approved	3	4	4
Average HDE FDA Review Time (FDA days approval)	294	300	400
PMA Supplements Received	148	160	160
PMA Supplements Approved	153	155	150
510(k)s Received (Trad., Special, Abbrev., 3rd party)	3,839	4,100	4,100
510(k)s Completed (All Decisions)	3,922	3,700	3,500
510(k) performance	98% [3/]	80%	80%
Investigational Device Exemptions Received	227	240	240
Investigational Device Exemptions Decisions	236	230	230
% Acted on Within 30 Days	100%	99%	99%
Investigational IDE Supplements	3,764	3,900	3,900
IDE Supplements (Approved/Total Decisions)	3,781	3,800	3,800
% Acted on Within 30 Days	100%	100%	100%
Total Standards Recognized for Application Review	939	980	1020

[1/] Received submissions based on the FY 2011 receipt cohort
[2/] Approved submissions based on the FY 2011 decision cohort
[3/] FY 2011 performance figures are estimates as the cohort is not yet mature enough to report complete figures.

Combined Field Activities – ORA
Program Activity Data

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,529***	***2,709***	***2,709***
Bioresearch Monitoring Program Inspections	317	302	302
Pre-Market Inspections	56	68	68
Post-Market Audit Inspections	39	46	46
GMP Inspections	1,713	1,567	1,567
Inspections (MQSA) FDA Domestic (non-VHA)	329	549	549
Inspections (MQSA) FDA Domestic (VHA)	37	43	43
Domestic Radiological Health Inspections	104	205	205
Domestic Field Exams/Tests	193	193	193
Domestic Laboratory Samples Analyzed	211	211	211
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***408*** [1]	***473***	***473***
Foreign Bioresearch Monitoring Inspections	17	31	31
Foreign Pre-Market Inspections	30	33	33
Foreign Post-Market Audit Inspections	16	19	19
Foreign GMP Inspections	335	380	380
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	35	40	40
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,937***	***3,182***	***3,182***
IMPORTS			
Import Field Exams/Tests	20,925	20,925	20,925
Import Laboratory Samples Analyzed	1,170	1,170	1,170
Import Physical Exam Subtotal	**22,095**	**22,095**	**22,095**
Import Line Decisions	9,584,415	10,411,972	11,310,984
Percent of Import Lines Physically Examined	0.23%	0.21%	0.20%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,123***	***8,277***	***8,287***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	***45***	**45**	**45**
Inspections (MQSA) by State Contract	7,004	7,147	7,147
Inspections (MQSA) by State non-Contract	1,103	1,110	1,115
GMP Inspections by State Contract	16	20	25
State Partnership GMP Inspections	45	50	55
State Contract Devices Funding	$77,516	$182,200	$193,100
State Contract Mammography Funding	$9,144,255	$9,964,320	$10,562,170
Total State Funding	**$9,221,771**	**$10,146,520**	**$10,755,270**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,105***	***11,504***	***11,514***

[1] The FY 2011 actual unique count of foreign inspections includes 11 OIP inspections (6 for China and 5 for India).

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$60,543**	**$60,563**	**$60,039**	**$59,231**	**-$808**
Center	$60,543	$60,563	$60,039	$59,231	-$808
FTE	215	272	272	270	-2
Program Level FTE	**215**	**272**	**272**	**270**	**-2**
Budget Authority	**$60,543**	**$60,563**	**$60,039**	**$59,231**	**-$808**
Center	$60,543	$60,563	$60,039	*$59,231*	*-$808*
Budget Authority FTE	**215**	**272**	**272**	**270**	**-2**

FDA's National Center for Toxicological Research (NCTR) operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act [21 U.S.C. 393(b) (1)]
Food and Drug Administration Modernization Act [1]
Food and Drug Administration Amendments Act of 2007 [1]

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

Established in 1971 as a national scientific resource, NCTR conducts toxicology research that translates knowledge and technology into processes that improve the ability of FDA and others to assess the safety of FDA-regulated products.

Science is the foundation of FDA's regulatory decision-making process and is vital to protecting and promoting the health of American consumers. Within FDA, NCTR interdisciplinary scientific experts conduct peer-reviewed research to identify health and safety issues related to new medical products, and to evaluate new safety concerns identified with established products. NCTR also conducts research on the risks and benefits of medical products and America's food supply – and thereby advances the FDA mission of protecting patients and consumers across the full spectrum of FDA regulated products.

In keeping with its mission, NCTR is responsible for protecting and promoting the public health by conducting regulatory research to:

[1] Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

- identify early predictors of toxicity-risk from FDA-regulated products
- develop, validate, and provide guidance for new technologies and regulatory tools that facilitate premarket review, postmarket safety assurance, and risk-based product safety decisions
- develop key research data for high-priority safety issues, such as pediatric anesthetics
- develop analytical tools to rapidly detect food contamination
- evaluate the biological effects of potentially toxic chemicals and microorganisms
- support personalized medicine including individualized therapy and identification of disease susceptibility.

The research at NCTR supports FDA's strategic priorities and guiding principles to:

- advance regulatory science and innovation with new scientific tools, technologies, and approaches critical for translating science into improving public health
- base FDA policies, regulations, and enforcement decisions on sound science
- provide the public with the accurate, science-based information needed to use medicines and foods to maintain and improve their health
- improve global public health through international collaboration including research and training
- ensure safety of the food supply from farm to table
- promote public health by advancing the safety and effectiveness of medical products.

NCTR provides expert technical advice and training to colleagues and leads national and international collaborations. NCTR-offered training enhances FDA's basis for sound science-based regulatory decisions that improve the health of the American people. NCTR supports FDA's strategic priority to "Advance Regulatory Science and Innovation" by leveraging resources through collaborations with government, industry, and academic partners to:

- address regulatory review needs
- develop innovative solutions and tools to address complex safety issues
- promote the international standardization and global harmonization of regulatory science.

In an effort to streamline work and reduce redundancy, NCTR examined its scientific focus, and as a result, redefined its subprograms — narrowing them from three to two subprogram areas:

- Evaluating Toxicity of FDA-Regulated Products
- Modernizing Toxicology to Support the FDA Mission.

Evaluating Toxicity of FDA-Regulated Products – Center Activities
FY 2012 Enacted Amount: $23,713,000 (All BA)

Public Health Focus

NCTR conducts research to evaluate the toxicity of FDA-regulated products with the goal of improving personal and public health. This research can save lives, increase patients' quality of life, and generate savings for all those who pay the cost of health care by:

- identifying early predictors of toxicity for FDA-regulated products
- defining and characterizing individual responses to FDA-regulated products
- identifying food-related health hazards to assist FDA in establishing science-based prevention standards
- defending the food system against bioterrorism.

NCTR's research in this subprogram supports the Department of Health and Human Services' (DHHS) priorities to:

- accelerate scientific advances in quality health outcomes
- improve health care quality and patient safety
- reduce health care costs
- implement a 21st century food safety system.

FSMA Strategy within the Evaluating Toxicity of FDA-Regulated Products Subprogram:

Within NCTR's Evaluating Toxicity of FDA-regulated Products subprogram, the FY 2013 resources will support FDA's multi-year effort to implement and enforce the FDA Food Safety Modernization Act (FSMA) and key priorities of the President's Food Safety Working Group to better protect public health by *preventing* food safety problems rather than primarily *reacting* to problems after they occur.

NCTR will conduct research to identify food-related health hazards and defend the food system against both the known and unknown sources of foodborne illness, such as Salmonella, and bisphenol A (BPA) found in food containers. Scientific research and analysis are especially critical to providing the basis for developing appropriate regulations and guidances for unknown sources of illness such as BPA. NCTR research also provides baseline data on the spread of multi-drug resistance, the increased virulence of foodborne pathogens and helps to determine what factors impact the development and dissemination of antimicrobial resistance in *Salmonella* strains.

This research is designed to decrease the frequency and severity of food- and feed-borne illness outbreaks and greatly diminish the burden on the U.S. economy due to these events.

NCTR research efforts also focus on developing techniques that will decrease detection time and improve monitoring antibiotic resistance among *Salmonella* in food samples allowing FDA to set standards and improve the speed and effectiveness of outbreak and contamination response.

Public Health Outcome

NCTR research will lead to:

- identification of product problems sooner so FDA can take faster action to protect the public health
- lower costs for industry, the health-care system, and ultimately the consumer because potential adverse effects can be identified earlier in the product development cycle, saving time and money
- new understanding of a contaminant's toxicity and the relationship to levels of exposure so that improved guidelines for use can be issued
- identification of an *individual's* response to a food, drug, nutrient, or environmental chemical, resulting in improved personal health
- strategies to reduce the occurrence of multi-drug resistant microorganisms and key pathogens in the U.S. food supply that can be used by FDA Product Centers to support the FSMA.

Promoting Efficiency

NCTR's research to support the "Evaluating Toxicity of FDA-Regulated Products" subprogram has the potential to save lives, increase patients' quality of life, and generate savings for the cost of health care.

Liver toxicity has been linked to as many as 1,000 drugs [Abboud and Kaplowitz, 2007] and is the second leading cause of acute liver failure in the United States – making it the most likely reason a drug is withdrawn from the market. As a result, NCTR's efforts to create a knowledge base of liver toxicity-related information support the development of predictive tools for identifying liver toxicity throughout the drug-development cycle, reduce the expense – both economic and patient health – of withdrawing drugs after they are on the market, and protect patients from liver injury.

The Centers for Disease Control and Prevention (CDC) estimates that approximately 76 million new cases of food-related illness – resulting in 5,000 deaths and 325,000 hospitalizations – occur in the United States each year. . NCTR's research provides scientific methods to identify foodborne pathogens, their sources, and ways to rapidly determine the spread of antibiotic resistance and the virulence of foodborne pathogens. This research will improve FDA's ability to identify the sources of bacterial contamination along the food supply chain and thereby help avoid associated health care costs and other economic burdens associated with foodborne illnesses.

Under this subprogram, NCTR conducts research to advance the safety of FDA-regulated products. Examples of this research and some of NCTR's accomplishments are described below:

Acetaminophen-Induced Liver Toxicity – NCTR scientists are conducting research to investigate the potential interaction between acetaminophen-induced hepatotoxicity (liver toxicity) and dietary supplements. Most dietary supplements have limited safety information, and most consumers think that supplements are inherently safe. It is possible that dietary supplements could increase the hepatotoxicity of acetaminophen, rendering a normally safe therapeutic dose harmful.

Recent NCTR studies conducted in mice have assessed the interaction of green tea extract, gingko biloba, and kava with acetaminophen. Research findings indicate that green tea either provides protection against or enhances the hepatotoxicity of acetaminophen depending on whether the tea is consumed before or after the dose of acetaminophen. Findings also indicate that kava enhances the hepatotoxicity of acetaminophen while gingko biloba had no effect. NCTR scientists are expanding this research to include other dietary supplements.

Leflunomide-Induced Liver Toxicity – NCTR scientists have shown increased toxicity in primary rat-liver cells caused by the anti-arthritic drug, leflunomide. The Black Box Warning for leflunomide was recently updated with stronger warnings about potential hepatotoxicity. Studies indicate that toxicity is caused by leflunomide and its major metabolite — the product that remains after the drug is broken down, or metabolized, by the body.

Furthermore, NCTR results indicate that drugs, dietary components — including dietary supplements and herbal remedies such as St. John's wort and certain fruits such as grapefruit — may affect the safety of leflunomide. An NCTR manuscript describing this study was accepted for publication in *Toxicological Sciences* in early 2011.

Evaluation of Potential Toxicity for Bisphenol A (BPA) – FY 2013 budget authority funds will allow NCTR to continue conducting research on BPA to provide FDA with a better understanding of the risk of BPA exposure in various stages of human development.

BPA is an environmental and food contaminant under great scrutiny from the public, academia, and government agencies worldwide. Because of its widespread use in consumer products such as storage containers for foods and beverages, and in medical devices, people are exposed to trace levels of BPA on a daily basis. According to the 2003-2004 National Health and Nutrition

Examination Survey, 93% of urine samples from people ages six and older had detectable levels of a BPA metabolite.

Health concerns about BPA are currently focused on its potential to disrupt normal hormone functions, particularly during perinatal development. Therefore, FDA needs more scientific data to assess the health risks from BPA, especially for sensitive populations such as neonates and pregnant women.

NCTR began conducting comprehensive research on BPA in partnership with the National Institutes of Environmental Health Science/National Toxicology Program in FY 2010 and builds on this research. One of these studies in nonhuman primates and rats is determining exposures to BPA in the fetus resulting from the mother's exposure to BPA and in newborns exposed directly to BPA. Data from these animal models will be combined with human data from the general population collected by the Centers for Disease Control and Prevention (CDC) for predictive modeling. Additionally, NCTR scientists are seeking to determine possible toxic effects in rats exposed to a wide range of BPA doses from conception through adulthood. As a result of this research, FDA will be better prepared to regulate the use of BPA.

NCTR research scientists use state-of-the-art analytical methodology to measure trace levels of BPA that enter the human body after consuming canned foods or in children undergoing surgery involving plastic medical devices which contain BPA. These measurements will help FDA understand the amounts of BPA consumed through foods and medical devices and the way in which the body detoxifies and removes BPA from the system.

Funding will allow NCTR to conduct a follow-on study that will use mathematical models to combine BPA exposure information from the experimental animal studies with those in people. The ultimate goal is to provide a scientific foundation for a risk assessment with minimal uncertainty by predicting levels of the bioactive form of BPA in the developing human as compared to those that could cause toxicity in laboratory animals.

Neurological Effects of Pediatric Anesthetics – Each year in the United States alone, more than one million children four years of age or less undergo surgical procedures requiring anesthesia.[2] NCTR scientists are evaluating the neurological effects of pediatric anesthetic use in developing nonhuman primates, an animal model closely related to humans. Concern over the use of ketamine, an anesthetic widely used in pediatric medicine, increased after animal experiments demonstrated increased neuronal-cell death when exposures occur during periods of rapid-brain development. NCTR studies conducted on animals exposed to ketamine suggest that cell death from ketamine exposure continues much longer than previously thought.

[2] Rabbitts J, Groenewald CB, Moriarty JP, Flick R. Epidemiology of Ambulatory Anesthesia for Children in the United States: 2006 and 1996. Anesth Analg 2010; 111: 1101-15.

Other NCTR research results demonstrate that Positron Emission Tomography (PET) imaging, in combination with a molecular tracer, provides a minimally invasive approach for monitoring brain-cell death with enough sensitivity to pinpoint different brain areas that are affected. In FY 2011, NCTR published research demonstrating that a single 24-hour episode of general anesthesia induced by ketamine during the first week of life causes long-lasting deficits in the cognitive abilities of nonhuman primates. The deficits are exhibited as decreased learning abilities that remain apparent for well over three years after the exposure without evidence of lessening over time. These findings and other researchers' findings prompted FDA's Center for Drug Evaluation and Research (CDER), Division of Anesthesia and Analgesia Products, to convene an Advisory Committee meeting to review recent studies on the use of anesthesia in the pediatric setting.

Assessing the Genotoxicity of Medical Products – A recent European regulatory decision prompted concern from FDA regulators and initiated research at NCTR both to challenge the conclusions reached in the European drug-contamination case and to develop methods to determine the "no-effect threshold"[3] of agents that cause genetic DNA (deoxyribonucleic acid) changes or are capable of causing cancer.

FDA regulators are concerned that the methods used to make regulatory decisions in Europe regarding drug-contamination events may be used as a guide in future events where "no-effect thresholds" are claimed for those agents. The NCTR research is increasing the sensitivity of the test methods for detecting low-dose effects and measuring the effects of exposure to genotoxic-compounds in neonatal as well as adult animals. This project will give FDA regulators vital information on how to treat future claims of "no-effect thresholds" when making regulatory decisions.

Antimicrobial Resistance of Foodborne Pathogens – FY 2013 budget authority funds will allow NCTR to continue supporting the Food Safety Modernization Act by conducting research that helps FDA establish risk-based strategies for antibiotic use in food-animal production. This research provides baseline data on the spread of multi-drug resistance and increased virulence of foodborne pathogens which can be used to strengthen risk assessments FDA uses to set antimicrobial drug-residue limits in animal products.

[3] the dose of a substance below which there is no biological effect

In FY 2010, NCTR scientists completed a study characterizing the genetic basis for multidrug-resistance in *Salmonella* strains isolated from human patients. The genetic similarity among strains isolated from human patients, animals, and food indicates the potential for food to serve as a source for multidrug-resistant human infections. Funding will allow NCTR to conduct follow-up work on this study that aims to determine what factors impact the development and dissemination of antimicrobial resistance in *Salmonella* strains associated with food animals and human infections.

Additionally, NCTR researchers performed DNA sequencing on plasmids — circular units of DNA — isolated from multidrug-resistant strains of *Salmonella*. Many of the plasmids, which are often able to spread genetic factors from one type of bacteria to another, were found to contain multiple antimicrobial resistance and virulence genes. Plasmids with both resistance and virulence genes are concerning because these plasmids could potentially increase disease-causing ability, while at the same time limiting potential treatment options which could result in a public-health crisis. Results of sequencing studies from *Salmonella* strains were recently accepted for publication in the journal *Food Research International* and were presented at the Annual Meeting of the American Society of Microbiology in May 2011.

To aid in risk assessment, scientists from NCTR and FDA's Office of Regulatory Affair's (ORA) Arkansas Regional Laboratory characterized antimicrobial resistance mechanisms and virulence genes in 81 strains of *Aeromonas veronii* isolated from farm-raised catfish. These studies illustrate that farm-raised catfish can serve as reservoirs for multiple virulence and antibiotic resistance genes.

Currently, NCTR researchers are examining *Aeromonas* isolated from imported shrimp for the presence of virulence and antimicrobial resistance genes. Although adequate cooking should eliminate pathogenic bacteria, undercooking or cross-contamination of utensils during the preparation of fish and seafood is a concern for the spread of sickness and a possible spread of antibiotic resistance.

In addition, NCTR researches factors that lead to infections caused by *Salmonella*, resulting in many cases of serious illnesses each year in the United States. NCTR scientists have characterized multiple *Salmonella* strains from various food sources using:

- molecular fingerprinting
- virulence factor analysis
- antimicrobial resistance profiling
- plasmid analyses

These studies can be used as part of an integrated strategy to evaluate the potential risks associated with *Salmonella* contamination along the food production, processing and consumption continuum. Improved pathogen-characterization schemes and strategies will enable FDA investigators to identify

the sources of bacterial contamination and suggest intervention strategies to improve public health. NCTR presented some of the results of these studies at the International Association for Food Protection meeting in Milwaukee, Wisconsin in July 2011.

Other NCTR research aims to decrease the detection time of contaminants by developing techniques that will improve monitoring antibiotic resistance among *Salmonella* in imported and domestic food samples. The current official FDA cell-culturing methods are time-consuming and labor-intensive, resulting in slower pathogen detection by regulatory laboratories. The new techniques offer a rapid means to detect *Salmonella* and facilitate simultaneous detection of antibiotic-resistance markers in food samples. NCTR is evaluating these new techniques in collaboration with ORA.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates. *(Output)*	FY 2011: 1) Preliminary data was presented as part of a panel organized to highlight the public launch of the SmartTots, a public-private partnership. (Target Met) 2) Study completed on co-exposure to melamine and cyanuric acid that adds support to the use of the five biomarkers as indicators of kidney injury and their corresponding gene expression (Target Met)	1) Establish an imaging consortium of scientific experts from NCTR, CDER, and from other government agencies, industry, and academia to refine the imaging tools 2) Determine pathways of toxicity and preventive strategies for pediatric anesthetics using a high-speed, high-volume method (zebrafish)	1) Determine if prolonged exposure to anesthetic agents nitrous oxide or isoflurane alone or in combination will induce long-lasting neuropathological changes. 2)Assess genetic changes in the liver from exposure to Tamoxifen. 3)Develop enhanced models to determine the potential impact of different antimicrobial exposures.	N/A

Modernizing Toxicology To Support the FDA Mission

FY 2012 Enacted Amount: $36,326,000 (All BA)

Public Health Focus

NCTR conducts research to modernize toxicology with the goal of improving personal and public health in support of FDA's mission. This research will result in new technologies and standards that provide enhanced risk assessment for reviewers and a stronger base for public-health assurance for new and existing products by:

- identifying and developing innovative tools and using new technologies to evaluate the toxicity of FDA-regulated products
- developing, validating, and providing guidance to FDA product centers for the use of new technologies
- developing new rapid-detection methods for regulated-compound contaminants
- characterizing biomarkers that will allow FDA to identify science-based individualized treatment therapies that increase treatment effectiveness and reduce the rate of adverse events in patients

NCTR's research in this subprogram supports the Department of Health and Human Services' priorities to:

- foster innovation
- accelerate scientific advances in quality health outcomes
- improve health care quality and patient safety
- reduce health care costs
- implement a 21st century food safety system.

FSMA Strategy within the Modernizing Toxicology to Support FDA's Mission Subprogram:

Within NCTR's Modernizing Toxicology to Support the FDA Mission subprogram, the FY 2013 resources will support FDA's efforts to achieve the Administration's vision of a strong, reliable food safety system that also sustains the economic health of all segments of America's food industry.

Funding will allow NCTR to focus research activities on novel sources, such as the disposition of nanoscale silver once ingested from either food-contact nanomaterials or dietary supplements. Using FY 2013 budget authority funds, NCTR will continue to improve and implement data-driven tools, such as the data-management tool ArrayTrack™, including a genomics knowledge base to allow for better analysis of genomics and gene expression data to speed up the understanding of how foodborne pathogens contribute to disease.

Funding will also allow NCTR to continue studies to extend the RAPID-B on-site surveillance method to target contaminants other than bacteria, such as viruses, parasites, and even very small particles.

Public Health Outcome

NCTR's research will lead to:

- biomarkers of risk identified for FDA reviewers, which will decrease the uncertainty, time, and expense of product development and improve FDA's ability to protect the public health
- improved imaging capabilities to track the effects of disease noninvasively and produce biomarkers as predictors of potential toxicity
- prevention of recurring illness as a result of expanded imaging capabilities, which reduces the need for costly and dangerous surgical procedures
- improved personalized medicine that will save the American public, the American health-care system, businesses, and the government the cost of medical products and therapies that are not safe or effective for individual patients
- potential for significant savings and long-term beneficial consequences for the health-care system and for the American public by reducing obesity and the associated chronic conditions in the U.S.
- improved FDA ability to identify the sources of bacterial contamination along the food supply chain
- innovative tools and science necessary to better evaluate the toxicity of FDA-regulated products
- rapid, reliable, and cost-effective methods to detect and determine the source of contaminants in food, resulting in health alerts issued faster to the public during an outbreak associated with consumption of contaminated foods
- new methods to assess mechanisms of antimicrobial resistance in foodborne pathogens, which will help mitigate their spread.

Promoting Efficiency

NCTR's research in the "Modernizing Toxicology to Support the FDA Mission" subprogram has the potential to revolutionize health care, save lives, increase patients' quality of life, and generate savings for all those who pay the cost of health care.

The new wave of medicine and health care is clearly seen in research and by the advances in personalized medicine. These advances can identify patients most likely to benefit from or experience adverse reactions from particular drugs. Through more personalized treatments, the American public, the American health care system, businesses and governments that pay health care costs will save time and money. Investment in this research will allow all parties to escape

the cost and failed expectations associated with medical products and therapies that are not safe or effective for individual patients.

Similarly, the interactions between foods, nutrients, and dietary supplements with an individual's genetic make-up can be characterized and used to address safety concerns and health issues, including obesity and the diseases exacerbated by or linked to obesity. Decreasing the incidence of obesity will have long-term beneficial consequences for Americans and the health care system. Obesity and the associated chronic conditions cost the U.S. health care system up to $147 billion a year. A small decline in obesity rates can produce significant savings for the health care system and for the American public.

The American public will also benefit from NCTR's imaging capabilities which are providing the development of noninvasive biomarkers used to track the effects of strokes in a noninvasive manner, reducing complications incurred with invasive methods. Using these biomarkers also offers the possibility of preventing recurring strokes, preventive treatments, and the reduction of costly and dangerous surgical procedures.

Under this subprogram, NCTR conducts research on new technologies and approaches to assess risk and assure the safety of products that FDA regulates. Examples of this research and some of NCTR's accomplishments are described below.

Biomarker Development for Early Detection of Liver Toxicity – Biomarkers are critical for the assessment of drug toxicity and for earlier detection of drug-induced organ toxicity. Liver toxicity is the most likely reason why drugs are withdrawn from the market, and liver toxicity is the second leading cause of acute liver failure in the United States. Liver toxicity has been linked to as many as 1,000 drugs [Abboud and Kaplowitz, 2007].

NCTR formed the Hepatotoxicity Working Group with experts from FDA, the pharmaceutical industry, and academia to identify the research needs of drug-induced liver injury. NCTR is collaborating with the working group and other government agencies to conduct studies to identify novel biomarkers for liver toxicity. Liver toxicity is usually investigated using animal-based studies which, unfortunately, fail to detect all compounds that induce human adverse events and do not provide detailed toxicity information. NCTR will supplement animal testing with a battery of *in vitro* and omics [4] technologies. The information and the biomarker models derived from this research will be useful when liver toxicity issues arise during the various stages of the FDA regulatory review process.

NCTR scientists are conducting a large project using multiple omics technologies to identify more sensitive and specific biomarkers of hepatotoxicity including:

[4] Omics sciences are fields of study in biology ending in "-omics" such as genomics,transcriptomics, proteomics.

- genomics – study of all genes of a cell or tissue
- transcriptomics – study of messenger RNA (recombinant DNA) molecules which can vary with external environment conditions
- proteomics – study of proteins
- metabolomics – study of chemical processes involving metabolites

In particular, the project focuses on using omics technologies in combination with preclinical animal models to identify compounds that are not typically identified as being toxic to the liver — hepatotoxicants. An early finding from this work is that urinary microRNA profiles could separate acetaminophen-treated animals from untreated animals. These results indicate that urinary microRNAs may serve as more sensitive and specific biomarkers of exposure to hepatotoxicants. A manuscript describing this study has been accepted for publication in the *Journal of Postgenomics: Drug & Biomarker Development*.

Liver Toxicity Knowledge Base – Since both prescription drugs and over-the-counter medication can contribute to liver toxicity, this public health issue is of great concern to FDA. To address this public-health issue, a Liver Toxicity Knowledge Base (LTKB) is being developed at NCTR. The LTKB will provide a tool that will improve drug safety, aid in the understanding of liver toxicity and enable the development of predictive tools for identifying liver toxicity issues along the various stages of drug development.

NCTR's efforts to create a database of liver toxicity-related information supports the development of predictive tools for identifying liver toxicity throughout the drug-development cycle and reduces the expense — both economic and patient health — of withdrawing drugs after they are on the market.

In 2010, NCTR scientists developed a set of criteria to select drugs for the Liver Toxicity Knowledge Base — a content-rich resource — and collected risk factors and mechanistic data for them from literature. In FY 2011, NCTR scientists expanded the list of drugs being characterized for their potential risk of liver injury from 287 to approximately 800. Several LTKB models were developed with a positive predictivity over 90%, which far exceeds the performance of the current animal models used in preclinical studies. The LTKB results hold the promise of developing alternative approaches for animal studies to address safety concerns in drug development related to liver injury. In FY 2012, NCTR scientists will develop an integrated strategy to combine various models developed in this project as a tier system to enhance the performance and robustness of the knowledge base.

Identifying Sensitive Subpopulations to Drug-Induced Liver Toxicity – The post-market discovery of unanticipated drug-induced liver toxicity may result from the existence of a small number of sensitive patients who are not detected during pre-clinical and clinical testing. However, when the drug is marketed to large numbers of people in the overall population, the liver toxicity starts to appear

because the number of subjects from the sensitive subpopulation becomes relatively large.

NCTR scientists are developing statistical models and data-mining algorithms using a prototype computerized system to characterize sensitive subpopulations and also to evaluate the potential side effects of drugs with data from the FDA Adverse Event Reporting System (AERS).

With this information, FDA can offer new and current patients the knowledge they need to decide whether they are willing to accept the *toxicity risk* associated with using a drug, or instead, accept the *medical risk* associated with not using a drug. Instead of withdrawing such a drug, the FDA can require the manufacturer to include appropriate warnings and to specify patient-marker criteria for prescribing it. Initial findings have been submitted for publication.

Nonalcoholic-Related Liver Toxicity – NCTR scientists are conducting research in an effort to create new approaches and tools, called epigenetic biomarkers, which can be used in epidemiological and clinical studies to identify individuals in the population who may be susceptible to dietary Nonalcoholic Steatohepatitis (NASH) development. NASH is a progressive form of Nonalcoholic Fatty Liver Disease (NAFLD). NAFLD is the most common cause of chronic liver disease in the United States, which, according to the American Liver Foundation, affects up to 25% of the U.S. population. NASH accounts for a substantial portion of liver-cell carcinoma. The results of these studies may have great significance for the identified vulnerable subpopulations,considering the potential reversibility of epigenetic alterations and novel cancer-prevention approaches.

MicroArray Quality Control Consortium Effort to Establish Standards – This consortium is an FDA-led, community-wide effort to address issues associated with using genomic technology in the scientific community. NCTR initially organized the MicroArray Quality Control (MAQC) project with participants from government, academia, and industry to focus on establishing uniform standards for conducting gene-expression experiments that can be reproduced in both the clinical setting and also by FDA reviewers. Their efforts resulted in an FDA companion guidance document for data submissions involving pharmacogenomics – the study of genetic variation's effects on individual responses to drugs.

The results of the second phase of the MicroArray Quality Control project (MAQC-II), were completed in FY 2010, and are expected to substantially impact the clinical and regulatory use of genomic data. The MAQC-II results were summarized in the 13 manuscripts published by *Nature Biotechnology* (2 papers) and *The Pharmacogenomics Journal* (11 papers), respectively. These manuscripts were republished again as a single supplementary issue by the *Nature Publishing Group*. It is anticipated that findings from MAQC-II will lead to an FDA guidance document to aid industry in developing and validating

microarray-based predictive models as biomarkers for diagnosis, prognosis, and toxicity assessment. The guidance would be a statistical "best practices" on utilizing the microarray data and can be applied to all FDA-regulated products.

The third-phase of the FDA-led MAQC effort, also known as the Sequencing Quality Control (SEQC) project, aims to establish a baseline reference, which can be used to standardize and streamline research using next-generation sequencing technologies. SEQC will help prepare FDA for the next wave of genomic data submissions generated from next-generation sequencing technologies to ensure the safety and efficacy of FDA-regulated products. In FY 2011, NCTR scientists developed a document to serve as guidance for the ongoing SEQC project, which includes over 400 participants from the research community.

Computational Models to Predict Adverse Drug Reactions and Efficacy – A pilot study is being conducted at NCTR and CDER to support the feasibility of utilizing patient-specific genomic information and molecular modeling to understand, predict, and eventually prevent adverse drug reactions. The goal is to develop models based on the patient's genetic make-up to predict how effective a regulated drug will be or if serious adverse drug reactions can be anticipated.

These prediction models may be implemented in an online knowledge base to alert reviewers, physicians, and patients of the potential for a drug to cause a serious adverse drug reaction in individuals carrying particular genetic variants *before* the drug is prescribed to or taken by the patient. These research studies should greatly enhance FDA's capability to detect, understand, predict, and prevent adverse drug reactions.

In FY 2011, researchers from NCTR developed several computational models to understand the underlying mechanisms of adverse reactions related to Stevens Johnson syndrome and other drug-induced diseases.

Mouse Embryonic Stem-Cell Research for Toxicity Testing – FDA scientists are gaining hands-on experience with an embryonic stem cell test (EST) model system. EST is currently used to screen potential drug candidates for possible embryonic toxicity and was validated in Europe as an alternative test for developmental toxicity.

Since animal-derived embryonic stem cells can become any cell type found in the body, EST may provide a path to reducing the number of animals used in safety testing and testing for reproductive toxicity and birth defects. Currently, the EST looks only at differentiation to one cell type, and FDA scientists will be examining differentiation to three or four different cell types.

NCTR-CDER research will also examine additional endpoints and additional cell lines. Collaboration between NCTR, CDER, and FDA's Center for Biologics

Evaluation and Research (CBER) scientists will also use this mouse embryonic stem-cell model system to look at the mechanism whereby some chemicals may produce birth defects.

Stem-Cell Research to Reduce Obesity – The CDC reports that over 70% of men and approximately 64% of women in the U.S. population are overweight or obese, creating a personal and public health crisis. Western diets in addition to sedentary life styles have produced an epidemic of obesity and a rise of obesity-induced metabolic disorders such as type 2 diabetes, atherosclerosis, metabolic syndrome and cardiovascular disorders.

NCTR's main objective is to identify gene-expression changes in stem cells that predispose individuals to obesity and the development of obesity-related metabolic disorders such as Type 2 diabetes. A clearer understanding of fat-tissue biology and the development of obesity are critical to identifying potential disease markers or drug targets leading to better treatment of obesity.

Identifying the genes and dietary components that affect the differentiation of stem cells provides data essential to developing diagnostics and strategies for preventing or delaying the onset of nutrition-related chronic diseases.

- Effects of Genistein – NCTR scientists examined the role of genistein, a natural-occurring chemical found in soybeans and soy-based products, on the differentiation of stem cells present in human fat tissue. Results suggest that genistein inhibited the ability of these stem cells to become fat cells. Researchers study how genistein may be regulating obesity since some *in vivo* studies reported that genistein can promote weight loss while other studies suggest that it may increase weight.

- Effects of Fructose Compared to Glucose – NCTR scientists are examining the effect of fructose on fat cells, because in the development and progression of obesity and type II diabetes, fat tissue may play an important role. Energy imbalance, excess nutrient consumption including excess consumption of refined carbohydrates and sugar-sweetened beverages, can trigger increases in the number and size of fat cells. This increase can result in insulin resistance and other metabolic syndromes. Uptake of fructose changes glucose metabolism within fat cells, which can lead to the development of obesity, insulin resistance, and type II diabetes.

- Adult Stem-Cell Research – Future studies with either adult stem cells or human pluripotent cell lines – cells capable of becoming different cell types – will examine possible adverse effects of nutrients, drugs, or other environmental exposures on various cell types including fat cells, skeletal muscle cells, liver cells, and pancreatic cells. These effects may play a role in the development of obesity and diabetes.

NCTR's continuing research in this area will provide FDA and the medical community insight into the relationship between nutrition and adult obesity.

Genomic Knowledge Base – FY 2013 budget authority funds will allow NCTR to continue, in collaboration with FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the U.S. Department of Agriculture (USDA), to develop the integrated genomic knowledge base that incorporates tools developed for the ArrayTrack™ software system. In FY 2010, several NCTR-developed tools were added to the knowledge base and described in the publication titled, "An FDA Bioinformatics Tool for Microbial Genomics Research on Molecular Characterization of Bacterial Foodborne Pathogens Using Microarrays."

Additionally, FY 2013 budget authority funds will allow FDA to continue developing and integrating additional tools into the knowledge base to allow for a more efficient analysis of genomics and gene expression data to speed up the understanding of how foodborne pathogens contribute to disease. Taken together, the tools in the integrated knowledge base will help accelerate our understanding of foodborne pathogens and aid in identifying their sources.

Rapid Detection Tools and Methodologies to Protect the Food Supply – CDC estimates that approximately 76 million new cases of food-related illness – resulting in 5,000 deaths and 325,000 hospitalizations – occur in the United States each year. FY 2013 budget authority funds will allow NCTR's research to improve surveillance and risk analysis to continue. Data gleaned from this research will help protect the food supply, protect the American public, and reduce the health-care costs and other economic burdens associated with foodborne illnesses.

- RAPID-B Method – LITMUS, LLC, licensed and is deploying RAPID-B, an NCTR-patented method for real-time, on-site surveillance of food for bacterial contamination. FDA and USDA lead an integrated network of food-testing laboratories at the local, state, and federal level – the Food Emergency Response Network (FERN). Commercialization efforts began in 2010 with Litmus, LLC,undertaking a project with a major agricultural biotechnology company for detecting bacteria in crops. Future development includes tests for additional bacterial pathogens and viruses. The system is rugged and can be transported and operated at the field site. In FY 2010, NCTR developed a RAPID-B test for *Mycobacterium tuberculosis* and its Cooperative Research and Development Agreement (CRADA) partner successfully applied it in human sputum as a pilot study. The RAPID-B test is capable of acquiring and reporting results in less than 15 minutes per sample. In FY 2011, NCTR scientists developed methods for the detection of bacteria present in difficult food products such as peanut butter. Funding will allow NCTR to continue studies in collaboration with CBER to extend the technique to targets other than bacteria such as viruses, parasites, and even very small particles.

- DICI Bacterial-Fingerprinting Technique – In FY 2010 NCTR scientists discovered a new and potentially patentable technique called Direct Impact Corona Ionization (DICI) mass spectrometry. This technique produces information-rich spectral fingerprints that can accurately identify bacteria invaluable to rapid detection methods. In FY 2011, DICI improved detection by one thousand times. NCTR researchers refined this technique and will apply it to a large bacterial culture library to establish a pathogen database. If successful, this will enable the identification of many bacterial species.

- Foodborne Pathogen Classification – In support of the Food Safety Modernization Act, NCTR scientists developed a statistical method that will improve FDA's ability to rapidly classify foodborne pathogens during outbreaks. The classification algorithm predicts *Salmonella* serotypes (major subgroups of bacteria) using a statistical method called random forest classification. This algorithm presented a new and more accurate approach—as a complement to the current method of cluster analysis—for rapidly predicting unknown *Salmonella* isolates based on the analysis of Pulsed Field Gel Electrophoresis (PFGE) fingerprinting. After the algorithm was developed and the results were published in 2010, NCTR began working with CDC and CFSAN scientists to collect PFGE profiles to refine the algorithm and conduct further analysis. In 2011, when NCTR applied the algorithm to 1500 PFGE profiles received from CFSAN, scientists discovered the prediction accuracy was positively affected. Results from the collaborative research with CFSAN were presented at the Annual Meeting of American Society of Microbiology in New Orleans in May 2011.

  Currently, NCTR is analyzing data from CDC's PulseNet, a national network of public health and food regulatory agency laboratories, which is home to the largest and most valuable database of PFGE fingerprints. As of May 2011, NCTR had obtained approximately 30,000 PFGE *Salmonella* isolates for prediction and analysis, including isolates from foodborne illness outbreaks. The output of PFGE data analysis that NCTR is pursuing allows FDA to rapidly assess the foodborne bacteria involved in the outbreaks and to better understand the relationship between antimicrobial resistance, pathogenicity — ability of an organism to cause disease — and potential transmission pathways of *Salmonella* along the food production and processing system.

Noninvasive Bio-Imaging Research – NCTR's Bio-Imaging facility provides advanced infrastructure for research to develop noninvasive, magnetic resonance imaging (MRI) biomarkers of disease progression and drug efficacy. The Bio-Imaging Facility houses instruments that operate at higher-field strengths, with higher image resolution, and with less variability than clinical instruments and provides investigators with opportunities for more complex experimental designs and resulting discoveries. As with clinical applications, the

noninvasive nature of these technologies enables monitoring of animals and provides new possibilities for biomarker discovery for safety and efficacy of FDA-regulated products:

- NCTR's imaging capabilities will lead to the development of new biomarkers that will serve as important tools for bringing new insight into areas such as step-by-step development of stroke complications — a leading cause of mortality and disability in the U.S. — related to micro-vascular disorders. These capabilities will also provide new safety-assessment tools for therapeutics devised to treat stroke victims, which offer the possibility of preventing recurring strokes, and reducing the need for costly and dangerous surgical procedures.

- PET imaging markers are useful in monitoring abnormal nerve-cell death associated with exposure of young animals to general anesthetic agents typically used in the pediatric setting. Several PET markers of neuronal apoptosis (programmed cell death) and brain inflammation are being used in our rodent models to define the time course, severity, and location of lesions associated with episodes of general anesthesia. Current efforts involve identifying similar biomarkers that can also be used in nonhuman primates and, ultimately, people. Using the tools available at the NCTR facility provides FDA with a unique opportunity to gather detailed information which was never previously obtainable.

- NCTR scientists are researching the usefulness of MRI images to direct traditional histopathological analyses – the study of the microscopic structure of diseased tissue. Application of this approach could result in a significant reduction in the number of animals needed to characterize toxicity in virtually any organ and provide information that will be invaluable in directing follow-on analyses using more traditional approaches.

- In FY 2010, NCTR scientists also developed a tool to discriminate up to nine categories of brain tissue with 96% accuracy using magnetic resonance spectroscopy (MRS) data. This tool is designed to aid physicians in making medical decisions based upon MRS information. MRS may improve the practice of medicine by reducing the need for surgical procedures and improving the quality-of-life for patients. NCTR produced two publications in 2010 presenting these research results.

- NCTR develops novel methods of validating MRI scans by comparing those scans that indicate adverse events, such as tumors, to those caused by benign outcomes, such as scarring. For example, follow-up scans performed on patients after brain surgery may reveal some abnormalities, but, at this time, there is no noninvasive method available to establish if the tumor has returned or if it is solely the presence of scar

tissue. If a data set of comparable patient scans can be located at a collaborating institution, NCTR plans in FY 2012 and FY 2013 to build models using in-house computer and personnel resources to help distinguish tissue status.

Zebrafish Technology to Study Pediatric Anesthetics – NCTR established a zebrafish facility in FY 2010 to provide adult fish and embryos for toxicity assessments. Zebrafish share many developmental and genetic similarities with humans and can provide information on ways to minimize risks of pediatric use of general anesthetics. At the facility, studies in the developing zebrafish have shown that some compounds, like L-carnitine, with apparently little inherent toxicity themselves can have remarkable protective effects against the toxicities induced by general anesthetic agents like ketamine. In addition to zebrafish studies, previous studies with nonhuman primates helped to identify developmental periods during which sensitivity to the pediatric anesthetic ketamine is greatest.

The use of these nonhuman primates' offspring informs about the underlying adverse effects of pediatric exposure to general anesthetics and is beginning to result in the development of translatable biomarkers for studying pediatric products. These research findings provide the medical community with an understanding of the relationship between the amount, type, duration, and frequency of pediatric anesthetic use and its adverse effects on children. The outcome is to provide rapid screening tests and understand pathways of toxicity so as to provide strategies for the safe use of pediatric anesthetics.

Nanotechnology – Nanotechnology research will aid in the development of guidelines for the safe and effective use of these materials in drug products, devices, foods, cosmetics, and dietary components. By continuing nanomaterials research, FDA will have a better understanding of the consequences of human exposure to nanoscale materials.

To strengthen its nanotechnology product evaluation capability, in FY 2010 FDA opened a fully equipped and staffed NCTR/ORA Nanotechnology Core Facility (NCF). The NCTR/ORA NCF provides FDA with a premiere state-of-the-art capability to support materials characterization, analysis, and electron microscopy for a broad range of nanomaterial studies. FDA established Standard Operating Procedures for all NCF equipment to ensure the quality and consistency of research results.

To address growing national attention on Nanotechnology, NCTR scientists conduct research to determine the relationship of material constitution, size, and shape on the toxic potential of nanomaterials that may be found in FDA-regulated products. Recently, nanomaterials received enormous national attention as new analytical tools for biotechnology and in the life sciences. Many materials, when manufactured to be in the nanoscale size domain, have unique properties that can be used for beneficial purposes; however, some of these nanoscale

materials, under certain conditions, have been shown to produce toxicity. NCTR research will provide FDA with a clarifying scientific base.

- **Manganese, copper, silver and iron nanoparticles** are being considered as nanomaterials with beneficial properties. Studies are being conducted to determine if these nanomaterials cross the blood-brain barrier in rodents and whether these materials produce toxicity in the brain tissue (neurotoxicity). Studies are also underway to determine if these materials pass through blood-brain-barrier cells isolated from rodents as an *in vitro* alternative to using animals. The data to date shows that some of these materials do interact with blood-brain- barrier cells and generate toxic generation of reactive oxygen species. The development of the dataset from these studies will provide a better understanding of the toxicity of these and other nanomaterials in use in many FDA-regulated products including prescription drugs, over-the-counter drugs, cosmetics, and dietary supplements.

- **Nanoscale zinc oxide and titanium oxide** are often found in sunscreen and cosmetics. These nanomaterials could penetrate the skin, impact the microbial ecology of the skin, or be absorbed in the gut following ingestion. NCTR will evaluate the effect of sunscreen and cosmetics on model microorganisms that are representative of the human skin to evaluate the potential risks of skin exposure. The goal is to determine if nanomaterials will affect human health by breaking the permeability barrier and encouraging bacterial growth on the skin. This research will provide the scientific underpinnings necessary to determine the potential health effects of skin exposure to nanomaterials. Also, since very limited information on the uptake of nanoscale materials from the gut exists, studies are focusing on the gut uptake of nanoscale zinc oxide to assess its safety.

- **Nanoparticles from food exposure or migration from food packaging** is the single greatest nano-related risk to consumers. FY 2013 budget authority funds will allow NCTR to continue conducting research that will provide FDA with a scientific basis to determine the magnitude of penetration of nanoscale materials into regulated products. Many dietary supplements and over-the-counter products marketed for use by women either claim to have nanoscale materials,or may contain nanomaterials. Nanoparticle-migration data are not available despite the fact that a number of nanomaterials are already available for use. Silver nanoparticles are a high priority for study because of their applications as antimicrobial agents in food and food packages. Funding will also allow NCTR to continue research to study the disposition of nanoscale silver once ingested (in rodents), and methods are being developed to measure the extent of nanosilver

migration from food-contact nanomaterials and the extent of nanomaterial inclusion in dietary supplements and other over-the-counter products.

NCF is supporting various collaborative studies with FDA/ORA, National Institute of Environmental Health Sciences/National Toxicology Program, National Cancer Institute/Nanotechnology Characterization Lab, and the U.S. Air Force on quantification and migration of nanosilver, particle-size determination of nanosilver, and the toxicity of nanomaterials on cultured brain cells and on cells used in genotoxicity assays.

Biomarkers for Cancer-Risk Assessment – In order for FDA to continue the important mission of protecting public health, biomarkers—or biological indicators—of health and disease status must continue to be developed. NCTR scientists conducted several key studies in FY 2010 that suggest that altered gene expression may be used as biomarkers for cancer risk assessment. NCTR scientists demonstrated in these studies that exposure to chemical carcinogens resulted in altered gene expression. These findings are particularly significant because they demonstrate that different carcinogenic agents induce similar genetic alterations – mutations – in the target organ DNA. In addition, these alterations typically appear early and correspond to those frequently found in tumor cells.

The recognition that epigenetic – or "gene-silencing" – mechanisms can have a significant role in the development of cancer has challenged the current approach to carcinogenicity testing and indicates the need for a new generation of cancer biomarkers. One remarkable feature of epigenetic abnormalities is their potential reversibility. Thus, rapid identification and regulation of carcinogens before dissemination into society is critical for the prevention of tumor formation.

NCTR scientists detected a rare mutation in the cancer gene K-Ras within one week after treatment of rats with the known carcinogen, azoxymethane. The mutation was detected using a sensitive molecular genetic approach developed at NCTR. This study illustrates how quantitative measurements of cancer-gene mutations may be a useful biomarker of genetic damage by carcinogens and their potential for estimating the carcinogenic potential and potency of test chemicals in 28- or 90-day toxicity studies. A manuscript describing the results of this study was published in a 2010 issue of *Environmental and Molecular Mutagenesis.*

Studies are currently being conducted to develop targeted therapeutic approaches for clinical management of breast cancer and will continue into FY 2013. Future research will be conducted to establish biomarkers for pancreatic cancer and to determine whether these biomarkers can detect reemergence of the disease before other invasive procedures are used.

Biomarkers of Drug-Induced Cardiotoxicity – NCTR is conducting research to develop molecular biomarkers for drug-induced cardiotoxicity. Identification of these biomarkers can be valuable tools to predict harmful effects of drugs on the heart during preclinical and clinical safety evaluations. Earlier detection of drug-induced cardiotoxicity is needed to reduce the rate of severe heart failure and improve therapeutic patient treatment. An understanding of the causes of toxicity will provide the basis for the design of therapeutic interventions to reduce or reverse cardiac injury.

Infrastructure to Manage Bioinformatic Data – NCTR-developed ArrayTrack™[5] which allows for the addition of new capabilities to handle priorities and evolving technologies and can be used to support Pharmacogenomics (PGx) research and review. PGx is an emerging scientific field focused on clinical and safety biomarker identification with great potential for advancing medical product development. PGx requires a bioinformatics infrastructure to review and understand how sponsors reach their biological conclusions.

Initially ArrayTrack™ was used predominately to analyze and manage large amounts of gene-expression data. ArrayTrack™ continues to be expanded to facilitate the review of other types of data and now includes a Microbial Library and new data processing and visualization tools. The Microbial Library currently holds 270,000 gene records from 84 strains, including *Escherichia coli*, *Salmonella enterica*, *Shigella spp.*, and *Vibrio spp*., which are common foodborne pathogens. These additions facilitate the analysis of data generated by NCTR researchers and the custom analytical tests developed at FDA's Center for Food Safety and Nutrition and U.S. Department of Agriculture, demonstrating ArrayTrack's use in microbial genomics research.

The ArrayTrack™ platform facilitates rapid identification of intestinal pathogens and their genetic traits including antimicrobial resistance, virulence, and DNA fingerprints in outbreak investigations, supporting the Food Safety Modernization Act. To make the functionality of ArrayTrack™ even more robust and easy to use, FY 2013 budget authority funds will allow NCTR researchers to develop a set of user-friendly wizards that greatly enhance the application of the tools.

[5] an integrated DNA microarray data management, mining, analysis, and interpretation software system

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)*	FY2011: SOPs for several methodologies were validated for the detection of nanoscale materials. (Target Met)	Establish and implement standard operating procedures (SOP) in research protocols for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/Arkansas Regional Laboratory (ORA/ARL)	1) Conduct research on the utilization of new genomics technologies and approaches to evaluate FDA-regulated products for adverse genetic effects. 2) Complete final report on the health safety assessment of coronaviruses(viruses that infect upper respiratory and gastro-intestinal tracts) circulating in different populations. 3.) Conduct research to provide the scientific underpinnings necessary to determine the potential health effects of skin exposure to nanomaterials.	N/A
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize therapeutic care. *(Output)*	FY 2011: Statistical analyses of gene-phenotype interactions and nutrient levels were conducted and target genes identified, further results are pending a final analysis and publication (Target Met)	1) Develop analytical methods to assess drug-induced heart damage 2) Identify target genes for obesity and the consequent	1) Analyze urine, blood , and tumor tissues samples to identity biomarkers that will facilitate early detection in new cases and in the reemergence of pancreatic cancer.	N/A

		development of metabolic syndrome diseases and heart disease	2) Develop a new targeted therapeutic approach to improve clinical management of breast cancer.	
264101: Develop risk assessment methods and build biological dose-response models in support of food protection. *(Output)*	FY 2011: Protocol initiated to examine a novel flow cytometer as a diagnostic platform for rapid determination of bacterial antibiotic resistance and the presence of viruses or parasites in clinical samples such as blood, sputum, urine, bile, and CNS fluid (Target Met)	Expand Rapid B system to include new pathogen-specific (PS) assays (tests)	Develop new methods for the rapid detection of new bacterial targets with even smaller particles.	N/A
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates. *(Output)*	FY 2011: The VISIONS system has been incorporated into the revised Manual of Policies and Procedures (MaPP) in CDER that layout a strategy in FDA to receive, process and review VXDS (Target Met)	Build a knowledge base to annotate existing drug-risk factor associations of immune-related drug reactions	1.) Develop integrated, multiple omics systems for predicting liver injury. 2.) Develop statistical models and data-mining algorithms using a prototype computerized system to characterize sensitive subpopulations and also to evaluate the potential side effects of drugs with data from the FDA Adverse Event Reporting System (AERS).	N/A

263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. *(Output)*	FY2011: The alpha version of SNPTrack has been delivered to and evaluated by the VXDS team (Target Met)	Develop 3D/4D Quantitative Spectrometric Data-activity Relationship (QSDAR) models for predicting endocrine disruptor activity	1.) Optimize the ability of FDA to use next generation sequencing (DNA sequencing that significantly accelerates biological research and discovery) to quickly predict serious adverse drug reactions at the individual patient level. 2.) Develop a bioinformatics infrastructure to support PGx: Pharmacogenomics (an emerging scientific field focused on clinical and safety biomarker identification)	N/A

Information Technology Investments – National Center for Toxicological Research Activities (FY 2012 Enacted Amount displayed as a non-add item: $8,112,879)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

Science management, via information technology, plays a vital role in helping FDA achieve its mission in protecting and advancing public health. The pace of scientific discovery places a high-demand on the Agency to maintain awareness of all the current trends and latest developments. Within this realm of

responsibility, scientists are constantly challenged with introducing new and innovative scientific-computing initiatives and streamlining data management processes. NCTR will expand FDA's commitments to the scientific information technology advancement trend by:

- focusing on developing new IT scientific platforms, for example, Knowledge Base initiatives in such areas as drug-induced liver injury. These knowledge bases will enrich the regulatory desktop with tools to carry out integrative analyses across multiple data types in search of safety signals.

- developing analysis and modeling methods in the fields of toxicology, biochemistry, and genomics, as well as other methods of data exploration, including statistics, artificial intelligence, and genetic algorithms. Also within the field of scientific computing, NCTR maintains the venue to develop innovative technologies that will further advance personalized medicine.

- expanding existing platforms such as the NCTR-developed ArrayTrack™ – an integrated DNA microarray data management, mining, analysis, and interpretation software system – to allow for the addition of new capabilities to handle priorities and evolving technologies.

  One such expansion will be used to support Pharmacogenomics (PGx) research that requires a bioinformatics infrastructure to review and understand how sponsors reach their biological conclusions. Special IT networks will enable collaborative interoperability with the external scientific community, leveraging FDA science efforts and providing for collection of more data to support science-based risk/benefit assessments.

These IT initiatives will enhance the research efforts of interdisciplinary scientists who conduct peer- reviewed research essential to identifying health and safety issues related to new and existing FDA-regulated products.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels for the National Center for Toxicological Research's program level and budget authority resources from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$44,443,000	$44,443,000	$0	192
FY 2009 Actual	$55,720,000	$55,720,000	$0	217
FY 2010 Actual	$58,531,000	$58,531,000	$0	246
FY 2011 Actual	$60,563,000	$60,563,000	$0	272
FY 2012 Enacted	$60,039,000	$60,039,000	$0	272

Summary of the Budget Request

The FY 2013 budget request for the National Center for Toxicological Research (NCTR) Program is $59,231,000. This amount is a decrease of $808,000 from the FY 2012 Enacted Level. The NCTR amount in this request supports 270 FTE.

The FY 2012 Enacted amount for the NCTR Program is $60,039,000.

FY 2012 funding allows the NCTR Program to advance the FDA mission of protecting patients and consumers – across the full spectrum of products that FDA regulates: animal and human drugs, devices, cosmetics, biologics and tissues, food safety, and tobacco. NCTR accomplishes its mission by conducting research on the risks and benefits of products under the framework of its two subprograms:

- Evaluating Toxicity of FDA-Regulated Products
- Modernizing Toxicology to Support the FDA Mission

The goal of these subprograms is to provide research data to assist FDA in making sound, science-based regulatory decisions and improve the health of the American people.

Budget Request

Data Consolidation and IT Savings (Total Program: -$530,000)

The request for $59,231,000 in total budget authority for NCTR also reflects data consolidation and IT savings reduction of -$530,000 for FY 2013.
NCTR will achieve the savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- Promoting efficiency through consolidation of responsibilities and duties within the current IT Contract to realize cost savings.
- Maximizing virtualization to achieve further cost efficiencies, while increasing uptime and providing faster server provisioning

Rent Absorption (-$277,000 / -2 FTE)

The National Center for Toxicological Research will absorb part of the cost of the FY 2013 rent increase, resulting in the loss of two FTE for NCTR public health activities.

The Data Consolidation and IT Savings and Rent Absorption affect all sub-programs.

Evaluating Toxicity of FDA-Regulated Products

Center Activities – FY 2012 Enacted Amount: $23,713,000 (All BA)

2013 Initiatives: None

Modernizing Toxicology to Support the FDA Mission

Center Activities – FY 2012 Enacted Amount: $36,326,000 (All BA)

2013 Initiatives: None

NCTR Program Activity Data (PAD)

NCTR Workload and Outputs	FY 2010 Actual	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
RESEARCH OUTPUTS				
Research Publications	165	160	165	173
Scientific Presentations	190	178	173	166
Patents (Industry)	6	6	5	5
LEVERAGED RESEARCH				
Federal agencies (Interagency Agreements)	4	8	3	3
Nongovernmental organizations	15	20	12	13
ACTIVE RESEARCH PROJECTS				
Personalized Nutrition and Medicine	64	60	59	
Strengthen Surveillance & Risk Analysis	42	42	39	
Enhancing Product Safety	55	50	53	
NEW FY13 Program: Evaluating Toxicity of FDA-Regulated Products				38
NEW FY13 Program: Modernizing Toxicology To Support the FDA Mission				104
Total Active Research Projects	***161***	***152***	***151***	***142***

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

FIELD ACTIVITIES – OFFICE OF REGULATORY AFFAIRS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$925,666**	**$912,120**	**$961,800**	**$1,128,029**	**$166,229**
Program Level FTE	**4,336**	**4,570**	**4,685**	**5,069**	**384**
Budget Authority	**$890,965**	**$890,474**	**$906,790**	**$894,826**	**-$11,964**
Budget Authority FTE	**4,234**	**4,479**	**4,487**	**4,487**	***0***
User Fees	**$34,701**	**$21,646**	**$55,010**	**$233,203**	**$178,193**
PDUFA	$13,608	$8,187	$14,225	$14,528	$303
FTE	54	56	56	56	0
MDUFMA	$1,688	$2,009	$1,572	$1,900	$328
FTE	13	13	13	13	0
ADUFA	$281	$277	$315	$464	$149
FTE	1	2	2	2	0
AGDUFA	$151	$151	$160	$211	$51
FTE	1	1	1	1	0
MQSA	$13,077	$9,459	$13,077	$13,077	$0
FTE	8	8	8	8	0
Center for Tobacco Products	$5,896	$1,563	$6,250	$9,400	$3,150
FTE	25	10	26	41	15
Voluntary Qualified Importer Program			0	0	0
FTE			0	0	0
Food Reinspection			9,375	9,800	425
FTE			66	66	0
Recall User Fee			10,036	10,491	455
FTE			25	25	0
Medical Products Reinspection [1]			0	7,029	7,029
FTE			0	46	46
Cosmetics User Fee [1]			0	4,320	4,320
FTE			0	18	18
Generic Drugs [1]			$0	$51,811	$51,811
FTE			0	150	150
Biosimilars User Fee [1]			0	1,290	1,290
FTE			0	5	5
Food Establishment Registration Fee[1]			$0	$104,074	$104,074
FTE			0	130	130
International Courier [1]			0	$4,808	$4,808
FTE			0	20	20
User Fees FTE	**102**	**91**	**197**	**582**	**384**

[1] Proposed User fee; the amount includes associated rent activity.

Authorizing Legislation:

The Office of Regulatory Affairs (ORA) plans and directs the management and administration of personnel and facilities to ensure the federal laws and regulations regarding FDA regulated products are enforced. Specifically, FDA administers the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. (FFDCA), and designated sections of the Public Health Service Act.

ORA directs field operations that are performed by several thousand scientific, regulatory, and consumer safety personnel throughout the nation and abroad. ORA also manages state-of-the-art scientific laboratories strategically located throughout the U.S. and in Puerto Rico.

In addition, the Secretary of the Department of Health and Human Services (HHS) has redelegated to the Commissioner of FDA the functions vested in the Secretary under the following statutes and orders:

Filled Milk Act (21 U.S.C. §§ 61-63)
Federal Import Milk Act (21 U.S.C. § 141, et seq.)
Federal Caustic Poison Act (44 Stat. 1406)
The Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.)
Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241)
Controlled Substances Act (21 U.S.C. § 801, et seq.)
Federal Meat Inspection Act (21 U.S.C. § 679(b))
Poultry Products Inspection Act (21 U.S.C. § 467f(b))
Egg Products Inspection Act (21 U.S.C. § 1031, et seq.)
Executive Order 11490, § 1103
Federal Advisory Committee Act (5 U.S.C. Appx. 2)
Lead-Based Paint Poisoning Prevention Act (42 U.S.C. § 4831(a))
Small Business Act (15 U.S.C. § 638)
Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. §§ 10007 and 10008)
Patent Term Extension (35 U.S.C. § 156)
Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. § 3701, et seq.)/Exec Order 12591
Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. §§ 1401-1403)
Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. §138a)
Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104-180)
Equal Access to Justice Act (5 U.S.C. § 504)
Best Pharmaceuticals for Children Act (Public Law 107-108), as amended by Pediatric Research Equity Act of 2003 (Section 3(b)(2) of Public Law 108-155)

The Office of Criminal Investigations (OCI) of ORA conducts criminal investigations and executes search warrants as permitted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372), the Public Health Service Act (42 U.S.C. 262) and the Federal Anti-Tampering Act (18 U.S.C. 1365).

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

ORA is the lead office for FDA field activities and advises FDA leadership on imports, inspections, and enforcement policy. ORA's field activities support the six FDA Product Centers by assessing industry compliance with applicable laws and regulations to protect public health. To assess industry compliance, ORA:

- inspects manufacturers and regulated products, conducting sample analysis on regulated products
- reviews imported products offered for entry into the United States
- develops FDA-wide policy on compliance and enforcement
- executes FDA's Import Strategy and Food Protection Plans
- directs and coordinates FDA's emergency preparedness and response programs.

ORA maintains offices in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming.

Over 85 percent of ORA's staff is stationed in five regional offices, 20 district offices, 13 laboratories, and 177 resident posts and border stations.

As a separate entity within ORA, the Office of Criminal Investigations (OCI) personnel are located in 32 field offices, resident offices, and domiciles throughout the United States.

In addition to its Federal workforce, ORA works with its State, local, tribal, and territory counterparts to further FDA's mission. ORA funds grants and cooperative agreements to perform State inspections and provide technical assistance in such areas as milk, food, and shellfish safety. State inspection staff attends and participates in ORA-sponsored training courses.

ORA's activities cross-cut FDA's major initiatives, including Transforming Food Safety and Nutrition, Protecting Patients, and FDA Regulatory Science and Facilities. However, to be consistent with the budget presentation in this Performance Budget Submission, the program description and accomplishments section below follows the six FDA Product Center themes of Foods, Drugs, Biologics, Animal Drugs and Feeds, Devices and Radiological Health, and Tobacco.

Foods Program

Prioritizing Prevention - Field Activities

FY 2012 Enacted Amount: $111,373,000 (All BA)

Public Health Focus

ORA's top priorities for advancing public health and protecting consumers focus on:

- prevention through outreach coordination and technical assistance to industry
- internal and external training, which increases expertise and encourages collaboration with external stakeholders
- preventative controls in the food supply chain from the point of production to delivery into the U.S. supply chain.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks that FDA to articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

In the case of the Prioritizing Prevention, ORA contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than relying primarily on reacting to problems after they occur and implementing the provisions of FSMA is through the development of regulations, standards and guidance documents. These activities are reflected within the draft FDA Foods and Veterinary Medicine (FVM) Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

In FY 2011 ORA participated in outreach events at a variety of public meetings, symposiums and conferences that are attended by regulated industry, other government agencies, and foreign regulatory bodies.

The FDA Compendium of Microbiological Protocols and Chemical Tests (COMPACT), a compilation of analytical detection methods for foods designed to support the mission of FDA was released in the Electronic Laboratory Exchange Network (eLEXNET). COMPACT serves as the primary resource in support of emergency analytical needs such as large-scale food-borne outbreaks and food safety surveillance activities. eLEXNET added six new labs in FY 2011.

FDA began regulating firms under 21 CFR 118, better known as the Egg Safety Rule in FY 2010. Since then, ORA has conducted more than 450 inspections and collected over 150 samples including over 2,000 environmental swabs. Of the samples collected by ORA, 22 of the samples were found positive for Salmonella Enteriditis. ORA has taken several regulatory actions including issuance of warning letters, untitled letters, and a voluntary recall. ORA works with industry to help ensure their response measures are appropriate within the regulation, including re-inspection of firms to determine their compliance status. ORA has also participated in industry outreach programs with the egg producing industry, providing education on compliance with the Egg Safety Rule.

FDA analyzes trends in the regulated marketplace to assure the safety of regulated commodities before there is a public health issue. FDA identified one such challenge related to caffeinated alcoholic beverages. ORA collected numerous samples and analyzed the products for the presence of caffeine. The analytical findings led to the issuance of several warning letters to manufacturers of these beverages offered for sale at retail locations throughout the nation, and subsequently, to cessation of marketing.

ORA awarded funds to associations under the Small Scientific Conference Grant and to state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources to foster communication and collaboration on a range of topics, including food safety, food security and protection, intervention, and prevention through the review of food supply vulnerabilities.

FDA developed and is currently implementing a new strategy, in collaboration with Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) under the Department of Homeland Security (DHS), to better prevent the entry of smuggled food/feed into the U.S., fulfilling the requirement of FSMA Section 309(a). When smuggled food/feed goes un-examined by regulators, it presents a hazard to consumers and erodes confidence in the safety of the food/feed supply. A comprehensive strategy to combat the entry of smuggled food/feed helps protect the public health. FDA is working closely with CBP to target and examine import shipments that could conceal undeclared foods/feeds, focusing on high risk parties and imported foods/feeds that pose a significant public health risk.

FDA awarded seven grants to enhance the ability grantee to design, develop, and deliver food safety training and personnel certification programs by leveraging the expertise of universities, professional trade associations, and non-profit organizations. The primary focus of the awardee and FDA collaborative venture is to design, develop, and disseminate food and feed safety training programs that are consistent with the Manufactured Food and Retail Food Regulatory Program Standards, as well as third party criteria for accreditation. This venture will emphasize public health safety according to the needs of FDA and our regulatory and public health counterparts, while also fostering the development of a network of food safety professionals. FDA aims to establish a fully integrated food safety system (IFSS) that will place priority on

preventing foodborne illness through the adoption and uniform application of model programs.

Promoting Efficiency

ORA conducts outreach to ensure transparency, communication, and sharing of information and ideas with consumers, regulated industry, and the import trade community. Prioritizing Prevention activities help anticipate and prevent food safety problems, which generates efficiencies for industry, consumers, and FDA. In addition to protecting public health, prevention leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

ORA also offers training to its state partners in conducting inspections of egg producers, low acid canned food manufacturers, and seafood processors By providing this training, FDA is strengthening the infrastructure of state inspection programs and furthering the implementation of an integrated food safety system.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance – Field Activities
FY 2012 Enacted Amount: $286,953,000 (All BA)

Public Health Focus

To strengthen food defense/safety, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- domestic product reconciliation examinations
- laboratory analyses including sample analysis, product testing, and methods development.

These activities serve to minimize consumers' risk of exposure to adulterated food products by detecting and preventing the marketing of unsafe products, removing products from the market, or ensuring that products do not reach the U.S. market. Early detection of contaminated or adulterated food products and their ingredients continues to be a priority within ORA.

Activities conducted on entries offered for import into the US are driven by risk-based and intelligence gathering activities that assist in identifying entries posing the highest risk to the consumer. Surveillance inspections are conducted to assess the manufacturing of products for compliance with established regulatory requirements to protect public health. Domestic product reconciliation examinations are conducted to assure manufacturers have programs in place to ensure the safety of products received for processing and also to guard against unknown individuals entering manufacturing facilities. These activities are both food defense and food safety measures.

ORA advances regulatory science by increasing the breadth of its analytical capacity and capability, while improving laboratory efficiencies and outputs. One way ORA accomplishes these advancements is through the continued development of laboratory methods to detect emerging microbiological, chemical or radiological contaminants of public health concern.

FDA Food Safety Strategy

In the case of the Strengthening Surveillance, ORA contributes to achieving the overall FDA strategy by establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and a model for evidence-based resource planning. This includes maintaining and strengthening mission-critical science capabilities, improving centralized planning and performance measurement, and improving information sharing internally and externally including effective communication of research plans and knowledge gaps.

Public Health Outcome

In FY 2011 ORA continued its usage of the Chemistry and Microbiological Mobile Laboratories in support of FDA's food defense initiatives and surveillance of import and domestic produce. In support of FDA's continued surveillance related to the recovery mission from the Deepwater Horizon Oil Spill, the chemistry mobile laboratory was deployed to Dauphin Island, Alabama and analyzed about 1000 finfish, shrimp and oyster samples for polycyclic aromatic hydrocarbons (PAHs). The microbiology mobile laboratory was re-deployed from a surveillance assignment in Salinas, California to Otay Mesa, California to support the 100 percent sampling and testing of Mexican Papayas implicated in an outbreak over the early late spring/early summer of 2011.

ORA, and state regulatory partners under contract with FDA, continued the use of environmental sampling during domestic, high-risk food facility inspections to assess the environmental conditions in which products are manufactured. These environmental samples are critical in identifying areas of concern within the production environment that have or could lead to product contamination. As a result of FDA's efforts, industry has taken many actions to recall or destroy products that were manufactured under such conditions.

For example, ORA inspected127 soft cheese manufacturers under an assignment designed to determine the environmental conditions of these establishments. More than 10,500 environmental swabs were collected to determine the presence of Listeria moncytogenes in the establishments. Violative analytical findings have led to voluntary recalls by the affected establishment and further regulatory actions including a product seizure.

Through implementation of Memoranda of Understanding (MOUs) with the Occupational Safety and Health Administration (OSHA) and the USDA Agricultural Marketing Service (AMS) and USDA Food Safety Inspection Service (FSIS), FDA is

leveraging resources and sharing information in a way that is expected to result in the reporting of egregious food processing conditions that might otherwise go unidentified until an inspection is conducted.

ORA increased the efficiency and effectiveness of import entry review through the nationwide implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources, analyzes available data, cross-matches data looking for anomalies, and overall enables ORA to target its resources in a more strategic manner. ORA's implementation of PREDICT allows for the expedited clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk food products.

In FY 2011, ORA continued its efforts to improve the reliability of foreign food facility registrations by continuing a contract to perform on site firm verifications of foreign food facilities to confirm the existence of the facility but also to verify the information supplied in the registration. As a result of the information obtained under these efforts, FDA has initiated for-cause inspection of facilities, added facilities to import alerts where the manufacturing capabilities were not what was purported in the registration, and increased targeting and review of prior notice submissions to ensure accurate data is submitted.

The ORA Prior Notice Center (PNC) exceeded the 80,000 prior notice review performance measure in FY 2011. PNC conducts targeted biosecurity analysis of food entries to protect the public from a threatened or actual terrorist attack on the US food supply and other food-related emergencies.

In FY 2011, ORA funded a pilot program for further deployment of the handheld portable analytical tools that were evaluated in FY 2010. These portable analytical tools are used in the early detection of contaminated food products further back in the supply chain. Portable tools return analytical screening results within minutes of implementing the test, providing ORA field personnel with data to assist in setting collection priorities based on emergent risk profiles. The first tier of tools was deployed to several ORA field offices in FY 2010, and they are the first in a series of portable analytical tools that were deployed to ORA field investigators to screen certain commodity/analyte combinations. The second wave of deployments of portable analytical tools took place in FY 2011 and included tools to check for the presence of undeclared active pharmaceutical ingredients in dietary supplement products, check for heavy metals in food products, and check for the presence of diethylene glycol substituted for glycerin.

Promoting Efficiency

FDA field operations are establishing high throughput laboratories for analyzing food samples. These laboratories will allow ORA to analyze a greater volume of food samples in less time. Through this analysis, FDA can better protect consumers, make more timely regulatory decisions, and reduce the impact on regulated industry. These efforts not only provide greater assurance that foods are safe, they also maintain the

efficient flow of trade. In addition, high throughput laboratories protect the public by identifying product adulteration and environmental contamination. With this analysis, FDA and industry can efficiently address such problems and allow a firm to resume business operations as quickly as possible after correcting the food safety problem.

The Field Operations of the Strengthening Surveillance Subprogram also allow ORA to identify, validate and implement new technologies to more readily detect adulterated food imports. These technologies prevent adulterated imported food from reaching U.S. consumers and allow FDA to more efficiently maintain the flow of commerce in foods that FDA regulates.

In FY 2011, FDA funded the electronic Laboratory Information Management System (LIMS) for implementation into the field labs over a five year period. LIMS directly supports management which includes automation of analytical processes, data collection from instrumentation, chain of custody, calibration, reagent and inventory tracking, accreditation support, reporting, trending, and general laboratory management. The project entails the development of and licenses for software, Commercial Off the shelf product, the purchase of equipment and lab hardware, and improvements to the server and network infrastructure. LIMS will be piloted in 4 labs in FY12 followed by implementation into 14 static and 2 mobile ORA laboratories with continuation over an additional four years.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214201: Number of prior notice import security reviews. *(Output)*	FY 2011: 88,057 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2011: 201,406 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain
214203: Number of Filer Evaluations. *(Output)*	FY 2011: 1,212 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2011: 11,789 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2011: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

Public Health Focus

One of ORA's main food safety duties is to perform risk-based inspections of food producers and provide strong, effective and efficient enforcement of FDA laws and regulations.

The safety of our nation's food supply continues to be a top priority for regulatory agencies. ORA views state-based contracts, grants and cooperative programs such as the Food Inspections Contracts as important mechanisms for providing increased enforcement activities through an enhanced integrated food safety system.

FDA Food Safety Strategy

In the case of the Strengthening Enforcement, ORA contributes to achieving the overall FDA strategy by conducting risk-based domestic and foreign food safety inspections, implementing new enforcement tools, improving mechanisms for assuring that imported foods and feeds meet preventive controls standards, and improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

Public Health Outcome

- ORA investigators conduct on-site inspections of regulated domestic and foreign food establishments
- ORA initiates enforcement actions to address violations of our public health laws and regulations.

In FY 2011, ORA performed 1,000 foreign food establishment inspections representing an increase of 640 foreign food inspections over FY 2010 and increased the overall number of foreign inspections by 54%. FDA uses risk factors to target firms to inspect, focuses the on-site inspections in the most critical areas, and continues to leverage the work of our dedicated foreign inspection cadre, FDA inspection staff located at FDA's foreign offices, and our district-based investigators to enhance overall coverage of the foreign establishment inventory.

For example, the ORA Dedicated Foreign Food Cadre alone conducted 470 foreign food inspections that resulted in nine foreign establishment Warning Letters, twelve establishments being placed on Import Alert, and five foreign manufacturers voluntarily recalling their products from the US market. Additionally, implementing new statutory authority provided under the Food Safety Modernization Act, two foreign food firms have been placed on import alert for refusing to allow FDA to inspect their facilities.

In FY 2011, ORA continued to protect US citizens from unsafe products of foreign origin by issuing over 800 notices that extended import controls to products and establishments related to concerns that include *Salmonella*, pesticides, and non-permitted or undeclared food additives violations.

In FY 2011, ORA awarded food inspection contracts to State agencies and territories. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections. The contracts also include a subset of high risk industries such as juice and seafood Hazard Analysis Critical Control Point (HACCP), egg safety and low acid canned foods and acidified foods. In FY11, Twenty six states received additional funding through the food contract to support the Manufactured Foods Regulatory Program Standards (MFRPS) implementation with an additional 23 states receiving funding to pursue laboratory accreditation in support of MFRPS implementation. Thirty eight states are currently enrolled in the MFRPS through either the food contract or the Rapid Response Team cooperative agreement. FDA also provided increased funding to support the Retail Program Standards in FY11.

In FY 2011, FDA classified 963 Class I; 800 Class II; and 90 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In May, 2011 a new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration at an early state in the process of case development; reduces paperwork by removing redundant and unnecessary documentation; removes a bias toward inaction by making the process less daunting and more collaborative; provides a mechanism for continuous improvement in case development; and shortens approval times. Overall in FY2011, FDA pursued 12 injunction actions and 11 product seizure actions. In FY 2011, FDA issued 324 warning letters alerting firms to violations of concern that require their immediate attention to correct and to prevent the continued distribution of adulterated human drug products in US commerce.

Submission of accurate prior notice data for imported food shipments by industry ensures meaningful food defense/security risk assessments can be completed by ORA. ORA initiated more than 1,050 compliance enforcement cases, taken in conjunction with CBP, where Bioterrorism Preparedness Act (BTA) registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. At the request of ORA in 2011, CBP also issued Letters of Reprimand to two import filers for failure to transmit accurate prior notice data relating to the importation of food products.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011, and included data for FY2009 and FY2010 inspections. This effort will provide the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

With cross agency collaboration, FDA initiated and implemented a strategy to monitor the marketplace: conduct undercover purchases and investigations as part of the "Operation Shady Supplement." The strategy emphasizes the development of criminal cases against distributors of tainted supplements by OCI. Additionally, FDA safeguarded the US marketplace from unsafe dietary supplements by collaborating internationally with Canada's Competition Bureau and issuing warning letters to US firms marketing dietary supplements in the US and Canada on the internet and Facebook with unapproved disease claims.

In May 2011, FDA implemented two new enforcement authorities under FSMA, both effective in July 2011. The first allows FDA to administratively detain food that FDA has reason to believe is adulterated or misbranded. The products will be kept out of the marketplace while FDA determines whether an enforcement action, such as seizure or injunction against distribution of the product in commerce, is necessary. FDA has used this authority multiple times in 2011.

The second authority provides FDA with more information about imports and allows for risk-based targeted examinations by requiring importers of food and feed into the United States to inform FDA if any country has refused entry to the same product. This new data requirement also allows FDA to make better informed decisions in managing the potential risks of imported food/feed.

During FY 2011, ORA's OCI made 11 arrests, and secured 20 convictions with fines, restitutions and other monetary penalties in excess of $10 million.

A sampling of some of the specific case activity that led to these positive public health outcomes are as follows:

Misbranded products - Distribution of cheese contaminated with salmonella and E. coli – In July 2011, a Miami company and its owners were sentenced after being convicted of conspiracy and smuggling for selling imported cheese found to contain salmonella and E. coli. The cheese had been detained by FDA, and was facing further FDA examination under FDA orders for destruction after the contamination was uncovered. The husband and wife owners were sentenced to 27 months and 40 months in prison, respectively after being found guilty in a May 2011 trial.

Product tampering - **Sentencing for tampering with salsa at restaurant** – In February 2011, a woman was sentenced to seven years in federal prison for tampering

with a consumer product by putting pesticide poison in salsa served to patrons at a restaurant in Lenexa, KS. In June 2011, her husband was sentenced to ten years in prison for his participation in the crime. The man and his wife devised the scheme after the husband lost his job at the restaurant. Nearly 50 individuals, from young children to senior citizens became ill from the poisoning, which occurred in August 2009.

Misbranded and adulterated products - **New Jersey dietary supplement firms and owners found guilty of contempt** – In June 2011, two companies were found guilty of multiple counts of criminal contempt along with three owners and officials of the companies. In December 2011, the owner of the two companies was sentenced to 40 months in prison and fined $60,000. Two managers of the companies were sentenced to 34 months in prison each. Both firms were also ordered to pay criminal fines totaling $1 million. The OCI investigation uncovered two New Jersey dietary supplement and food manufacturers were violating a March 2010 consent decree ordering the business to shut down after FDA inspections found that their products were misbranded and adulterated due to unsanitary conditions at the plant. Despite the court order, the defendants set up new operations at a different location without first getting the required FDA approval.

Adulterated products - Florida Corporation and Owners Sentenced for Distribution of Contaminated, Imported Cheese – In December 2010, a Florida corporation and its two owners were sentenced for the importation of cheese from Nicaragua, which was subsequently placed on hold by FDA to determine if the cheese was adulterated. FDA testing determined the cheese contained bacteria. The defendants though had already sold the 440 boxes of cheese after being notified about the detention. One owner was sentenced to 6 months confinement and 2 years probation while the other defendant received five years probation.

Promoting Efficiency

The Food Inspection Contract Program and similar contracts, grants, and cooperative agreements that ORA executes through this subprogram build an integrated food safety system designed to protect the nation's food supply and minimize consumers' exposure to adulterated and contaminated food products. FDA support for state inspections often supplements two to three state-funded food inspections, thereby increasing the reach of state food safety programs ensuring a broader network of food safety for consumers. Through these grants and cooperative agreements, FDA increases the efficiency of an integrated food safety system, increasing our capabilities to respond to food incidents and outbreaks while facilitating the release of safe food products for US consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214205: Number of domestic high-risk food inspections. *(Output)*	FY 2011: 7,218 Target: 6,806 (Target Exceeded)	7,435	7,435	Maintain

Improving Response and Recovery - Field Activities

FY 2012 Enacted Amount: $ 49,327,000 (All BA)

Public Health Focus

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. ORA continues its work with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors.

The Reportable Food Registry (RFR) is an electronic portal to which industry, public health officials and consumers can report when an article of human food may cause serious adverse health consequences or death to humans. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

To protect consumers from foodborne pathogens and to rapidly and accurately trace and identify the sources of pathogens in the food supply, it is necessary to determine species and discriminate the pathogens isolated from food. This additional identification is needed to track pathogen to the source and origin of the food exposure whether from plant, farm, or human contamination sources.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA continues to identify and develop new investigational resources, tools, and training programs while establishing an infrastructure that will support continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on states and counties to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow states and counties to increase efficiency in the areas of response, prevention and intervention in addition to allowing for a larger pool of resources nationwide to strengthen food defense and mitigate safety issues.

Molecular techniques are available to provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide

evidence for rapid traceback to contamination sources. All microbiology laboratories have equipment to perform this testing and microbiologists are certified to perform this analysis. The results of these determinations inform inspections and provide evidence on source, level and extent of contamination by food borne pathogens. The focus of the activities in this area is also to deliver a timely response to an emergent threat to minimize the impact to public health.

FDA Food Safety Strategy

In the case of the Improving Response and Recovery, ORA contributes to achieving the overall FDA strategy by investigation and adoption of innovative technologies and processes to detect and investigate such events, enhancement of the Reportable Food Registry, and effective risk communications related to outbreaks and contamination incidents. ORA is able to do this by responding to issues that occur across Farm-to-Table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

ORA continues to partner with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, Partnership for Food Protection, and 50 State meetings. This work enables federal and state partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern.

ORA continues to devote resources to the prompt and efficient response to foodborne outbreaks and other events associated with FDA regulated commodities. Prompt mobilization of individual resources and response teams by ORA facilitates the reduction of exposure times through early investigation initiation and the collection of samples for analysis

As part of FDA's response to the March 2011 Japan earthquake and tsunami, FDA issued Import Alert 99-33 and Import Bulletin 99-B38 which increased surveillance of Japanese food and drug products and provided a network of coverage to ensure that no radiation-contaminated product reached the US consumers. As the situation developed, FDA issued revisions and updates to both the Alert and Bulletin to ensure the most appropriate coverage. Field offices have conducted over 28,000 examinations and field laboratories have analyzed over 1,100 samples, with no objectionable findings.

As part of FDA's response to a multi-state Salmonella Agona outbreak, FDA issued an Import Bulletin to increase surveillance of suspected food products to prevent the entry of potentially contaminated products without first being analyzed. As the situation developed, FDA revised the bulletin to ensure appropriate coverage. Eventually our surveillance activities led to the issuance of a countrywide Import Alert specific to

papayas from Mexico. ORA's field operations helped identify a potential source of microbiological contamination in produce, and continue to ensure contaminated product does not reach US consumers.

Deepwater Horizon Oil Spill:
In April 2010 the Deepwater Horizon Oil Rig owned and operated by BP exploded causing release of millions of gallons of crude oil into the Gulf. FDA worked with the affected Gulf States to respond to this emergency threatening seafood safety. States closed their waters to harvesting until oil receded. ORA developed a rapid analytical method and tested hundreds of samples to inform decisions about reopening waters to commercial fishing.

ORA continues to perform inspections, sample collections, and analyses of gulf coast seafood products to assure their safety and to support the recovery. In FY 2011, conducted 192 inspections at Gulf state seafood firms and collected 137 samples of the targeted products. ORA also deployed the Mobile Laboratory which analyzed another 1000 seafood samples.

Phthalate Contamination of Processed Foods in Taiwan:
At end of May 2011 Taiwanese Food and Drug Administration shared with FDA some intelligence on uncovered adulteration of some raw ingredients with phthalates which are chemicals used in the plastic industry. Phthalates were being substituted as clouding agents in certain ingredients by various manufacturers in Taiwan. Upon receipt of this information, ORA immediately mobilized its laboratories and launched a collaborative method development work force to rapidly put in place an analytical method to test samples from Taiwan. Concurrent with mobilizing its laboratories, ORA also mobilized its field force to start stopping and collecting imports from Taiwan suspected of being contaminated with phthalates. ORA's phthalate response continues to date with over 600 samples collected.

Promoting Efficiency

FDA has improved the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams to minimize the public health consequences of a food safety incident. Better coordination also promotes more efficient food safety response by Federal, State, and local governments through improved coordination and stronger communication during a response.

In FY 2011, FDA improved the efficiency of field analytical resources by developing new, rapid analytical methods, developing portable analytical tools for field use, and deploying the mobile chemistry and microbiology laboratories to perform rapid analytical work to assess safety of products.

Finally, to improve FDA's ability to support response and recovery, FDA Field operations continue to evaluate new technologies that provide faster, more efficient results. ORA is currently developing portable computer applications for use in the field

during inspections. These applications are designed to assist the investigator in conducting an inspection, capture data on industry compliance with specific regulations to target outreach and follow-up activities, and to improve efficiencies in preparing reports of investigations.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2011: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Reinventing Cosmetics Safety
FY 2012 Enacted Amount: $3,253,000 (All BA)

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the U.S..

In FY 2011, ORA issued 67 notices identifying modifications to cosmetics-related Import Alerts encompassing violations related to microbiological contamination and non-permitted or undeclared color additives (this is not inclusive of all cosmetic-related program areas). These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the U.S. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

Human Drugs Program

Provide Field Support to the Human Drugs Program
FY 2012 Enacted Amount: $140,011,000 (BA: $129,993,000 / UF: $10,018,000)

The ORA field force supports the Human Drugs Program by advising FDA leadership on enforcement, import inspection, and laboratory policies. Through its field offices nationwide, ORA conducts risk-based domestic and foreign premarket and post-market inspections of drug manufacturers to assess their compliance with GMPs.

Public Health Focus

ORA's public health focus addresses multiple program areas such as New Drug Review, Generic Drug Review, Drug Quality and Post Market Safety Oversight within

the Human Drugs Program.

ORA performs New and Generic Drug reviews and conducts inspections. The reviews assess the methods and facilities used to ensure strength, quality and purity. The establishment inspections verify their ability to manufacture the product to the specifications stated in the application. ORA can build enforcement cases using a number of enforcement tools such as seizures, injunctions, and prosecutions. ORA is also responsible for the oversight and monitoring of drug industry recalls

ORA conducts Bioresearch Monitoring (BIMO) program inspections to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects.

Consumers risk of exposure to defective drug products is minimized by conducting inspections, monitoring imports, and collecting and analyzing product samples of domestic and foreign drug manufacturers. These activities prevent the marketing and assist in removing violative drug products from the market. Early detection of contaminated or defective human drug products and their ingredients continues to be a priority within ORA.
.
ORA's public health focus regarding post market safety oversight is to reduce adverse events such as injuries and deaths associated with unsafe, illegal, fraudulent, substandard, or improperly used products. ORA's inspection activities include inspections of Adverse Event Reporting and Risk Evaluation Mitigation Strategies (REMS). The REMS inspection is an evaluation of compliance with the risk evaluation plan which the Food and Drug Administration Amendments Act (FDAAA) mandated.

Public Health Outcome

In an effort to increase public awareness and knowledge, and achieve beneficial public health outcomes from NDA reviews, FDA shares a series of lists on its website containing information on clinical investigators who have:

- received notification from FDA of the intent to initiate administrative proceedings to determine if the person should be disqualified from receiving investigational products
- been disqualified or 'totally restricted' and are no longer eligible to receive investigational drugs, biologics, or devices
- been recommended for disqualification
- agreed to certain restrictions
- agreed to restrictions which have been subsequently removed
- provided FDA with adequate assurances of their future compliance with requirements applicable to the use of investigational drugs and biologics.

Additionally, FDA makes available a separate list of firms or persons who have been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act.

ORA supports the generic drug review program area and achieves positive public outcomes through pre-approval and post-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with GMPs. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness and regulatory compliance.

ORA uses additional strategies to achieve positive public health outcomes in drug quality. In FY 2011, ORA entered into a 3 year Cooperative Research & Development Agreement (CRADA) with the United States Pharmacopeia (USP), to participate in the establishment of USP reference standards for drug quality assessments. The CRADA allows for ORA and USP collaboration in the USP Monograph Modernization. This will include revising and/or replacing USP monographs in order to ensure the quality and potency for active pharmaceutical ingredients and their utilization in the manufacturing of drug products.

Throughout FY 2011, select ORA field laboratories actively participated in a Pharmacy Compounding Validation pilot program. The program called for ORA laboratories to perform method verification for 10 proposed USP pharmacy compounding monographs.

ORA and the Center for Drug Evaluation and Research (CDER) implemented the pilot program for handheld portable analytical tools for use in the field for the early detection of contaminated drug products. ORA qualified a variety of tools and began a multi-tiered implementation program. The first class of tools allows for field staff to perform a limited analytical screen of drug products at the time they are offered for import into the U.S. to determine if toxic elements are present in the drug product. This tool has the capacity to test for additional elements, as reference standards and methods continue to be developed within ORA. The second class of tools allows ORA import staff to detect suspected counterfeit drugs and/or packaging, providing ORA field personnel with advanced technology to assist in screening imported drugs and identify suspect shipments. As a result of the completed pilot deployment of one class of tools in limited locations, ORA performed more than 230 field examinations. The second pilot program is ongoing. ORA will continue the phased development and deployment of the remaining classes of tools through FY 2012.

ORA continues to see an ever increasing number of drug products being offered for import into the U.S through international mail and courier facilities. ORA works with other government agencies in joint operations to address imported shipments to detect counterfeit and unapproved versions of approved medications such as "Operation Safeguard. Additionally, ORA participated in Operation Pangea IV, a global collaborative effort of government agencies in 43 countries, to perform targeted blitzes on counterfeit drug products sold via the Internet.

In FY 2011, ORA issued or updated 16 Import Bulletins and issued more than 110 notices identifying modifications to drugs related to Import Alerts. These actions were a result of ORA import surveillance collections and testing of regulated drug products at the time they were offered for import into the U.S. They also resulted from for-cause

sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These notices serve to provide increased coverage at the border to assure that these products are not available to the US consumer.

ORA drafted a new Compliance Policy Guide (currently in final clearance status with the Department) describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection. This CPG will facilitate the Agency's ability to prevent the introduction of foods and medical products in US commerce from facilities that have delayed, denied, or moved to avoid an FDA inspection.

ORA exceeded the FY 2011 performance goal targets and completing more foreign drug inspections than in the history of the program, for high risk foreign drug surveillance inspections by working with FDA global offices and continued staffing of the ORA dedicated foreign drug cadre, consisting of 15 experienced drug investigators, which augments the existing foreign inspection program.

In March 2011, FDA filed a consent decree of permanent injunction against a large manufacturer of over-the-counter drug products and two of the firm's officers for failing to comply with current good manufacturing practice requirements as required by federal law. Deficiencies at these facilities resulted in several extensive recalls.

In February 2011, FDA seized all lots of an unapproved drug solution used to treat pain and inflammation associated with ear infections. The seizure, estimated to be worth more than $16 million, was the final step in a regulatory process stemming from a 2009 inspection of the manufacturer and a Warning Letter that was issued in 2010.

ORA inspected several firms potentially involved in the manufacture of drug products of concern in relation to an outbreak of *Bacillus cereus*. The inspectional findings led to the recall of several drug products and the seizure of more than $6 million in products. A variety of drug products were seized, including povidone-iodine and benzalkonium chloride antiseptic products, cough and cold products, nasal sprays, suppositories, medicated wipes, antifungal creams, hemorrhoidal wipes, in-process drug products, and raw materials. FDA sought injunction and a consent decree of permanent injunction was entered in June 2011.

In response to post-marketing complaints of contamination of purported sterile marketed products manufactured in India, ORA investigators in the Global office performed inspections of manufacturing establishments while ORA field investigators completed follow-up inspections of domestic facilities involved in the issue. ORA investigations identified violations of post-marketing adverse drug experience reporting and resulted in subsequent recalls of three marketed products.

In January 2011, FDA worked to stop importations of "Fruta Planta," a product implicated in the death of a Florida woman. The product, labeled as a dietary supplement, contained the active pharmaceutical ingredient sibutramine, which can

cause serious adverse reactions, including death. ORA subjected the product to detention without physical examination and also worked with our CBP partners to seize a number of shipments. FDA also issued a warning to consumers not to use the product.

ORA continued to staff the Commercial Targeting and Analytical Center (CTAC), a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA will work closely with other government agencies on issues including products with undeclared active pharmaceutical ingredients or unapproved drug products.

ORA monitors recalls of human drugs that have been found to present safety concerns to assure that a firm's recall action is adequate to effectively remove the defective product from commerce. In FY 2011, FDA classified and issued recall numbers for 91 Class I; 1,279 Class II; and 246 Class III recalls of human drug products. A searchable FDA webpage and database for recalls was established. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. The Agency is committed to updating the data periodically, but at least twice per year and has already updated the data to include the first six months of FY2011. This action will provide the public and regulated industry with more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

FDA's MARCS-Compliance Management System indicated three approved CDER injunctions and two seizures for drug products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

ORA issued 108 warning letters to prevent the continued distribution of adulterated human drug products in US commerce.

ORA and CDER co-led an FDA and Federal Trade Commission (FTC) joint enforcement and outreach initiative targeting fraudulent products to treat and prevent sexually transmitted diseases (STDs). FDA and FTC issued 12 joint warning letters and FDA issued one independent letter to internet and retail firms marketing supplements and external products to treat STDs. A national roll-out for the initiative featured a press call led by ORA and a public health physician, consumer education materials, a podcast and a video.

In September 2011 in coordination with ORA's Health Fraud communication campaign, ORA launched the Health Fraud website to help raise awareness and educate

consumers, many of whom include vulnerable and underserved populations, on scams that can lead to ineffective or delayed treatment and cause serious or even fatal injuries. Videos and print materials have been developed in both English and Spanish and can be accessed through the website.

In cooperation with CDER, OCI, ORO and CFSAN, ORA initiated and implemented a strategy to monitor the marketplace, conduct undercover purchases and investigations as part of the "Operation Shady Supplement" enforcement initiative. An updated strategy emphasizes the development of criminal cases against distributors of tainted supplements by OCI. In addition, a CDER-issued sampling assignment to intercept and analyze imported samples at international mailrooms is being conducted in several districts. A white paper that describes the results of the sampling assignment will be presented at the Bilateral meeting with China in December 2011. At the meeting, CDER and ORA will again convey to the Chinese government the serious health threat posed by tainted supplements and ingredients from China and will attempt to gain cooperation from the Chinese authorities to combat the problem.

FDA issued numerous press releases citing concerns about dietary supplements that contained active pharmaceutical ingredients. The press releases warn about potentially harmful marketed dietary supplements and provided guidance to consumers on possible interactions with other medications. The releases also provide a next step if a consumer has a product of concern. FDA also issued a warning to consumers to avoid a dietary supplement because the product contained a variation of an active drug ingredient. In May 2011, FDA identified a dietary supplement of concern that was deemed to be counterfeit and to contain active pharmaceutical ingredients. FDA's analysis of the product identified two lots of counterfeit dietary supplements.

In collaboration with Canada's Competition Bureau, FDA issued two ORA - recommended warning letters to US firms marketing dietary supplements in the US and Canada on the internet and Facebook with unapproved disease claims. The warning letters were intended to target the rapidly expanding promotion of health products with illegal and deceptive claims on social networking media sites such as Facebook. One of the firms has complied and follow-up continues with the other firm.

For the 2011 Internet Week of Action, ORA Office of Enforcement (OE) reviewed nearly 1,700 websites identified by OCI to be selling unapproved prescription drugs with or without a prescription. OE captured more than 1,000 violative websites to be used as evidence to support CDER warning letters to website operators.

Based on referrals from the OCI and other sources, ORA debarred fifteen individuals with criminal convictions from participating in certain aspects of human drug industry activities.

During FY 2011, OCI made 258 arrests, and secured 214 convictions with fines, restitutions and other monetary penalties in excess of $981 million in drug related activities.

During the H1N1 epidemic, OCI conducted a significant number of test purchases of Tamiflu products from internet pharmacies. None of the test purchases required a prescription. As a result of these efforts, FDA issued an alert to consumers after it was determined that a potentially harmful product represented as “Generic Tamiflu” sold over the internet did not contain Tamiflu’s active ingredient, oseltamivir. Instead it contained cloxacillin, an ingredient in the same class of antibiotics as penicillin, which could result in injury or death for consumers who are allergic to it.

OCI continued the coordination and communication between criminal investigators, regulatory components of FDA, and the United States Attorney’s Offices in health care fraud-related investigations where OCI secured two indictments. In addition, sixteen criminal investigations were initiated including the following: 1) four investigations involving allegations of off-label drug promotion by different manufacturers of brand name drugs; 2) one investigation involving allegations of off label drug promotion and other violative promotional issues by a manufacturer of brand name drugs including unsubstantiated superiority claims and omission of risk information; 3) one investigation involving a medical device manufacturer pertaining to issues involving a recalled device product; 4) one investigation involving allegations that a company withheld nonclinical studies from FDA regarding Investigational Device Exemption applications because the studies demonstrated that the products in the applications could be hazardous to patients, and; 5) nine investigations involving allegations of clinical trial fraud and/or application fraud.

OCI received special funding from the Department of Justice (DOJ) to apply towards the completion of the recently established OCI National Document Center. This center supports OCI criminal investigations in order to obtain substantive data relating to fraudulent activity involving FDA regulated products in order to maximize monetary recoveries related to illicit proceeds. Many OCI investigations are complex and very document intensive which require a scanning and optical character resolution (OCR) solution, in order to search, identify, extract and analyze key information relating to fraudulent activity involving FDA regulated products. The OCI Document Center is being used for, but not limited, to OCI criminal investigations such as those that include the Off-Label Promotion of FDA approved drugs and medical devices, application fraud, clinical investigator fraud, healthcare fraud involving FDA regulated products, and import investigations involving any criminal investigations national in-scope or document intensive cases involving FDA regulated products.

ORA’s post market safety oversight activities to reduce adverse events involves the review of manufacturers’ adverse event and complaint files during inspections to determine if the firm is submitting all adverse drug event reports to FDA in accordance with regulatory time frames. ORA conducts follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. The final activity involves investigations of reported errors and product recalls so that program managers can collect information and develop error reduction strategies with manufacturers and the medical community in order to better protect the public health.

ORA field laboratories expanded drug surveillance activities to include a toxin/poison screening for select post market drug products. In addition, ORA laboratories also increased microbiological screening for drug products as well as vitamin Active Pharmaceutical Ingredient (API) screening for economic adulteration concerns.

Promoting Efficiency

Through its pre-approval inspection program, ORA assures the release of safe and effective drugs while preventing the sale of harmful and ineffective products. ORA also assures that a manufacturer named in a drug application is capable of manufacturing a drug in compliance with Current Good Manufacturing Practice (CGMP), and that data that supports drug review are accurate and complete.

Through the post approval program, ORA audits foreign and domestic drug manufacturers to assure that any changes in the manufacturing and process control comply with CGMP regulations, to assure that all changes are documented in supplemental applications or annual reports, and to confirm that requirements concerning Adverse Reaction Reports, NDA Field Alerts, and Annual Reports are met.

Through its inspection program, ORA achieves program efficiencies by ensuring that generic drugs marketed in the United States are shown to be both safe and effective prior to marketing and widespread use in the general population, allowing for the marketing of lower cost generics to US consumers. ORA collaborated with CDER to develop a priority listing of ANDA inspections.

The Predictive Risk-based Evaluation for Dynamic Import Compliance Testing (PREDICT) tool allows ORA to focus resources on high risk commodities while expediting the release of low risk commodities.

ORA continues to identify violations during inspections of foreign facilities to establish pre-emptive import controls. These internal actions provide for the increased surveillance of products regulated in the violative firms to ensure a higher level of scrutiny if products are offered for import into the United States.

A new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration, reduces paperwork, removes a bias toward inaction, provides a mechanism for continuous improvement in case development, and shortens approval times. In order to achieve these changes, the CMS was modified to capture milestones and allow concurrent review; the RPM was updated to incorporate the significant process changes.

ORA coordinates information sharing with the Veteran's Administration (VA) regarding the regulatory compliance of drug establishments. This collaboration has resulted in the VA's removal of violative products from its hospitals. The VA has also implemented stricter policies to ensure that products purchased and listed in its Federal Supply Schedule are produced in compliance with FDA's GMPs.

Congress requires that adverse prescription drug experience information be made available to FDA. To meet this requirement, FDA operates an inspection program to confirm that regulated industry is submitting adverse drug experience reports to FDA within the required time frames. This program also verifies the completeness and accuracy of submitted adverse event data. In so doing, FDA is able to take appropriate action to protect the public health when necessary.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2011: 788 Target: 750 (Target Exceeded)	750	750	Maintain

Biologics Program

Provide Field Support to the Biologics Program

FY 2012 Enacted Amount: $45,232,000 (BA: $40,513,000 / UF: $4,719,000)

The ORA field force supports the Biologics Program by ensuring the safety, purity, potency and effectiveness of biological products, including vaccines and allergenics, blood and blood products, and cell, tissue and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions or injuries. The field program plays a vital role in defending the public against the threats of emerging infectious diseases and bioterrorism. ORA accomplishes this public health mission by:

- conducting domestic and foreign inspections
- performing entry review and field exams on imported products at the borders
- investigating and building enforcement cases.

Public Health Focus

Inspections are focused on an establishment's ability to procure and process biological products in accordance with regulations to prevent the spread of communicable disease. Inspections are also conducted on clinical trials to ensure that:

- trials are conducted in accordance with the protocol
- human subject rights are protected
- all adverse events are reported
- data demonstrating effectiveness of the therapy is generated and collected in a manner to protect its integrity.

FDA uses a number of enforcement tools to bring about industry compliance with the law. Injunctions stop or prevent future violations of the law. Orders of Retention, Recall, or Destruction of Human Cells, Tissues, and Cellular and Tissue-based

Products (HCT/Ps) are used when conditions do not provide adequate protections against the risk of communicable disease transmission.

Public Health Outcome

ORA conducts inspections at manufacturing and processing facilities, clinical study sites used by clinical investigators and institutional review boards, blood establishments, donor centers, and laboratories that either perform testing on blood products and donors or perform quality control testing for licensed blood establishments. These inspections are conducted prior to products being approved or licensed for use and in the post-market arena after approval or licensing.

Inspections are conducted to ensure that the:

- rights of human subjects participating in clinical trials are protected through proper oversight
- data submitted to FDA used in support of applications are valid and reliable
- HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing
- blood and blood products are safe, effective, and adequately labeled as required by law and to determine the level of compliance and adherence with applicable Federal regulations
- vaccines and allergenic products comply with GMPs
- gene therapy and cell therapy products are processed according to GMPs
- laboratories are competent and adhere to contractual agreements with the licensed establishments.

In FY 2011, ORA exceeded its' goal of inspecting 1,000 of the highest risk registered blood bank and biological product manufacturers, conducting 1,112. ORA's Team Biologics completed its annual work plan, which includes manufacturers of plasma derivative biological drug products. Inspections of blood banks and plasma centers are conducted to ensure the safety of the nation's blood supply.

In FY11, FDA again exceeded the human tissue goal of 533 inspections, accomplishing 605 inspections. These inspections focus on the safe procurement and processing of human tissue for implantation. These inspections assess tissue processors to determine that appropriate procedures are in place and they have been followed to result in safe tissue available for implantation. Implanted tissue includes bone, skin, corneas, ligaments, tendons, dura mater, heart valves, and stem cells among others.

ORA conducts annual and biennial inspection coverage of foreign and domestic vaccine manufacturers that market vaccines for the US. In 2011, an ORA inspection of a foreign influenza vaccine manufacturer revealed that the firm failed to adequately evaluate strain changes and changes to the manufacturing process prior to manufacturing the 2010 seasonal influenza vaccine and also failed to conduct adequate investigations into deviations of US marketed products. The firm was issued a Warning Letter for these and other deficiencies observed.

Biennial inspections are also conducted of foreign and domestic plasma derivative and viral marker test kits manufacturers that market these products for the U.S.. In FY 2011, FDA issued a warning letter to a foreign plasma derivative manufacturer of U.S. marketed product based on violations of current GMPs uncovered during a surveillance inspection.

ORA conducts entry reviews and import field exams to determine if import entries comply with Federal regulations, assure that import entries declared as import for export are approved by the Center for Biologics Evaluation and Research (CBER) and detains all import entries not in compliance with applicable regulations.

In FY 2011, ORA continues to staff the CTAC, a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis across numerous government agencies. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA is working closely with other government agencies to ensure coverage of products within the biologics program.

ORA monitors recalls of human biological products that present safety concerns and assures the adequacy of the firm's recall to effectively remove the defective product from commerce. In FY 2011, ORA classified and issued recall numbers for 16 Class I; 1,598 Class II; and 586 Class III recalls of biologic products. In FY 2011, the agency's MARCS-Compliance Management System has indicated no approved injunctions and/or seizures of biologic products.

ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In FY 2011, FDA issued 8 warning letters to prevent the continued distribution of adulterated biologic products in US commerce.

ORA has expanding efforts to protect the American public against the marketing of counterfeit and adulterated products. During FY 2011, ORA's OCI made six arrests, and secured four convictions with fines, restitutions and other monetary penalties in excess of $1,000,000.

Promoting Efficiency

ORA continues to staff a dedicated team of investigators with specialized training and experience whose primary responsibility is to conduct inspections of all vaccine manufacturers. This team approach ensures consistent inspections by an experienced staff whose actions facilitate the timely release and marketing of safe products.

The ORA team works collaboratively with CBER product specialists. This comprehensive approach provides a single, robust inspection which makes inspections

faster and more efficient and assures that products are safe and effective for use by U.S. consumers. These efficiencies benefit both industry and U.S. consumers by facilitating the marketing and/or the release of safe products in a timely manner.

ORA achieves program efficiencies by identifying tissue processors through establishment registration and collaboration with CBER. ORA inspects the tissue processors that present the most risk to ensure products of higher risk are processed in accordance with FDA regulations and are safe and effective for U.S. consumers. Internal pre-inspectional collaboration efforts with CBER results in more efficient and thorough inspections that target human subject protection and ensure the integrity of clinical trial data. In addition, ORA works with CBER reviewers to conduct inspections of clinical trials involving gene and cellular therapies to ensure any concerns presented in the application are investigated during the inspection. This collaboration results in a more efficient process for FDA and for industry. These efforts not only allow for the timely marketing of safe products but also support efficient manufacturing of products through increased communications between regulated industry and the Agency.

ORA has provided basic and advanced training to all investigators conducting inspections in the blood and blood products area. This training resulted in a cadre of investigators who consistently use the same approach to conduct inspections, communicate regulatory requirements and document violations, providing efficient uniform inspectional findings and guidance to industry. This consistency leads to greater program efficiency.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2011: 1,112 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2011: 605 Target: 533 (Target Exceeded)	533	570	+37

Animal Drugs and Feed Program

Prioritizing Prevention - Field Activities

FY 2012 Enacted Amount: $ 12,288,000 (All BA)

Public Health Focus

To advance public health and protect consumers, ORA focuses on prevention through outreach coordination and technical assistance. To gain expertise and encourage collaboration with external stakeholders, internal and external training remains a top priority of the Field.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks that FDA articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

In the case of Prioritizing Prevention, ORA contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than relying primarily on reacting to problems after they occur and implementing the provisions of FSMA is done through the development of regulations, standards and guidance documents. These activities are reflected within the draft FDA Foods and Veterinary Medicine (FVM) Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

ORA views state-based grant programs such as the Small Scientific Conference (SSC) and Food Protection Task Force grants (FPTF) as important mechanisms for providing feed safety and feed defense program coordination. SSC and FPTF grants support an enhanced focus on topics of intervention and prevention by reviewing feed supply vulnerabilities, performing risk-based inspections, sampling, and surveillance as a means of enhancing an integrated feed safety system.

ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advance FDA policies and initiatives to internal and external stakeholders. In FY 2011, ORA outreach efforts included participation at a variety of public meetings, symposiums, webinars and conferences attended by regulated industry, other government agencies and foreign regulatory bodies.

In FY 2011, ORA awarded contracts to states under the Feed Safety BSE Contract program. These contracts aid FDA in establishing an expanded level of inspection coverage as well as surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

ORA's focus on prevention includes non-research international harmonization activities.

ORA's work with FDA's Office of International Programs (OIP) Global Offices in China, India and Latin America enables cooperation between FDA and its counterpart regulatory authorities. This cooperation improves the safety and quality of animal feed and other FDA regulated products exported to the United States, and enhances the level of feed safety and public health protection provided to consumers in the United States.

Working in collaboration with CVM/Office of Research, ORA's Denver Laboratory and the Animal Drugs Research Center (ADRC) developed, validated, implemented and published a total of twelve analytical methods. Several multiclass screening methods were developed for drug residues in food products such as milk, shrimp, finfish, and frog legs. In addition, a study in the bioaccumulation of cyanuric acid in the edible tissue of shrimp was completed.

FDA developed and is currently implementing a new strategy, in collaboration with the Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE), to better prevent the entry of smuggled food/feed into the U.S., fulfilling the requirement of FSMA Section 309(a). FDA is working closely with CBP to target and examine import shipments that could conceal undeclared foods/feeds, focusing on high risk parties and imported foods/feeds that pose a significant public health risk.

The enactment of FSMA in FY 2011 shifts the regulatory paradigm from response to prevention. During FY 2011 ORA awarded seven grants to enhance the agility and capacity of the organization to design, develop, and deliver food safety training and personnel certification programs by leveraging the collaborative efforts and expertise of prestigious academic institutions, professional trade associations, and non-profit organizations. By working with federal, state, territorial, and local regulatory and public health partners, FDA aims to establish a fully integrated food safety system (IFSS) that will place priority on preventing foodborne illness, in both food for humans and animals, through the adoption and uniform application of model programs, such as Manufactured Food and Retail Food Regulatory Program Standards and other appropriate program standards.

Promoting Efficiency

The use of grant and contract programs allows ORA to increase its focus on prevention. Grants such as the SSC and FPTF enhance evaluation of feed supply vulnerabilities, risk-based inspections, sampling, and surveillance bolster an integrated feed safety system and U.S. feed defense efforts. These efforts aid in the support of more efficient manufacturing and product development.

ORA was recently accepted into the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This will be a more efficient use of inspection resources through the sharing of GMP inspection reports with the 37 participating global authorities in PIC/S, as well as the development and promotion of harmonized GMP standards and guidance documents and training of competent authorities.

ORA's outreach events provide FDA with the opportunity to ensure transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. ORA is able to identify areas where regulated industry can work as partners to more efficiently protect the public health and serve to address safety issues related to products on the market and/or in development. These efforts also create a sense of ownership of the important role the import trade community and regulated industry play in ensuring safe and secure products for U.S consumers.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Field Activities
FY 2012 Enacted Amount: $ 13,774,000 (All BA)

Public Health Focus

To strengthen animal food/feed defense/safety, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses

Laboratory analyses activities include sample analysis, product testing and method development to enable FDA to develop solutions for specific regulatory problems. ORA applies risk based principles to the life cycle of ORA scientific operations including sample collection, sample analysis, data reporting, and data analysis.

FDA Food Safety Strategy

In the case of Strengthening Surveillance, ORA contributes to achieving the overall FDA strategy by implementing the development of risk-based systems, includes establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and a model for evidence-based resource planning, maintaining and strengthening mission-critical science capabilities, improving centralized planning and performance measurement, and improving information sharing internally and externally.

Public Health Outcome

ORA utilizes a combination of techniques to perform import surveillance:

- electronic information technology for risk-based screening
- intensive ORA staff surveillance
- physical exams
- laboratory analysis

Because the number and complexity of FDA-regulated imported products is increasing

exponentially, ORA increased its efforts to strengthen surveillance and risk analysis by:

- continuing to staff the Commercial Targeting and Analytical Center (CTAC)
- issuing 21 notices identifying modifications to animal feed and animal drug program related Import Alerts
- developing and implementing a multi-residue regulatory method designed to increase the scope of analysis for feed products in the “Distiller’s Grain” surveillance program
- conducting routine surveillance examinations, sampling, and analysis
- conducting targeted inspection and or sample collection and analysis assignments
- establishing a committee, in collaboration with the Association of American Feed Control Officials, that consists of state and FDA officials to develop Animal Feed Regulatory Program Standards (AFRPS).

In 2011, ORA awarded contracts and grants to the states to increase collaborative efforts, leverage existing resources and to bolster an integrated feed safety system. These types of ORA-awarded contracts include:

- tissue residue program contracts to states to provide for completion of tissue residue inspections by state inspectors
- Food Protection Task Force grants to state and local groups
- Small Scientific Conference grants to associations that allow for increased interactions at operational levels to assure uniformity and consistency in enforcement activities.
- contracts awarded to states under the Feed Safety BSE Contract program. These contracts aid FDA in establishing an expanded level of inspection coverage as well as surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

ORAs Prior Notice Center (PNC) was established in response to the requirements of the Public Health Security and Bioterrorism Preparedness Act of 2002 (BPA), which required FDA to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. human food and animal feed supply and other food and feed-related emergencies. In FY 2011, the PNC continued to improve its targeting and vetting processes, increase intelligence-related food and feed shipment data mining, and contribute to ORA’s response to emerging global incidents to more effectively target high risk food/feed shipments prior to their arrival.

Promoting Efficiency

ORA is increasing efficiencies by reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). PREDICT allows ORA to target its resources in a more strategic manner. PREDICT expedites clearance of low risk products while allowing ORA to focus

examination and sample collection resources on higher risk animal feed and drug products.

ORA implemented the Analytical Tools Initiative (ATI) to assess tools for the investigator toolbox to provide greater capabilities to field staff to identify and address safety issues. This includes the evaluation of field deployable kits and instruments to enhance an investigator's ability to quickly test and assess products in the field for potential public health risks as well as the evaluation of additional instrumentation for laboratory use that will enhance laboratory capacity and capability.

ORA continues to resource violative findings during inspections of foreign facilities to establish pre-emptive import controls to address safety issues related to products that are destined for the U.S. market. ORA increases examination and sampling of products manufactured under violative conditions for a higher level of scrutiny for products destined for import into the United States.

ORA's expansion of prior notice bio-security targeting capabilities and intelligence data mining have allowed ORA to provide an increased focus on imported animal food and feed shipments that pose the highest risk of an intentional act of bio-terrorism. These advances have increased bio-security review efficiency and increase FDA's ability to detect and prevent high risk feed shipments that pose a bio-security threat from reaching domestic distribution chains.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
FY 2012 Enacted Amount: $15,787,000 (BA: $ 12,598,000 / UF: $3,189,000)

Public Health Focus

One of ORA's main feed protection duties is to conduct risk-based inspections and enforcement activities. ORA investigators conduct physical inspections of regulated domestic and foreign feed establishments and conduct follow-up investigations on reports of tissue residues.

FDA Food Safety Strategy

In the case of Strengthening Enforcement, ORA contributes to achieving the overall FDA strategy by implementing new enforcement authorities designed to achieve higher rates of compliance with prevention-based and risk-based food safety standards, conducting risk-based domestic and foreign food safety inspections, implementing new enforcement tools, improving mechanisms for assuring that imported foods and feeds meet preventive controls standards, and improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts. By adopting risk-based approaches to conducting inspections, ORA is able to more efficiently utilize scarce resources and maximize the public health benefit to consumers by ensuring high rates of compliance.

Public Health Outcome

Currently, the best approach to improving the safety and security of feed is to utilize resources to expand targeting and follow through in potentially high-risk areas such as:

- reviewing risk-based scenarios of bioterrorism and develop criteria that target animal feed and feed ingredients that pose an increased risk for intentional contamination
- working in conjunction with CVM compliance to take steps to reinstate the milk monitoring program including developing methods
- creating and launching a searchable FDA webpage and database for recalls to include a process and tracking system
- implementing a new streamlined enforcement process for seizures and injunctions
- issuing 69 warning letters to prevent the continued distribution of adulterated animal products in US commerce
- drafting a new Compliance Policy Guide (currently in final clearance status with the Department) describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection supporting the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs which assures a broader regulatory framework for the U.S. feed supply.

During FY2011, there were 410 recalls involving 60 firms/manufacturers of products regulated by FDA. These included recalls of pet food, animal feed, animal drugs and animal devices. This is more than twice the number in FY 2010. In FY2011, the agency's MARCS-Compliance Management System has indicated 11 approved CVM injunction actions, two seizure actions and 10 untitled letters.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. In FY 2011, ORA made more than 1,170 informed compliance calls to regulated trade due to incomplete or inaccurate prior notice data submissions. In addition, ORA initiated more than 1,050 compliance enforcement cases, taken in conjunction with CBP, where BTA registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These actions require resubmission of accurate prior notice data before the imported food and feed shipments are allowed to enter the U.S.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are made during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011, and included data for FY2009 and FY2010 inspections. The Agency is committed to updating the data periodically, but at least twice per year and has already updated the data to include the first six months of FY2011. This action will provide the public and regulated industry with

more information about company practices that may jeopardize public health, as well as about companies that are complying with the law.

In May 2011, FDA implemented two new enforcement authorities under FSMA, both effective in July 2011. The first allows FDA to administratively detain food/feed that FDA has reason to believe is adulterated or misbranded. The products will be kept out of the marketplace while FDA determines whether an enforcement action, such as seizure or injunction against distribution of the product in commerce, is necessary. Before this new rule, FDA would often work with state agencies to embargo a food product under the state's legal authority until federal enforcement action could be initiated in federal court. In keeping with other provisions in FSMA, FDA will continue to work with state agencies on food safety and build stronger ties with those agencies.

The second authority provides FDA with more information about imports and allows for risk-based targeted examinations by requiring importers of food and feed into the United States to inform FDA if any country has refused entry to the same product. This new reporting requirement will be administered through the prior notice submission for incoming shipments of imported food/feed established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. With prior notice, in the event of a credible threat for a specific product linked to a specific manufacturer or processor, FDA will mobilize and assist in assuring products that may pose a serious health threat to humans or animals do not enter the U.S. food/feed supply. This new data requirement also allows FDA to make better informed bio-security decisions in managing the potential risks of imported food/feed.
During FY 2011, ORA's OCI opened 16 investigations that are still active. None resulted in arrests and/or convictions during FY 2011.

In FY2011, ORA worked with CVM to develop a milk sampling assignment to determine whether illegal drug residues are in the nation's milk supply. Illegal drug residues are sometimes found in the tissue of animals offered for slaughter. Many of these animals originated at dairies. To determine if the dairy industry is complying with regulations governing the treatment of cows with veterinary drugs including observing withhold times that apply to reintroducing the animal to the milking herd. This sampling assignment targets dairies that have had positive tissue residue samples in the past, but the samples will be blinded so as not to negatively impact the milk industry. This sampling assignment will be issued and is expected to be completed in FY 2012.

Promoting Efficiency

The FDA RPM was revised to provide a process for issuing Warning or Untitled Letters based on evidence obtained by state personnel. The process allows FDA to issue Warning or Untitled Letters if the standards and criteria used by state personnel provide reliable support for regulatory action consistent with FDA's guidance on regulatory actions and laboratory procedures. This process increases the number of enforcement actions and decreases the time and resources required to prevent the continued distribution of adulterated products in U.S. commerce, resulting in greater efficiency. These leveraged activities allow for greater efficiency of FDA resources, allowing for the release of safe products into the U.S. market.

Informing the import trade community of the importance of submitting accurate prior notice data via informed compliance calls, compliance actions and joint cases with CBP serves to increase the reliability and specificity of ORA bio-security assessments and targeting. These enforcement efforts have added operational efficiency to both the animal food/feed import trade community and FDA while continuing to ensure the U.S. animal feed supply is not impacted by an act of bio-terrorism. These activities continue to assist in facilitating the release of foreign sourced products into the U.S. market.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2011: 275 Target: 250 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2011: 572 Target: 490 (Target Exceeded)	500	500	Maintain

Improving Response and Recovery - Field Activities

FY 2012 Enacted Amount: $ 9,851,000 (All BA)

Public Health Focus

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to food borne illnesses. In FY 2011, ORA continued to work with the states on establishing new and develop further existing rapid response teams (RRTs), comprised of both ORA and state inspectors.

Another tool, in FDA's response and recovery efforts is the Reportable Food Registry (RFR). The RFR is an electronic portal to which industry, public health officials and consumers can report when there is a reasonable probability that an article of animal food and feed will cause serious adverse health consequences or death to animals. RFRs provide regulated industry and consumers with an immediate reporting mechanism to FDA and also supply key information that is vital for effective FDA follow up activities.

FDA Food Safety Strategy

In the case of Improving Response and Recovery, ORA contributes to achieving the overall FDA strategy by better responding to and containing problems when they occur, investigating and adopting of innovative technologies and processes to detect and investigate such events, enhancing the Reportable Food Registry, and effective risk communications related to outbreaks and contamination incidents. ORA is able to do this by responding to issues that occur across Farm-to-Table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

To rapidly respond to outbreaks and facility recovery, ORA leverages its regulatory partnerships. Examples of these partnerships include state contracts, FERN laboratories, rapid response and state lab cooperative agreements, BSE contracts, and 50-State Meetings. ORA develops and supports FERN, a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. FERN laboratories provide critical analytical surge capacity during food emergency events. The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination.

ORA developed nine RRTs through the use of cooperative agreements and continues to develop the existing teams while working to enroll remaining states in the program. The established teams continue to work with Federal and local partners (including ten ORA districts) to explore, develop, implement, and share best practices. This work enables Federal and state partners to improve their systems to quickly and effectively stop an outbreak; mitigate the concern; and when possible and appropriate, identify sources of contamination and contributing factors for the outbreak and reach conclusions and possible interventions for the prevention of future cases. The RRTs have developed tools and guidance to share and facilitate improvement on key capabilities that are essential for effective responses to emergencies.

ORA continues to respond to numerous pet foods and animal feed RFRs in FY 2011.

Promoting Efficiency

Improving the coordinated, rapid response of federal, state, and local partners to feed related emergencies through the use of RRTs helps to minimize the public health consequences of an incident while diminishing unnecessary costs at the federal, state, and local levels resulting from poor response coordination or communication.

RFR is an example of how FDA uses technology to prevent animal feed safety threats from resulting in consumer illness or injury, providing a reliable mechanism to track patterns of adulteration in feeds. Pre-emptive investigations into reports received assured ORA investigations were comprehensive and affected products were contained and recalled before illness or injury could occur. In addition, these efforts provide information to FDA in a manner which allows the Agency to follow up with regulated industry to timely cease the production of unsafe products resulting in savings for manufacturers.

Provide Field Support to the Animal Drugs Program
FY 2012 Enacted Amount: $5,286,000 (BA: $4,811,000 / UF: $475,000)

Public Health Focus

The ORA field supports the Animal Drugs Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its field offices nationwide, ORA supports the Animal Drugs Program by conducting premarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products. ORA supports the Animal Drugs Program by evaluating manufacturing practices to determine the safety and effectiveness of manufactured products.

Public Health Outcome

ORA's field force conducts preapproval inspections to support CVM's review of New Animal Drug Applications (NADA) and Abbreviated New Animal Drug Applications (ANADA) by the following:

- inspecting manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application
- performing inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed
- supporting the Animal Drugs Program by conducting post-market inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products
- monitoring and sampling imports to ensure the safety of the animal drug supply. In instances of criminal activity, ORA's OCI and the Forensic Chemistry Center complement the regular field force activities
- supporting CVM's evaluation of adverse event reports by conducting follow-up

inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved

- reviewing adverse event and complaint files during inspections for compliance with FDA reporting regulations. In the event of a public health incident concerning a disease from an animal, for example salmonella from pet turtles, ORA will assist CVM by conducting any appropriate investigations.

Promoting Efficiency

ORA provides continuous training for the inspection of animal drug manufacturers and non-clinical laboratories assuring a consistent inspection process. When significant violations are observed, ORA works collaboratively with CVM to determine and implement the appropriate follow-up regulatory actions to assure the safety of U.S. public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2011: 275 Target: 250 (Target Exceeded)	250	250	Maintain

Devices and Radiological Health

Provide Field Support to the Devices Program

FY 2012 Enacted Amount: $95,334,000 (BA: $81,197,000 / UF: $14,137,000)

Public Health Focus

The ORA field advises FDA leadership on device enforcement, import, inspection, and laboratory policies. ORA conducts risk-based domestic and foreign post-market inspections, field exams, and sampling of medical device manufacturers to assess their compliance with the Quality Systems regulations. ORA's radiological health activities include inspecting radiation emitting products such as lasers, sunlamps and x-ray equipment to ensure that they comply with applicable performance standards. In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods.

ORA conducts premarket inspections of foreign and domestic establishments to

determine if the facility is able to manufacture products according to the specifications stated in their application. ORA also conducts bioresearch monitoring inspections of clinical research studies, including clinical investigators, sponsors, monitors and Institutional Review Boards (IRBs), to safeguard patients and validate laboratory methods and data submitted for device premarket application decisions.

ORA provides support to post-market safety by conducting follow-up investigations and inspections of Medical Device Reporting (MDR) reports at either the reporting medical facility or the manufacturer. These inspections are conducted to identify significant GMP problems by analyzing recurring manufacturing and product problems and by performing trend analyses. ORA collects data on complaints, significant problems and potential hazards so that corrective actions can be initiated for hazardous products in the marketplace. ORA also conducts bioresearch monitoring inspections of post-approval studies, which monitor the post-market safety of products already available to the public for use.

ORA works with state contractors through the inspection contract program to assure the safety, quality, and effectiveness of medical devices. Inspections ensure that medical device manufacturers are in compliance with the Quality Systems Inspection Technique (QSIT)/Good Manufacturing Practices (GMP) regulations.

ORA's Winchester Engineering and Analytical Center (WEAC) conducts analyses and develops new analytical test methods for medical devices and radiation emitting electronic products.

ORA continues to focus resources on health prevention by carrying out the mammography facility inspection contract program with the states, which includes an annual audit of state inspections and FDA-provided training for state inspectors.

Public Health Outcome

A major focus for ORA in 2011 is the leveraging of information and communication with other local, state, and federal entities to increase efficiency and broaden the scope of public health coverage including:

- managing the medical devices contract with Texas for a total of 20 inspections, including eight Quality Systems Inspection Technique (QSIT) Level one and 12 QSIT Level two inspection
- staffing the CTAC, a facility designed to identify safety risks in imported products by leveraging information sharing and data analysis by numerous government agencies
- continuing to develop new and improved methodology to support regulatory analysis, validate analytical methods to support enforcement activities, and conduct product evaluation study projections to provide comprehensive post-market surveillance information about devices
- creating and launching a searchable FDA webpage and database for recalls, as

well as a process and tracking system
- conducting import entry reviews and import field examinations to ensure imported medical devices and their components are in compliance with FDA requirements
- collecting surveillance samples of imported medical devices and their components to assure industry conformance with FDA regulations and standards as well as for cause sample collections when concerns or issues arise that indicate possible non-conformances with FDA regulations.
- implementing a new streamlined enforcement process for seizures and injunctions
- monitoring recalls of medical devices that have been found to present safety concerns. This monitoring assures that a firm's recall is adequate to effectively remove the defective product from commerce
- drafting a new Compliance Policy Guide (currently in final clearance status with the Department) describing policy for refusing imports of foods and medical products exported from facilities that have refused an FDA inspection.
- developing new and innovative test methods for automatic external defibrillators (AEDs), infusion pumps, ventilators, endotracheal tubes, and hemodialysis blood tubing sets to evaluate imports of medical devices ensuring products meet FDA quality standards
- conducting criminal investigations involving the internet. OCI investigates wide variety of alleged violations, including illegal Internet pharmacies and any other websites engaged in the illegal marketing and/or sale of any FDA-regulated products. Violative websites are proactively identified, researched, and investigated.

In FY 2010, ORA established a dedicated foreign device cadre consisting of ten experienced medical device investigators to augment the existing foreign inspection program. The cadre continues to perform foreign device firm inspections which will provide greater assurance that products manufactured abroad are safe for use in the United States. In FY 2011, the dedicated foreign device cadre conducted approximately 170 inspections. In follow-up to objectionable conditions noted during these inspections, FDA has issued twenty-five Warning Letters, nine of which included placing the firm on Import Alert with automatic detention. In addition, in FY 2011 FDA established a new import alert for foreign medical device firms that refuse ORA surveillance inspection, and ORA added one firm to that Import Alert.

The focused efforts of ORA's laboratories, in conjunction with leveraged advances through collaboration with academia, federal and state partners, continue to ensure that suspect medical devices are removed from U.S. commerce. In FY 2011, new methods, analyses and expert scientific testimony by ORA staff assisted U.S. Attorneys in New York and Georgia obtain criminal convictions.

In FY 2011, efforts made by ORA led to several medical device product recalls including billions of Huber-style needles used for chemotherapy delivery, counterfeit surgical mesh distributed to hospitals and surgical centers nationwide, and tainted contact lens eye solution distributed to retail establishments throughout the U.S.

ORA field offices investigate and build enforcement cases. A number of enforcement tools bring about industry compliance with the law. Seizure removes a violative commodity from commerce. Injunction stops or prevents future violations of the law. Administrative Detention prevents distribution or use of violative devices until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action. Civil Money Penalties (CMP) serve to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

In FY 2011, ORA issued 91 notices identifying modifications to medical device-related Import Alerts encompassing numerous products and firms determined to be manufacturing or shipping violative medical device products. These actions were a result of ORA import surveillance collections and testing of regulated products, as well as for cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. These actions serve to provide the ORA with a mechanism for automatic detention of violative products and the notices provide increased communication of those actions.

ORA conducted 1,513 medical device laboratory analyses in FY 2011 using a risk-based approach focusing on device categories that historically have been responsible for a disproportionate share of adverse events and recalls. Some of these laboratory analyses led to medical device product recalls including infant and neonatal filter line sets used by emergency medical services and hospitals during ventilation of newborn infant patients; blood tubing sets used during hemodialysis; Automatic External Defibrillators (AEDs) distributed to fire departments, Emergency Medical Services (EMS), health clubs and schools; and tainted contact eye solution distributed to retail establishments throughout the U.S.

In FY 2011, FDA classified and issued recall numbers for 427 Class I; 2,665 Class II; and 119 Class III recalls of medical device products.

In FY 2011, ORA issued 175 warning letters to prevent the continued distribution of adulterated medical device products in US commerce

ORA has expanded efforts to protect the American public against the marketing of counterfeit and adulterated products. OCI made twenty arrests, and secured eighteen convictions with fines, restitutions and other monetary penalties in excess of $278 million in device related activities.

Promoting Efficiency

ORA is increasing efficiencies by :

- reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) – PREDICT allows ORA to target its resources in a more strategic manner. PREDICT

expedites clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk device products

- implementing a joint initiative to create and issue a series of field advisories to assist ORA investigators – This effort to establish and implement nationwide guidance resulted in uniform national procedures that increase the efficiency of admissibility decisions while minimizing delays in processing import shipments. ORA scientists leveraged ongoing research with federal partners and academia to develop new analytical methods using advances in technology. The Science Board cited one specific scientific collaboration between ORA labs and MIT/Harvard on the fracture of stents to FDA as a model federal government-academia collaboration.
- working with CDRH to develop pilot programs designed to increase the efficiency of the review of inspectional findings related to pre-clearance 510(k) and MDR violations – The expected outcome of the pilot programs is to speed the review of inspectional findings and issue Warning Letters in a more efficient and quicker manner. This outcome would result in more rapid decision making and communication with the manufacturer so industry can take swifter action to comply and improve public health protection.
- issuing press releases, guidance to industry and alerts providing industry, health care professionals and consumers with FDA recommendations, guidance or warnings on specific medical devices – These FDA communications ensured efficient and timely public health response and industry and consumer awareness.
- working with the states to maintain Mammography Quality Standards Act (MQSA) contract program quality standards – This collaboration ensures that women receive high quality mammography for early breast cancer detection.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2011: 322 Target: 300 (Target Exceeded)	300	300	Maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2011: 1,799 Target: 1,445 (Target Exceeded)	1,515	1,600	+85

Tobacco Act Program

Regulation and Compliance Activities

FY 2012 Enacted Amount: $6,250,000 (All UF)

Public Health Focus

ORA supports the Tobacco Control Act Program by providing training to field and State employees, conducting surveillance activities such as investigations and inspections with State counterparts of regulated industry, and collecting and analyzing samples of tobacco products to ensure compliance with the requirements of the Tobacco Control Act and other applicable regulations as they become effective. These activities help reduce the number of more than 400,000 Americans dying from tobacco-related illnesses every year and tobacco-related health care costs exceeding $100 billion annually.

The Tobacco Control Act bans flavor compounds – with the exception of menthol – from being added to tobacco products that are cigarettes.

In FY 2011, ORA began to establish a tobacco testing laboratory which will develop the expertise and capacity to analytically enforce the mandates of the Tobacco Control Act. The ORA laboratory will acquire tobacco-specific testing equipment such as smoking machines and will service CTP assignments which may include testing cigarettes for flavor compounds and other potentially harmful contaminants. Analytical test results obtained by the ORA laboratory will be used to remove tobacco products from the market and will provide legal evidence to enforce the mandates of the Tobacco Control Act. Concurrently, ORA is collaborating with the Alcohol and Tobacco, Tax and Trade Bureau and CTP on method development and validation studies to expand analytical capabilities for detecting harmful chemical contaminants. In addition, ORA's Forensic Chemistry Center (FCC) laboratory will provide support to OCI related to the identification and characterization of counterfeit cigarettes.

In FY 2012, ORA began inspections of registered tobacco product establishments to determine their compliance with the law . These include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products,

Public Health Outcome

In order to enforce tobacco regulations and to comply with the statute, FDA contracts with State and Territorial governments to conduct compliance inspections to ensure that retail establishments are not selling tobacco products to persons under the age of eighteen and are complying with other aspects of "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents", as well as with other provisions of the Tobacco Control Act. FDA is currently on track to meet the FY 2012 goal of contracting with 95 percent of States and

Territories to assist with compliance and enforcement.

- In FY 2011, FDA issued 1,040 warning letters to prevent the continued distribution of adulterated tobacco products in US commerce.
- Four criminal investigations were initiated during FY 2011 as a result of outreach performed coupled with OCI's internal monitoring of the marketplace.
- ORA will conduct surveillance, investigations, and inspections of regulated industry to ensure compliance with the Tobacco Control Act and related regulations.
- ORA will collaborate with the CTP to conduct initial inspections of tobacco manufacturers. These efforts will lead to the development of a formal training course for investigators and a compliance program.

Promoting Efficiency

FDA will continue to engage in enforcement activities, including laboratory-based support, to ensure that industry complies with the regulations issued by FDA to implement the Tobacco Control Act.

Specific examples of program efficiencies that may flow from these activities include development and promulgation of standards for laboratory testing such as testing for harmful and potentially harmful ingredients of tobacco products. Once developed and promulgated, the laboratory and testing standards will create uniform methods and standards by which the tobacco manufacturers can analyze their products in an efficient and targeted manner, and assure compliance with FDA requirements. Thus, the tobacco industry will avoid inefficient use of its resources for broad or unnecessary product testing.

ORA has begun the process of developing a trained cadre of investigators to perform tobacco manufacturer inspections. ORA and CTP have identified the establishments to be inspected, and ORA is collaborating with CTP to develop and present training to ORA investigators. By using a cadre approach to conducting these types of inspections, ORA will develop a staff of investigators who are well trained in tobacco regulation, policy and inspection techniques.

ORA's tobacco commissioning program further increases FDA's efficiency in in sharing information with State and local agencies. This program is modeled on the traditional food and drug commissioning process and allows states to complete inspections on behalf of FDA. As of the end on FY 2011, officials have been commissioned in 37 states and one U.S. territory to support contracts with FDA to conduct retail tobacco inspections.

Information Technology Investments – Field Activities (ORA) (FY 2012 Enacted Amount is included in the applicable Program Description and Accomplishments sections.)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

The following are examples of IT development efforts that support of field activities to enhance FDA's ability to collect, store and analyze large volumes of regulatory, scientific, and compliance risk-based data for action and reporting. While continuing the maintenance of fragile legacy systems, the Mission Accomplishment and Regulatory Compliance Services (MARCS) program is integrating, reengineering and enhancing ORA's automated work flows, replacing outdated and failing technology. The reengineering effort results in a more sustainable paradigm for maintenance and agility. MARCS improves the efficiency of FDA Field Operations staff by:

- making existing functionality and data much easier to access and use
- leveraging economies of scale with shared technology services
- employing an integration acquisitions model to reduce risk
- enhancing the ability to store and retrieve findings obtained during both import and domestic investigations, inspections, compliance, and laboratory actions
- improving compliance targeting and analysis to better protect the public health and more quickly provide information to Congress, other Federal agencies, affected states and the public.

FDA will continue to improve processing of the import data received through automated compliance targeting assessment algorithms using the screening tool Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) within MARCS, deployed in CY11.Under the Automated Laboratory Management (ALM) program, integration and assimilation in MARCS and thus FDA systems continues, enabling greater volumes of data analysis on samples of products and substances, improving safety, compliance, automation, and information sharing.

The Regulatory Business Information Services (RBIS) is integrating reporting needs with program integration to reduce redundancy and increase efficiency, creating a fully leveraged program of services and applications.

These modernization efforts along with the ongoing operations and maintenance of legacy systems will measurably improve and automate FDA's field operations. FDA's increased automated coordination with other agencies enhances the public health and the FDA safety mission for protecting American consumers.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2008 Actual	$573,181,000	$555,450,000	$17,731,000	3,314
2009 Actual	$780,690,000	$761,036,000	$19,654,000	3,895
2010 Actual	$869,112,000	$847,000,000	$22,112,000	4,235
2011 Actual	$912,120,000	$890,474,000	$21,646,000	4,570
2012 Enacted	$961,800,000	$906,790,000	$55,010,000	4,685

Summary of the Budget Request

The FY 2013 budget request for the Office of Regulatory Affairs is $1,128,029,000. This amount is an increase of $166,229,000 above the FY 2012 Enacted Level.

The FY 2012 Enacted amount for ORA is $961,800,000. Base funding allows ORA to meet its mission of ensuring that food, feed, and medical products available to the American public are safe and effective. This is accomplished by maximizing compliance of FDA regulated products with safety and quality standards and minimizing the risks associated with the use of those products. ORA serves as the traditional "eyes and ears" of FDA through its network of investigators and laboratory analysts to enforce laws that protect and advance public health. ORA's activities are aimed at improving the safety of FDA-regulated food, feed, and medical products, and providing inspectional oversight for the administration of the Tobacco Control Act.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Nutrition and Protect Patients.

Budget Request

Pay Increase (Commissioned Corps): +$626,000

The request for $894,826,000 in total budget authority for ORA reflects a pay increase of $626,000 for the Commissioned Corps.

Data Consolidation and IT Savings
Total ORA (-$8,012, 000 / 0 FTE)

The budget request for $894,826,000 in total budget authority for the Field Programs also reflects data consolidation and IT savings reduction of -$8,012,000 for FY 2013.

The Office of Regulatory Affairs will achieve savings by:

- reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs.
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams and achieve economies of scale in the 24/7/365 network and server operations.
- streamling user enhancements by leveraging economies of scale, completing the build-out of the Mission Accomplishment and Regulatory Compliance Services (MARCS) program, and providing the support architecture for other integrated systems.
- economizing on maintenance costs of the MARCS program through use of state-of-the-art technology and the retirement of costly legacy systems.

Rent Absorption (-$4,578,000 / 0 FTE)

The request for $894,826,000 in total budget authority for ORA also reflects rent absorptions of -$4,578,000 for FY 2013. ORA will absorb part of the cost of the FY 2013 rent increase by cutting operating costs.

The Pay Increase (Commissioned Corps), Data Consolication and IT Savings, and Rent Absorption affect all sub-programs.

FOODS

Prioritizing Prevention

Field Activities – FY 2012 Enacted Amount: $111,373,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$49,360,000 / 39 FTEs)

2013 Initiatives:

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF $9,360,000 / 39 FTEs)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire two FTE to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard
- hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- hire 25 FTE to perform program oversight through ORA audits of regulatory and public health partners to measure their performance against FDA program standards
- hire six FTE to serve as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire three FTE to develop and validate certification testing instruments.

Transforming Food Safety: Regulations and Guidance (UF $40,000,000 / 0 FTE)

To implement and enforce preventive controls in food processing facilities, FDA will train more than 9,600 ORA inspections personnel, as well as a portion of FDA's State, Tribal, and Territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

Field Activities – FY 2012 Enacted Amount: $286,953,000 (All BA)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$12,961,000 / 51 FTEs)
FY 2013 Increase for Proposed User fees (International Courier): **(**+$721,000; 3 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF $11,040,000 / 43 FTE)

This investment will allow FDA to continue to administer the Foreign Supplier Verification Program (FSVP) and conduct import verification inspections using risk-based strategies to target inspections and rapid field tests to better target sampling at the border. FDA will establish and implement procedures for electronic verification of importers compliance status with FSVP. This electronic verification will allow FDA to make appropriate admissibility determinations for foods offered for import.

- hire 43 FTE to support the FSVP, which is a subcomponent of the Import Accountability Verification Program

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF $1,200,000 / 5 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. With these resources, ORA will :

- hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the states as FDA moves to national standards for laboratories.

Strengthening Surveillance and Enforcement – B. Strengthening Enforcement

Field Activities – FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$39,164,000 / 32 FTE)
FY 2013 increase for Current Law User Fees (Food Re-inspection): (+$309,000 / 0 FTE)
FY 2013 increase for Current Law User Fees (Recall): (+$426,000 / 0 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 305, 306 and 307 (UF $10,204,000 / 30 FTE)

With this investment FDA will continue to conduct foreign food safety system comparability assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs. FDA will also increase staff to conduct accredited third party certification performance audits and assessments. FDA will work with foreign regulatory counterparts on an individual and/or coalition basis to improve information sharing, outreach to the private sector, and other collaboration to facilitate implementation of the import safety provisions of FSMA.

Concurrently, FDA will use budget authority to expand critical enforcement and compliance support for foreign food facility inspections. These activities include planning inspections, notifying foreign firms to request permission to conduct inspections, reviewing inspection reports, developing decision support systems, and managing follow-up on compliance actions.

- hire 15 FTE to conduct audits of foreign regulatory bodies
- hire 15 FTE to perform performance assessments and audits of the Third-Party Certification Recognition/Accreditation Program.

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF $15,225,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- provide funding to Federal, State, Local, Territorial and Tribal regulatory and public health partners in the form of at least ten states grants, contracts, cooperative agreements or inter-agency agreement between federal agencies. Ten of the state grants, contracts, cooperative agreements or inter-agency agreements between federal agencies will be funded with budget authority and ten will be funded with user fees.
- improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Transforming Food Safety: Domestic Inspections and Technology for Greater Efficiency – FSMA Sections 201 (UF +$13,000,000 / +2 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic

inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable for their responsibility to produce safe products.

The resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs and improve FDA food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. These improvements are essential to achieve the most public health value from FDA inspection and compliance programs and successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote Access Devices will allow field staff to:

- examine shipments and complete all required electronic submissions for data entry on site
- print labels for samples collected
- complete collection reports and all necessary documentation.

In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Improving Response and Recovery

Field Activities – FY 2012 Enacted Amount: $49,327,000 (All BA)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$240,000 / 1 FTE)

2013 Initiatives:

Transforming Food Safety: Planning and Response – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF +$240,000 / 1 FTE)

This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private industry.

- fund one FTE to develop and implement traceback procedures

Reinventing Cosmetics Safety

Field Activities – FY 2012 Enacted Amount: $3,253,000 (All BA)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$4,320,000 / 18 FTE)
FY 2013 increase for Proposed User Fee - Cosmetics User Fee: (+$4,320,000 / 18 FTE)

FDA is proposing new legislative authority to require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and list their products with FDA as well as pay an annual fee on a sliding scale for certain small businesses. Registration will provide both FDA and industry with a better understanding of the cosmetic products being marketed. The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used by consumers.

Without this initiative, FDA will continue to lack vital information necessary to provide domestic regulatory oversight and leadership, as well as leadership in international harmonization efforts. Moreover, without knowledge of the full range of cosmetic products and ingredients marketed in the United States and the facilities that are involved in providing such products to American consumers, including foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe products.

This initiative provides long-term, stable funding for the FDA Cosmetics Program which, in turn, ensures better public health protection for all Americans. The initiative will also better enable FDA to obtain critical data about the industry in an increasingly global marketplace, and provide increased public confidence and continued U.S. leadership in international harmonization efforts. These benefits are largely realized by industry in terms of increased sales and lower costs.

HUMAN DRUGS

Field Activities – (FY 2012 Enacted Amount: $140,011,000 (BA: $129,993,000 / UF: $10,018,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$54,641,000 / 175 FTE)
FY 2013 Increase for PDUFA: (+$213,000 / 0 FTE)
FY 2013 Increase for Proposed User Fees (GDUFA): (+$51,811,000 / 150 FTE)
FY 2013 Increase for Proposed User Fees (Re-inspection): (+$2,749,000 / +18 FTE)
FY 2013 Increase for Proposed User Fees (International Courier): (+$481,000 / +2 FTE)

2013 Initiatives:

Protecting Patients Initiative: Generic Drug User Fee (+51,811,000 / 150 FTE)

ORA supports the generic drug program through increased pre-approval ANDA inspections to verify application data and assess the firm's ability to manufacture products in accordance with CGMPs. ORA also conducts inspections of bioequivalence studies to substantiate source data and verify accuracy, completeness and regulatory compliance.

ORA supports the drug quality program through increased post-market GMP surveillance inspections in order to assess the finished dosage form (FDF) and active pharmaceutical ingredient (API) generic drug firms' abilities to manufacture their products in accordance with CGMPs.

Protecting Patients Initiative: Biosimilars User Fee (+$1,290,000 / 5 FTE)

FDA will develop scientific and regulatory policies to facilitate the review and availability of biosimilars. ORA will hire investigators to conduct 30 domestic and 12 foreign biosimilars pre-approval inspections per year. After receiving the necessary training, the full performance year for achieving the domestic inspections will be FY 2015. For foreign inspections, full performance will occur in FY 2016.

BIOLOGICS

Field Activities – FY 2012 Enacted Amount: $45,232,000 (BA: $40,513,000 / UF: $4,719,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$190,000/ 3 FTE)
FY 2013 Increase for PDUFA: (+$90,000 / 0 FTE)
FY 2013 Increase for MDUFMA: (+$107,000 / 0 FTE)
FY 2013 Increase for Proposed User Fees (Re-inspection): (+$561,000 / 3 FTE)

ANIMAL DRUGS AND FEED

Prioritizing Prevention

Field Activities – (FY 2012 Enacted Amount: $12,288,000 (BA: $12,288,000 / UF: $0))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$2,440,000 / 6 FTE)

2013 Initiatives:

Transforming Food Safety: Regulations and Guidance - FSMA Section 110 (UF $1,000,000 / 0 FTE)

Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources:

- support the implementation and enforcement of preventive controls in feed processing facilities
- continue to train some 400 inspection personnel – consisting of ORA inspection personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners – in preventive controls inspections and enforcement methods.

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$1,440,000 / 6 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the animal food and feed supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the animal food and feed supply. ORA will conduct the following activities with the resources in this subprogram:

- fund two FTE to develop and validate certification testing instruments
- fund four FTE for program oversight through ORA audits of regulatory and public health partners to measure performance against FDA program standards.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Field Activities – (FY 2012 Enacted Amount: $13,774,000 (BA: $13,774,000 / UF: $0))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$480,000 / 2 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$480,000; 2 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. In this subprogram, ORA will hire:

- one FTE to serve as an Official Establishment Inventory (OEI) Coordinator for the field
- one FTE to serve as a Scientific Coordinator to support the states as FDA moves to national standards for laboratories.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Field Activities – (FY 2012 Enacted Amount: $15,787,000 (BA: $12,598,000 / UF: $3,189,000))

FY 2013 Total Increase above FY 2012 Enacted Level: (+$1,030,000 / 2 FTE)
FY 2013 Increase for Current Law User Fees (Re-inspection): (+$116,000; 0 FTE)
FY 2013 Increase for Current Law User Fees (Recall): (+$29,000; 0 FTE)

2013 Initiatives:

Transforming Food Safety: Inspections and Technology for Greater Efficiency – FSMA Section 201 (UF +$645,000 / 1 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable for their responsibility to produce safe products.

The resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs and improve FDA food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. The improvements are essential to achieve the most public health value from FDA inspection and compliance programs and successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote Access Devices will allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$240,000 / 1 FTE)

Investment supports a comprehensive prevention-focused import feed safety program that will rely more heavily on entities in the feed supply chain – feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the feed imported to the United States are safe and meet regulatory requirements. With these resources, ORA will:

- hire one FTE to conduct import verification inspections in support of the Foreign Supplier Verification Program.

Improving Response and Recovery

Field Activities – (FY 2012 Enacted Amount: $9,851,000 (BA: $9,851,000 / UF: $0))

Provide Field Support to the Animal Drugs Program

Field Activities- (FY 2012 Enacted Amount: $5,286,000 (BA: $4,811,000 / UF: $475,000)

FY 2013 Increase above FY 2012 Enacted Level: (+$340,000 / 1 FTE)
FY 2013 Increase for Current Law User Fees (ADUFA): (+$149,000; 0 FTE)
FY 2013 Increase for Current Law User Fees (AGDUFA): (+$51,000; 0 FTE)
FY 2013 Increase for Proposed User Fees (Medical Products Re-inspection): (+$140,000; 1 FTE)

DEVICES AND RADIOLOGICAL HEALTH

Field Activities – (FY 2012 Enacted Amount: $95,334,000 (BA: $81,197,000 / UF: $14,137,000)

FY 2013 Total Increase above FY 2012 Enacted Level: (+$6,207,000 / 39 FTE)
FY 2013 Increase for MDUFMA: (+$221,000 / 0 FTE)
FY 2013 Increase for Proposed User Fees (Medical Product Re-inspection): +$3,579,000 / 24 FTE
FY 2013 Increase for Proposed User Fees (International Courier): (+$3,606,000 / 15 FTE)

TOBACCO

Field Activities – (FY 2012 Enacted Amount: $6,250,000 (All UF)

FY 2013 Increase for Current Law User Fees (Tobacco): (+$3,150,000 / +15 FTE)

FDA will work to expand inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers and importers in FY 2013. FDA's Office of Regulatory Affairs will conduct inspections of tobacco product manufacturers to ensure their compliance with the laws. These inspections will determine whether a company is properly submitting registration, product and ingredient listing information; complying with the packaging, labeling and advertising requirements; and other statutory and regulatory requirements.

There are several other activities associated with expanding inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers, and importers that FDA will initiate or continue in FY 2013 including:

- utilizing the FDA laboratory that tests, evaluates, and processes regulatory samples of tobacco products that will be used to support enforcement actions.
- expand internet surveillance and investigation of tobacco product manufacturers, distributors and retailers to ensure their packaging, labeling, marketing, and advertisements of tobacco products is in compliance with the laws
- continue to send Warning letters and initiate other enforcement actions for violations identified.

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***10,517***	***12,517***	***12,517***
Domestic Food Safety Program Inspections	7,385	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	305		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	483		
Domestic Fish & Fishery Products (HACCP) Inspections	1,752		
Import (Seafood Program Including HACCP) Inspections	353		
Juice HACCP Inspection Program (HACCP)	220		
Interstate Travel Sanitation (ITS) Inspections	1,088		
Domestic Field Exams/Tests	4,092	3,945	3,945
Domestic Laboratory Samples Analyzed	11,240	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***999*** [2]	***1,200***	***1,200*** [1]
All Foreign Inspections	999	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***11,516***	***13,717***	***13,717***
IMPORTS			
Import Field Exams/Tests	201,406	160,200	160,200
Import Laboratory Samples Analyzed	35,292	35,300	35,300
Import Physical Exam Subtotal	**236,698**	**195,500**	**195,500**
Import Line Decisions	10,167,887	10,616,840	11,085,616
Percent of Import Lines Physically Examined	2.33%	1.84%	1.76%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	88,057	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,765***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***273***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,535	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,123	1,104	1,104
State Contract Juice HACCP	93	103	103
State Contract LACF	79	68	68
State Partnership Inspections	273	273	273
State Contract Foods Funding	$19,068,458	$11,507,200	12,312,710
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$18,270,000	$18,390,000	$18,490,000
Total State & Annual FERN Funding	**$37,338,458**	**$29,897,200**	**$30,802,710**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***21,554***	***24,513***	***24,513***

[1] For investigators hired with FY 2013 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2013 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2011 actual unique count of foreign inspections includes 35 OIP inspections (25 for China and 10 for India).

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**153**	***100***	***100***
Domestic Inspections	153	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***2***	***0***	***0***
Foreign Inspections	2	0	0
IMPORTS			
Import Field Exams/Tests	3,034	1,600	1,600
Import Laboratory Samples Analyzed	626	630	630
Import Physical Exam Subtotal	**3,660**	**2,230**	**2,230**
Import Line Decisions	2,121,088	2,389,000	2,690,751
Percent of Import Lines Physically Examined	0.17%	0.09%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT	***155***	***100***	***100***

Combined Field Activities – ORA
Program Activity Data

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,215***	***2,325***	***2,325***
Pre-Approval Inspections (NDA)	140	197	197
Pre-Approval Inspections (ANDA)	64	153	153
Bioresearch Monitoring Program Inspections	512	453	453
Drug Processing (GMP) Program Inspections	1,193	1,023	1,023
Compressed Medical Gas Manufacturers Inspections	296	317	317
Adverse Drug Events Project Inspections	84	147	147
OTC Monograph Project and Health Fraud Project Inspections	68	184	184
Domestic Laboratory Samples Analyzed	1,311	1,310	1,310
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***727*** [2]	***676***	***676*** [1]
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	177	117	117
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	105	62	62
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	177	231	231
Foreign Drug Processing (GMP) Program Inspections	518	488	488
Foreign Adverse Drug Events Project Inspections	5	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,942***	***3,001***	***3,001***
IMPORTS			
Import Field Exams/Tests	9,080	6,200	6,200
Import Laboratory Samples Analyzed	369	370	370
Import Physical Exam Subtotal	**9,449**	**6,605**	**6,605**
Import Line Decisions	477,818	557,223	649,825
Percent of Import Lines Physically Examined	1.98%	1.19%	1.02%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***150***	***150***	***150***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	122	122	122
State Partnership Inspections: GMP Inspections	5	2	2
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***3,092***	***3,151***	***3,151***

[1] For investigators hired with FY 2013 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2013 funding increase for inspections will allow OIP to conduct an additional 120 foreign human drug safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2011 actual unique count of foreign inspections includes 42 OIP inspections (14 for China and 28 for India).

Combined Field Activities – ORA
Program Activity Data

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,051***	***1,723***	***1,764***
Pre-Approval /BIMO Inspections	50	79	79
Drug Process and New ADF Program Inspections	248	205	222 [3]
BSE Inspections	1,571	1,205	1,205 [2]
Feed Contaminant Inspections	29	25	25
Illegal Residue Program Inspections	405	440	473 [1]
Feed Manufacturing Program Inspections	191	141	141
Domestic Laboratory Samples Analyzed	1,674	2,458	2,458
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***53*** [4]	***68***	***68***
Foreign Pre-Approval/Bioresearch Monitoring Program	26	45	45
Foreign Drug Processing and New ADF Program Inspections	33	33	33
Foreign Feed Inspections	7	7	7
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,104***	***1,791***	***1,832***
IMPORTS			
Import Field Exams/Tests	6,254	3,600	3,600
Import Laboratory Samples Analyzed	747	750	750
Import Physical Exam Subtotal	**7,001**	**4,350**	**4,350**
Import Line Decisions	284,973	342,600	411,881
Percent of Import Lines Physically Examined	2.46%	1.27%	1.06%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,651***	***5,949***	***5,949***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***151***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,630	5,850	5,850
State Contract Inspections: Feed Manufacturers	444	321	321
State Contract Inspections: Illegal Tissue Residue	204	412	412
State Partnership Inspections: BSE and Other	151	151	151
State Contract Animal Drugs/Feeds Funding	$2,552,632	2,750,000	3,000,000
BSE Cooperative Agreement Funding	$2,766,282	2,702,830	2,572,920
State Contract Tissue Residue Funding	$663,018	665,610	712,200
Total State Funding	**$5,981,932**	**$6,118,440**	**$6,285,120**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,906***	***8,040***	***8,081***

[1] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013. During the full performance year (FY 2013), the FY 2011 BA enacted funding increase for inspections will allow ORA to conduct and additional 33 domestic tissue residue inspections. Resources are being shifted from the BSE program into the Tissue Residue program area, which is why the number of BSE inspections decreases and the number of Tissue Residue inspections increases from the FY 2011 level (the change in inspections is not equivalent for both categories because the time it takes to conduct a tissue residue inspection is longer than the time required to conduct a BSE inspection with the same level of resources, thus resulting in fewer inspections conducted by comparison).

[2] The decrease in inspections (366) from FY 2011 is due to program resources being shifted to the Tissue Residue program.

[3] For ORA investigators hired with FY 2011 BA enacted increases, the full performance year is FY 2013. During the full performance year (FY 2013), the FY 2011 BA enacted funding increase for inspections will allow ORA to conduct and additional 17 domestic animal drug inspections.

[4] The FY 2011 actual unique count of foreign inspections includes 2 OIP inspections (both in China). One was for Animal Drugs and the other was for Animal Feeds.

Combined Field Activities – ORA
Program Activity Data

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,529***	***2,709***	***2,709***
Bioresearch Monitoring Program Inspections	317	302	302
Pre-Market Inspections	56	68	68
Post-Market Audit Inspections	39	46	46
GMP Inspections	1,713	1,567	1,567
Inspections (MQSA) FDA Domestic (non-VHA)	329	549	549
Inspections (MQSA) FDA Domestic (VHA)	37	43	43
Domestic Radiological Health Inspections	104	205	205
Domestic Field Exams/Tests	193	193	193
Domestic Laboratory Samples Analyzed	211	211	211
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***408*** [1]	***473***	***473***
Foreign Bioresearch Monitoring Inspections	17	31	31
Foreign Pre-Market Inspections	30	33	33
Foreign Post-Market Audit Inspections	16	19	19
Foreign GMP Inspections	335	380	380
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	35	40	40
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,937***	***3,182***	***3,182***
IMPORTS			
Import Field Exams/Tests	20,925	20,925	20,925
Import Laboratory Samples Analyzed	1,170	1,170	1,170
Import Physical Exam Subtotal	**22,095**	**22,095**	**22,095**
Import Line Decisions	9,584,415	10,411,972	11,310,984
Percent of Import Lines Physically Examined	0.23%	0.21%	0.20%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,123***	***8,277***	***8,287***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	***45***	**45**	**45**
Inspections (MQSA) by State Contract	7,004	7,147	7,147
Inspections (MQSA) by State non-Contract	1,103	1,110	1,115
GMP Inspections by State Contract	16	20	25
State Partnership GMP Inspections	45	50	55
State Contract Devices Funding	$77,516	182,200	193,100
State Contract Mammography Funding	$9,144,255	9,964,320	10,562,170
Total State Funding	**$9,221,771**	**$10,146,520**	**$10,755,270**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,105***	***11,504***	***11,514***

[1] The FY 2011 actual unique count of foreign inspections includes 11 OIP inspections (6 for China and 5 for India).

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

TOBACCO CONTROL ACT PROGRAM

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$421,463**	**$135,708**	**$454,751**	**$482,398**	**$27,647**
Center	$415,567	$134,145	$448,501	$472,998	$24,497
FTE	345	225	366	471	105
Field	$5,896	$1,563	$6,250	$9,400	$3,150
FTE	25	10	26	41	15
Program Level FTE	**370**	**236**	**392**	**512**	**120**
User Fees	**$421,463**	**$135,708**	**$454,751**	**$482,398**	**$27,647**
Center	$415,567	$134,145	$448,501	$472,998	$24,497
FTE	345	225	366	471	105
Field	$5,896	$1,563	$6,250	$9,400	$3,150
FTE	25	10	26	41	15
User Fees FTE	**370**	**236**	**392**	**512**	**120**

The FDA Tobacco Control Act Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31)
The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333)
Public Health Service Act of 1944 (42 U.S.C. 201)
Federal Advisory Committee Act (FACA) of 1972, as amended

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA executes its regulatory and public health responsibilities in four subprograms:

- protecting the public health
- scientific standard-setting and product review
- compliance and regulation
- public education and outreach

FDA has three strategic priorities in implementing the Tobacco Control Act:

- decreasing initiation of tobacco product use;
- decreasing the harms of tobacco products; and
- encouraging cessation among tobacco product users.

To achieve its goals, FDA relies on its authorities to regulate the manufacturing, marketing, and distribution of tobacco products. Some of these authorities include:

- prohibiting tobacco product labeling or advertising or other marketing that is inaccurate, false, or misleading
- establishing tobacco product standards to protect the public health
- issuing Good Manufacturing Practice regulations for the manufacture of tobacco products
- requiring tobacco product manufacturers, importers, and distributors to register with FDA and requiring manufacturers and importers to provide a list of tobacco products they sell
- requiring industry reporting of tobacco product ingredient and constituent data,
- inspecting tobacco product establishments, including retailers, to assure compliance with existing FDA tobacco product regulations.
- strengthening health warnings for cigarettes and smokeless tobacco products
- educating the public about tobacco products and their harms and about FDA's related regulations and other activities
- initiating enforcement actions for violations of the Tobacco Control Act.

Protect the Public Health from the Harmful Effects of Tobacco Use – Center Activities

FY 2012 Enacted Amount: $88,840,496 (All UF)

Public Health Focus

The Tobacco Control Act provides FDA with the authority to regulate the manufacturing, distribution, and marketing of tobacco products based on whether such regulation "will benefit the health of the population as a whole."[1] The Agency's public health goals are to reduce the morbidity and mortality from the use of tobacco products by addressing three principle public health strategic priorities:

- decreasing initiation of tobacco product use,
- decreasing the harms of tobacco products, and
- encouraging cessation among tobacco product users.

Public Health Outcome

FDA is supporting research on the impact of altering nicotine levels in tobacco products to assess how these changes might affect the way people might use those products. In

[1] Section 2 (36) of the Family Smoking Prevention and Control Act (PL 111-31).

addition, FDA will release additional funding announcements in 2012 for the development of research to support many of its regulatory authorities.

FDA has already initiated the first ever longitudinal prospective cohort study of tobacco users in the United States, known as the PATH study (Population Assessment of Tobacco and Health), in collaboration with the National Institutes of Health (NIH)/National Institute of Drug Addiction (NIDA) to better understand the patterns of tobacco use and how it changes over time in adolescents and adults. This longitudinal study will provide a valuable platform for scientific investigations to assess and focus FDA regulatory actions.

In order to determine the effectiveness of the statutory and regulatory requirements on the public health, FDA will continue to conduct evaluation and behavioral research that analyzes the effects of regulatory actions on users and non-users of tobacco products. For example FDA plans to analyze the impact of the new graphic health warning statements on cigarette packaging and in advertisements on consumer perceptions of the harms of tobacco products, interest in quitting and susceptibility to start using tobacco products. FDA will use research and evaluation of the graphic health warnings required to appear on all cigarette packages and advertisements in developing ancillary public education messages.

Given that FDA has expressed the intent to propose regulations to assert jurisdiction over other tobacco products (deeming rule)[2], FDA also plans to support research to assess the impact on public health of new and emerging tobacco products. In particular, FDA plans to support research assessing the constituents, components, and design features of these products, as well as their impact on tobacco use behaviors (including dual- and poly-use of tobacco products) and consumer perceptions about these products.

Promoting Efficiency

The Tobacco Control Act and FDA regulations and guidance documents protect the public health by significantly minimizing the exposure of youth to tobacco products and their marketing by 1) prohibiting the manufacture, distribution, and sales of fruit or candy flavored cigarettes that have special appeal to young people and, 2) by restricting the sales, advertising and promotion of cigarettes, smokeless tobacco products and roll-your-own tobacco to those under the age of 18. Furthermore, FDA is protecting the public health by prohibiting misleading descriptors on tobacco products, and requiring graphic health warnings depicting the harmful effects of smoking on cigarette packs and

[2] The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The law also permits FDA to issue regulations deeming other “tobacco products,” such as novel products like e-cigarettes or certain dissolvable tobacco products; cigars; pipe tobacco; hookah, etc., to be subject to Chapter IX of the Food Drug & Cosmetic Act (FD&C Act).

in cigarette advertisements. All of these public health-driven regulatory actions are currently being enforced through FDA-funded State- based enforcement programs.

Preventing youth initiation would result in enormous public health benefits. Specifically, the Tobacco Control Act finds that "reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75 billion in savings attributable to reduced health care costs."[3]

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)*	FY 2010: Issued regulations protecting the public health from the harmful effects of tobacco use including: prohibiting misleading descriptors, requiring new warning labels on smokeless tobacco products, and the "Reissued 1996 Rule." (Target Met) FY 2010: Initiated and conducted research on the impact of tobacco control regulations. (Target Met) FY 2010 Target: Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products. (Target Met)	Conduct research on how to assess the public health impact of modified risk products, and continue to evaluate the impact of tobacco regulations on the public health. Issue regulations to protect the public health.	Research the impact of changing nicotine levels on product addictiveness and use of products. Through a longitudinal cohort study, monitor the trajectory of tobacco use. Study the impact of reduced levels of toxic harmful/poten-tially harmful constituents on health outcomes. Develop better measures of toxicity appropriate for tobacco, and identify new biomarkers of harm. Carry out on-going	NA

[3] Section 2(14) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).

			consumer research on the impact of product information (warnings, label claims, descriptors, advertising and marketing) on perceptions of risk and the likelihoods of tobacco use initiation and cessation.	

Tobacco Product Scientific Standard-Setting and Tobacco Product Review – Center Activities
FY 2012 Enacted Amount: $156,455,773 (All UF)

Public Health Focus

In order to protect the public health, the Tobacco Control Act authorizes FDA to conduct or support scientific programs and data collection to provide the data and research to support the development of regulations and guidance documents, and to implement many provisions of the law, including those related to the manufacturing, distribution, sale, and marketing of tobacco products. FDA's scientific, research and data collection/assessment focus on the strategic priorities to implement the Tobacco Control Act of:

- decreasing initiation of tobacco product use;
- decreasing the harms of tobacco products; and
- encouraging cessation among tobacco product users.

Public Health Outcome

FDA is developing improved analytical methods to measure harmful and potentially harmful constituents in order to expand the number of tools available to assess product characteristics. Work is also underway to examine the impact of reduced levels of the identified harmful and potentially harmful constituents as a way to mitigate the morbidity and mortality associated with the use of tobacco products, as well as studying how design features of tobacco products impact tobacco use behavior.

FDA will review public comments received on the list of proposed harmful and potentially harmful tobacco product constituents. FDA will conduct additional research

and revise the list, as appropriate, in order to meet the statutory requirement that the list is understandable and not misleading to a lay person. FDA will use this list to better educate the public about the constituents contained in tobacco products and smoke through appropriate public education and communication programs, as well as assess the impact of this information.

FDA will support the Tobacco Product Scientific Advisory Committee's (TPSAC) work on dissolvable tobacco products. FDA will review the TPSAC report on dissolvables and review additional scientific evidence to determine what regulatory actions, if any, are warranted to protect the public health.

FDA continues to review new tobacco product and modified risk applications in a timely manner, as well as continue its review of the substantial equivalence submissions for products currently on the market.

Promoting Efficiency

FDA has taken a number of science-based regulatory actions as required by law. These include issuing guidance to industry on substantial equivalence. Also, tobacco product manufacturers are reporting the ingredients of each tobacco product by brand and by quantity in each brand and sub-brand. This information helps FDA better understand the products it regulates and promotes efficiency within the FDA Tobacco Program.

Significant program efficiencies accrue to the tobacco industry as well for each of the individual regulatory actions, guidance, or technical assistance documents FDA releases.

FDA achieves these efficiencies by establishing the regulatory framework and processes for FDA review and issuance of marketing orders to industry for new tobacco products, products purported to be modified risk tobacco products, and products proposed to be substantially equivalent to predicate tobacco products. For example:

- FDA provided technical assistance to small tobacco manufacturers to help them understand guidance and regulations related to substantial equivalence. Technical assistance includes information how manufacturers might provide documentation to FDA on predicate products.
- FDA provided flexibility to tobacco manufacturers by allowing them to supplement initial substantial equivalence reports, which allowed companies to continue marketing certain products while FDA conducts substantial equivalence evaluations.
- FDA has issued draft guidance to industry about how to submit new tobacco product applications and plans to issue guidance and/or regulations on tobacco products purported to be modified risk tobacco products. These regulatory

documents provide industry with increased clarify regarding the FDA review processes and expectations.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280001: Protect the public health by developing and issuing regulations related to tobacco control and limiting access to tobacco products by youth. *(Output)*	FY 2010: Issued regulations protecting the public health from the harmful effects of tobacco use including: prohibiting misleading descriptors, requiring new warning labels on smokeless tobacco products, and the "Reissued 1996 Rule." (Target Met) FY 2010: Initiated and conducted research on the impact of tobacco control regulations. (Target Met) FY 2010 Target: Identify population-based data available to begin assessing impact of tobacco control regulations, their impact on youth and adult access to and use of tobacco products. (Target Met)	Conduct research on how to assess the public health impact of modified risk products, and continue to evaluate the impact of tobacco regulations on the public health. Issue regulations to protect the public health.	Research the impact of changing nicotine levels on product addictiveness and use of products. Through a longitudinal cohort study, monitor the trajectory of tobacco use. Study the impact of reduced levels of toxic harmful/poten-tially harmful constituents on health outcomes. Develop better measures of toxicity appropriate for tobacco, and identify new biomarkers of harm. Carry out on-going consumer research on the impact of product information (warnings, label claims, descriptors, advertising and	NA

			marketing) on perceptions of risk and the likelihoods of tobacco use initiation and cessation.	

<u>Compliance and Regulatory Activities</u> - Center Activities
FY 2012 Enacted Amount: $97,954,376 (All UF)

Public Health Focus

The Tobacco Control Act requires the issuance of regulations and guidance in accordance with certain statutory deadlines. This includes promulgating regulations requiring the testing and reporting of tobacco product constituents, ingredients, and additives by brand and sub-brand. In order to protect the public health, FDA vigorously enforces provisions of the Tobacco Control Act and its implementing regulations.

Public Health Outcome

As required by the Tobacco Control Act, FDA contracts with States and Territories to assist FDA in conducting compliance check inspections of retail establishments. These inspections ensure tobacco product retailers' compliance with "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" and other provisions of the Tobacco Control Act. In FY 2011, FDA provided direct financial support to U.S. States and Territories through the award of approximately $30 million to 37 States and the District of Columbia to conduct compliance check inspections to ensure that tobacco product retailers are complying with the requirements of the Tobacco Control Act. FDA will continue to contract with additional States and Territories and with Tribes and will continue to expand the State Enforcement Program.

FDA will continue to allocate significant resources to enforce statutory requirements of the Tobacco Control Act. FDA will begin enforcing the requirements for graphic health warnings on cigarette packages and in advertisements. This will include the review of cigarette health warning plans submitted by manufacturers. FDA will continue to review new submissions and supplements involving health warning plans for smokeless tobacco products.

As part of its compliance and enforcement program, FDA will continue to conduct routine surveillance, investigation, and evaluation of regulated industry websites that promote and sell tobacco products in the U.S. market. In addition, FDA will continue to monitor the compliance of magazines and publications that contain tobacco advertisements, including those that target youth and minorities.

Promoting Efficiency

The nation's more than 2 million tobacco product retailers are important new partners in FDA's efforts to decrease youth initiation through tobacco product regulations. Retail establishments nationwide are responsible for complying with *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* and other provisions of the Tobacco Control Act.

To help ensure compliance with these regulations and the law, FDA will continue to provide guidance to industry and retailers to ensure a better understanding of the new law and regulations through CTP's monthly compliance education webinars directed towards tobacco product retailers, which will allow manufacturers and retailers to meet regulatory requirements efficiently and effectively as possible. FDA will also assist tobacco retailers to appreciate their role in protecting America's youth from initiation and use of tobacco product use as required by the Tobacco Control Act.

FDA established the Office of Small Business Assistance in the Center for Tobacco Products to assist small tobacco product manufacturers and retailers comply with the Tobacco Control Act. The Office has a dedicated webpage, e-mail address, and staff to assist small businesses with their questions, comments, and concerns. Additionally, the Office provides educational webinars and training for small tobacco product businesses. Examples of webinar topics include compliance with the requirements related to the new graphic cigarette health warnings on packaging and in advertising and FDA's guidance on new tobacco product applications.

This enforcement and compliance program also significantly increased efficiencies by providing a uniform framework for FDA enforcement through a robust training program for credentialed State and Territorial officials. Additionally, CTP implemented a mobile device inspection tool using customized software known as the Tobacco Inspection Management Systems (TIMS) Mobile Application. The tool eliminates the need to mail, fax, or scan paper forms to and from field inspectors, and eliminates days of data entry thereby decreasing the time for conducting and reviewing inspections and gathering evidence.

Compliance and Regulatory Activities - Field Activities
FY 2012 Enacted Amount: $6,250,000 (All UF)

Public Health Focus

In order to ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention of tobacco products . Among other provisions, the law bans the manufacture, distribution or marketing of cigarettes with fruit or candy characterizing flavors, with the exception of menthol.

In FY 2011, the FDA Office of Regulatory Affairs (ORA) began work to establish a testing laboratory with expertise and capacity to analyze tobacco products. The ORA laboratory will acquire tobacco-specific testing equipment such as smoking machines and will complete assignments requested by CTP which may include testing cigarettes and/or other tobacco products for flavor compounds, other potentially harmful constituents and future tobacco product standards. Concurrently, ORA is collaborating with the Alcohol and Tobacco, Tax and Trade Bureau and CTP on method development and validation studies to expand analytical capabilities to additional harmful chemical ingredients and constituents. In addition, ORA's Forensic Chemistry Center laboratory will be providing support to the Office of Criminal Investigations (OCI) related to the identification and characterization of counterfeit cigarettes.

In FY 2012, ORA began inspections of registered tobacco product establishments to determine their compliance with the Tobacco Control Act. These include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products,

Public Health Outcome

ORA carries out a multi-tiered approach towards enforcing the requirements of the Tobacco Control Act. For example, working with CTP, ORA issued import bulletins relating to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes. This required increased surveillance of imported tobacco products at the borders ensures that imported tobacco products are not adulterated and conform to the same regulatory requirements as domestically-manufactured cigarettes.

Promoting Efficiency

ORA will continue to engage in these enforcement activities, which could include laboratory-based support for enforcement actions to ensure that industry complies with the Tobacco Control Act and its regulations. Specific examples of program efficiencies that may flow from these activities include development and promulgation of standards for laboratory testing, such as for harmful and potentially harmful ingredients of tobacco products. Once developed and promulgated, these laboratory and testing standards will create a uniform set of methods and standards by which the tobacco manufacturers can analyze their products in an efficient and targeted manner. Thus, the tobacco industry will avoid inefficient use of its resources for broad or unnecessary product testing.

ORA has begun the process of developing a trained cadre of investigators to perform tobacco manufacturer inspections. ORA and CTP have identified the establishments to be inspected and ORA is collaborating with CTP to develop and present training to ORA investigators. By using a cadre approach to conducting these types of inspections, ORA will develop a staff of investigators who are well trained in tobacco regulation, policy and inspection techniques.

ORAs tobacco commissioning program further increases the efficiency in which FDA can share information with State and local agencies. This program is modeled on the traditional food and drug commissioning process and allows inspections to be completed by States on behalf of FDA. As of the end on FY 2011, officials have been commissioned in 37 states and one U.S. territory in support of contracts with FDA to conduct retail tobacco inspections.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2011: 24,419 (Historical Actual)	84,000	150,000	+66,000

Tobacco Product Health Communication and Education – Center Activities

FY 2012 Enacted Amount: $105,250,355 (All UF)

Public Health Focus

As required by statute, FDA is promoting the public health by leading comprehensive, science-based communication and outreach efforts to protect and educate the nation about the dangers of tobacco products. All aspects of FDA's three strategic priorities (decreasing initiation of tobacco product use, decreasing the harms of tobacco products, and encouraging cessation among tobacco product users) have important public health education and communication components with respect to implementing the Tobacco Control Act.

Public Health Outcome

The Tobacco Control Act authorizes FDA to educate the public about tobacco products and their dangers. FDA will communicate broadly and effectively to the general public and to priority audiences about tobacco product content and their harms. Specifically, FDA will:

- Develop comprehensive youth and young adult prevention campaigns educating these audiences about the harms of tobacco use and the potential for addiction as required by the Tobacco Control Act;
- Support the HHS-wide effort to communicate accurate and effective messages about tobacco products FDA regulates and describe the harms resulting from

their use to distinct audiences, including the media, opinion makers and stakeholders;
- Design an evaluation program to demonstrate effectiveness of communication programs and to measure changes in attitudes and behaviors toward tobacco product usage over time

For example, FDA is currently educating retailers and the public about "Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" and about the restrictions on use of misleading descriptors such as "light," "low," and "mild" on tobacco product packaging or in advertisements.

In enacting the Tobacco Control Act, Congress found that in 2005, cigarette manufacturers spent more than $13 billion to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use. Therefore, as required by FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Children and Adolescents", the Agency will continue its health education efforts to reduce perceived attractiveness and access of tobacco products to youth, and provide users with the information needed to understand the harms of tobacco products and tobacco use.

In addition, FDA continues to engage all stakeholders about the Tobacco Control Act and how to comply with its requirements. Specifically, FDA is providing "Break the Chain of Tobacco Addiction" educational and display materials at no charge to U.S. retailers to promote compliance with the law. The materials were developed with input from retail establishments and include posters, flyers, and syndicated content for retailer websites. FDA is also creating customized tools that enable the public and other stakeholders to better access and understand the TCA in a plain language format. This includes plain language summaries, interactive timelines, and customized searches by audience, type of tobacco product, and topic.

Promoting Efficiency

The Tobacco Control Act requires FDA to inform the nation about the harmful and potentially harmful constituents of tobacco products which in turn will increase public understanding about the dangers of tobacco. The public health impact will be a decrease in the enormous economic toll from health care costs and lost productivity from the many diseases caused by tobacco use.

The implementation strategy for all public education campaign materials developed, including research studies, will include sharing this public education information among stakeholders, thereby greatly leveraging FDA resources and amplifying the Agency's message to local communities.

FDA also is launching a "Tobacco Regulations 101" education campaign for various stakeholders to help promote understanding of how regulations are issued, identify

opportunities for involvement in the regulatory process, and provide information about public dockets, notice and comment rulemaking activities, etc

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	FY 2010: First ever retailer education program was implemented, including PR, direct mail, web updates and educational webinars. In addition a media outreach strategy was developed to proactively communicate tobacco related public health messages to the general public. FY 2011 Target: Implement and refine education program directed to retailers and the general public, especially youth. (Target Met)	Continue to implement and improve programs designed to educate the public and industry.	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education on prevention and cessation.	NA

Information Technology Investments –Tobacco Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $21,818,276)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure

facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

In order to implement the Tobacco Control Act, FDA has leveraged existing IT systems supporting Foods and Medical Product programs to provide an electronic solution to regulate the manufacture, distribution and sale, and content of tobacco products. As a specific example, FDA has developed an electronic submission tool, eSubmitter, to streamline submission and receipt of registration and product listing information required by section 905 of the act. CTP also plans, assigns, and tracks regulatory activities for state compliance check inspections of retails using the newly-created Tobacco Inspection Management System (TIMS). With such information management technologies, the FDA will be able to regulate tobacco products with transparency, collaboration, knowledge management, agility and improved efficiency.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) program levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2008 Actual	N/A	N/A	N/A	N/A
2009 Actual	$4,908,000	$4,908,000	$0	0
2010 Actual	$64,418.000	$0	$64,418,000	90
2011 Actual	$136,225,000	$0	$136,225,000	236
2012 Enacted	$454,751,000	$0	$454,751,000	392

Summary of the Budget Request

The FY 2013 budget request for the FDA Tobacco Act Program is $482,398,000 for an increase of $27,647,000 above the FY 2012 Enacted Budget. The Center for Tobacco Products amount is $472,998,000 supporting 471 FTE. The Field amount is $9,400,000, supporting 40 FTE.

The amount requested in the FY 2013 budget is authorized by the Tobacco Control Act and comprise entirely of tobacco user fees. The Tobacco Control Act requires that these user fees may only be used for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

Protect the Public Health from the Harmful Effects of Tobacco Use

Center Activities (FY 2012 Enacted Amount: $88,840,496)
FY 2013 increase above FY 2012 Enacted: +$6,081,504; 31 FTE

The Tobacco Control Act provides FDA with the authority to protect the public health by initiating actions to regulate tobacco products addressing issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco. In addition, FDA is to set national standards controlling the manufacture of tobacco products, regulate the levels of tar, nicotine, and other harmful components of tobacco products, and to ensure that consumers are better informed by requiring tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products.

The foundation of science upon which tobacco product regulation is being built will continue to expand in FY 2013. FDA will collect the first wave of data in FY 2013 in the ground-breaking Population Assessment of Tobacco and Health Study (PATH). PATH is a national, prospective, longitudinal cohort study funded by FDA to involve more than 40,000 tobacco users. PATH is designed to provide better understanding of the patterns of tobacco use and how it changes over time in adolescents and adults. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

In FY 2013 FDA will continue and expand funding for biomedical research collaborations within FDA and with NIH and CDC in the areas of tobacco product addictiveness, tobacco product chemistry and engineering related to abuse liability thresholds, measurement and standards for assessment of harmful ingredients, biomarkers for health effects of exposure to tobacco ingredients, cognitive and behavioral determinants of tobacco initiation/maintenance and cessation related to marketing and health warnings, and building the foundation of knowledge of the chemistry, toxicology, health and public health impact of new and emerging tobacco products.

Additionally, in FY 2013, CTP will continue to invest in building the cadre of regulatory science leaders needed to address tobacco product regulation today and into the future. FDA will expand the FDA Tobacco Regulatory Science Fellowship Program in conjunction with the National Academy of Sciences, Institute of Medicine and initiate a research training grant program in conjunction with NIH using the National Research Service Award (NRSA) grant mechanism. The multi-year NRSA grants will support a broad array of scientific disciplines from basic and physical sciences to clinical and social sciences research. These programs will insure that there is a diverse pool of highly trained professionals available to address the tobacco regulatory science needs well into the future both by attracting mid-career and experienced professionals to move into tobacco product regulatory science as well as to attract young investigators into tobacco regulatory science research at different stages in their research careers.

In FY 2013 FDA fully intends to implement additional provisions of the Tobacco Control Act by drafting and issuing regulation and guidance documents to protect and improve the public health. As required by the Tobacco Control Act, FDA intends to publish a regulation that requires testing and reporting of tobacco product constituents, ingredients and additives, including smoke constituents, by brand and sub-brand.

Finally, in FY 2013, FDA intends to develop a regulation specifying how tobacco product manufacturers must provide market share information to FDA which will then be used to calculate tobacco user fees. The Tobacco Control Act requires the transfer of the calculation of user fees from the Department of Agriculture to FDA by FY 2014. User fees support all activities undertaken by FDA related to tobacco regulation.

Tobacco Product Scientific Standard-Setting and Tobacco Product Review

Center Activities (FY 2012 Enacted Amount: $156,455,773)
FY 2013 increase above FY 2012 Enacted: +$4,589,227; 3 FTE

FDA's tobacco product regulatory and public health goals are guided by the scientific data developed and evaluated by CTP. This scientific knowledge is required for FDA's regulatory activities and the Agency's review of tobacco products.

In FY 2013, FDA will continue review of regulatory submissions from the tobacco industry, including Substantial Equivalence Reports and requests for Substantial Equivalence Exemptions as well as New Tobacco Product applications.

As new products emerge, including those making modified risk claims, FDA is required to evaluate them based on a population health standard that analyzes the impact of that product on both tobacco product users and non-users. FDA is also required to study the public health impact when consumers switch from conventional to new and emerging tobacco products and conduct research to explore the motivation for users and non-users to initiate use of these products.

FDA will continue and expand its research base in order to study issues relevant to scientific standards and authorities for evaluation of tobacco products proposed to be marketed with a modified risk claim. Marketing of modified risk tobacco products is authorized under the Tobacco Control Act if FDA determines that such products have the potential to reduce the burden of tobacco-related disease, death, and disability in our nation.

Also, in FY 2013 FDA will publish a harmful and potentially harmful tobacco product constituent (HPHC) list that will provide the public with critically important new information about the content of tobacco products. The HPHC list will be published by brand and sub-brand.

Compliance and Regulatory Activities

Center Activities (FY 2012 Enacted Amount: $97,954,376)
FY 2013 increase above FY 2012 Enacted: +$6,189,624; 32 FTE

In FY 2013, FDA will continue its expansion of the State Retail Enforcement Program. This work includes re-awarding contracts to U.S. States and Territories that are already under contract with FDA to conduct compliance check inspections of retail establishments that sell tobacco products. FDA will also begin awarding contracts to Tribal Nations to assist in conducting compliance check inspections of retail establishments on tribal lands as envisioned in the Tobacco Control Act. These compliance check inspections help FDA enforce provisions of the Tobacco Control Act and regulations.

The State Retail Enforcement Program has several other associated activities that will begin or continue in FY 2013, including:

- Increasing the total number of inspections of tobacco retailers within U.S. States and Territories.
- Conducting quality assessment of performance under the State contracts.
- Maintaining effective internal controls that meet the objectives of the Federal Managers' Financial Integrity Act to ensure effective and efficient operations and compliance with applicable laws and regulations.
- Continuing to issue Warning Letters and initiating Civil Money Penalty actions, and other applicable enforcement actions against retailers that violate the law and applicable regulations.
- Include newly-deemed tobacco products in the State Retail Enforcement Program.

However, CTP's efforts to ensure compliance with the law are not limited to enforcement efforts. To encourage voluntary compliance, CTP will continue to educate retailers about their responsibilities to protect the Nation's young people as required by the Tobacco Control Act. These efforts will include outreach to small businesses and to those in minority communities. CTP plans to hold monthly compliance education webinars during which retailers will be provided with an opportunity to ask questions about FDA regulatory activities and provide feedback to CTP's Office of Compliance and Enforcement on topics to include in future compliance webinars. CTP will also hold quarterly compliance education webinars directed towards small manufacturers to provide information about the Tobacco Control Act, FDA regulations and other activities, including what to expect during an FDA inspection of a manufacturing facility.

Field Activities (FY 2012 Enacted Amount: $6,250,000)
FY 2013 increase above FY 2012 Enacted: +$3,150.000; 14 FTE

FDA will work to expand inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers, and importers in FY 2013. FDA's Office of Regulatory Affairs will conduct inspections of tobacco product manufacturers to ensure

their compliance with the laws. These inspections will determine whether a company is properly submitting registration, product and ingredient listing information, complying with the packaging, labeling and advertising requirements, and other statutory and regulatory requirements.

There are several other activities associated with expanding inspections, investigations and surveillance of tobacco product manufacturers, distributors, wholesalers, and importers that FDA will initiate or continue in FY 2013 including:

- Utilizing the FDA laboratory that tests, evaluates, and processes regulatory samples of tobacco products that will be used to support enforcement actions.
- Expand internet surveillance and investigation of tobacco product manufacturers, distributors and retailers to ensure their packaging, labeling, marketing, and advertisements of tobacco products is in compliance with the laws.
- Continue to send Warning letters and initiate other enforcement actions for violations identified.

Tobacco Product Health Communications and Education

Center Activities (FY 2012 Enacted Amount: $105,250,355)
FY 2013 increase above FY 2012 Enacted: +$7,636.645; 39 FTE

Directly related to FDA's tobacco product regulatory authorities, FDA will continue to educate the public about tobacco products and their harms in FY 2013. Specifically, FDA plans to develop several public health education campaigns related to FDA's mandate to educate the public about harmful and potentially harmful constituents of tobacco products; the statutory requirement to require health warnings on cigarettes and smokeless tobacco products packages and in advertising; restrictions on marketing and sales of tobacco products to youth; use of misleading descriptors like "light," "low," and "mild" on tobacco products; and other FDA regulatory authorities as they are implemented. Examples of these public health education programs include:

- Development of comprehensive youth and young adult public health education programs designed to inform them about the harms of tobacco use and the potential for addiction;
- Development of comprehensive youth and young adult public health education programs about the benefits of tobacco cessation in reducing the harms of tobacco use;
- Support for a HHS-wide effort to provide accurate messages about tobacco products and the harms resulting from their use; and
- Development of a comprehensive benchmark and tracking evaluation program that will assess the effectiveness of FDA public health education programs.

CTP Performance Activity Data (PAD)

The following table lists the CTP Program Activity Data (PAD) over a three year fiscal period.

CTP Workload and Outputs	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	7	4	6
Number of Warning Letters Issued	1,024	2,500	3,900
Percentage of Tobacco User Fees Collected	99%	99%	99%

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

FDA HEADQUARTERS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
FDA Headquarters

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$212,580**	**$186,665**	**$222,811**	**$280,635**	**$57,824**
Program Level FTE	**899**	**922**	**972**	**1,089**	**117**
Budget Authority	**$149,900**	**$149,477**	**$153,704**	**$163,030**	**$9,326**
Center	$149,900	$149,477	$153,704	$163,030	$9,326
Budget Authority FTE	**665**	**673**	**706**	**725**	**19**
User Fees	**$62,680**	**$37,188**	**$69,107**	**$117,605**	**$48,498**
PDUFA	$40,693	$28,982	$42,541	$43,447	$906
FTE	172	195	195	186	-9
MDUFMA	$6,417	$3,795	$5,975	$7,221	$1,246
FTE	23	26	21	26	5
ADUFA	$780	$651	$873	$1,224	$351
FTE	4	4	4	4	0
AGDUFA	$216	$165	$228	$304	$76
FTE	1	1	1	1	0
MQSA	$238	$268	$238	$238	$0
FTE	2	2	2	2	0
Center for Tobacco Products	14,336	3,327	15,196	15,196	0
FTE	32	21	34	34	0
Voluntary Qualified Importer Program			0	0	0
FTE			0	0	0
Food Reinspection			3,395	3,549	154
FTE			7	7	0
Recall User Fee			661	691	30
FTE			2	2	0
Cosmetics User Fee [1]			0	980	980
FTE			0	3	3
Food Contact Notification User Fee [1]			0	267	267
FTE			0	1	1
Generic Drugs [1]			$0	$24,196	$24,196
FTE			0	50	50
Medical Product Reinspection [1]			$0	$6,169	$6,169
FTE			0	10	10
Food Establishment Registration Fee [1]			$0	$12,544	$12,544
FTE			0	32	32
International Courier [1]			0	$289	$289
FTE			0	1	1
Biosimilars User Fee [1]			0	1,290	1,290
FTE			0	5	5
User Fees FTE	**234**	**250**	**266**	**364**	**98**

[1] Proposed User fee; the amount includes associated rent activity

Following is a list of the Headquarters legal authorities:

The Federal Food Drug and Cosmetic Act* (21 U.S.C. 321-399)
Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss)
The Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Foods Additives Amendments of 1958*
Color Additives Amendments of 1960*
Animal Drug Amendments (21 U.S.C. 360b)
Controlled Substances Act (21 U.S.C. 801-830)
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Federal Anti-Tampering Act (18 U.S.C. 1365)
Medical Device Amendments of 1976*
Infant Formula Act of 1980*
Orphan Drug Act of 1983, as amended*
Drug Enforcement, Education, and Control Act of 1986*
Generic Animal Drug and Patent Term Restoration Act*
Prescription Drug Marketing Act of 1987*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Prescription Drug Amendments of 1992*
Safe Medical Devices Act of 1990*
Safe Medical Device Amendments of 1992*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Animal Medicinal Drug Use Clarification Act of 1994*
Animal Drug Availability Act of 1996*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Medical Device User Fee and Modernization Act of 2002*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12)
Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3)
Minor Use and Minor Species Animal Health Act of 2004*
Food Allergy Labeling and Consumer Protection Act of 2004*
Medical Device User Fee Stabilization Act of 2005*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1)
Food and Drug Administration Amendments Act of 2007*
Protecting Patients and Affordable Care Act of 2010*

* Authorities under this act do not appear in sequence in the U.S. Code (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.

The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31)
The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333)
FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011)

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

FDA provides Food and Drug Administration (FDA)-wide program direction and administrative services to ensure that FDA's consumer protection efforts are managed effectively and efficiently. FDA Headquarters consists of seven offices that provide: policy making, program direction, coordination and liaison, and expert advice to FDA leadership and programs.

The following table provides a description of each office's functions.

Headquarters Office	Description
Office of the Commissioner	Provides program direction, coordination and liaison, and expert advice to FDA leadership and programs in support of FDA's foods, medical products and science based work. Provides advice and assistance in policy development and oversees FDA rulemaking. Serves as the focal point for coordinating FDA strategic, performance and business-process planning and evaluation.
Office of Chief Counsel	The office of the Chief Counsel provides legal advice and policy guidance and acts as liaison to the Department of Justice and other Federal agencies and programs.
Office of the Chief Scientist	Provides strategic FDA-wide leadership, support and coordination for FDA's scientific and public health capacity and infrastructure. Works to foster science and innovation in cross-cutting areas of product development and review, and enhances collaboration with both governmental and outside stakeholders — including through the Critical Path initiative. Supports high quality mission targeted FDA research. Coordinates efforts to recruit, retain and train FDA scientists through the Commissioner's Fellowship Program, scientific exchanges, and other professional development activities. Promotes scientific integrity and supports sound processes for addressing scientific differences. Advises on scientific issues that impact policy, direction, and long-range goals. Provides leadership, coordination and support for public health preparedness activities, including pandemic and counterterrorism.

Office of Operations	Provides advice and direction for day-to-day operational activities and the interaction and execution of initiatives across all FDA Centers, Field Offices, Regions and Headquarters. Plans, organizes and carries out annual and multi-year budgeting in support of FDA's public health mission and programs. Provides administrative and program support services, assures strategic and operational management of information technology, financial management, and administrative programs.
Office of Foods	Provides advice and counsel to ensure that all elements of FDA's food program have the scientific and regulatory capacity they need and are working in a closely integrated fashion to prevent foodborne illness and improve the nutrition quality and labeling of the food supply.
Office of Medical Products and Tobacco	Provides policy making, program direction, coordination and liaison, and expert advice to FDA leadership and programs in support of FDA's medical products and tobacco products work.
Office of Global Regulatory Operations and Policy	Serves as FDA's primary lead and clearing authority for all international programs, activities and interactions, including negotiating and managing bilateral agreements; managing all aspects of FDA's foreign locations, information sharing, capacity building, coordinating and participating in international harmonization activities; and coordinating and supporting interactions with international organizations.

Office of the Commissioner (OC)
FY 2012 Enacted Amount: $48,034,583 (BA: $38,608,044 / UF: $9,426,538)

Provides program direction, coordination and liaison, and expert advice to FDA leadership and programs in support of FDA's foods, medical products and science based work. Provides advice and assistance in policy development and oversees FDA rulemaking. Serves as the focal point for coordinating FDA strategic, performance and business-process planning and evaluation.

Includes the following offices:
Office of the Counselor to the Commissioner
Office of Legislation
Office of Policy and Planning
Office of External Affairs
Office of Executive Secretariat
Office of Women's Health
Office of Minority Health

Office of the Counselor to the Commissioner (OCTC)

Includes the following office:
Office of Crisis Management

Public Health Focus

The Office of the Counselor to the Commissioner formulates and renders advice to the Commissioner related to policy development, interpretation and integration that cuts across program lines.

Public Health Outcome

OCTC provides a leadership role in advocating for and advancing the Commissioner's priorities, provides leadership in the development and management of emergency and crisis management policies and programs in the FDA and oversees the Office of Policy and Planning, the Office of Legislation, and the Office of External Affairs.

Office of Crisis Management (OCM)

The FDA Office of Crisis Management (OCM) provides coordination and strategic management and evaluation of FDA's response to incidents involving or impacting FDA regulated commodities, including natural or man-made disasters, Pandemic Influenza and actual or potential product defects that pose a risk to human or animal health. OCM also coordinates the planning, execution and evaluation of inter- and intra-agency emergency exercises to strengthen FDA's preparedness to respond to a wide variety of significant incidents.

Public Health Focus

OCM is charged with meeting the HHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the Presidential Policy Directives (PPDs), the National Preparedness Goal and System, National Response Framework, National Disaster Recovery Framework, National Incident Management System (NIMS), National Exercise Program and Homeland Security Exercise and Evaluation Program.

Public Health Outcome

The OCM, Office of Emergency Operations, uses the EON IMS to assist in the coordination and strategic management of FDA's incident responses. OCM uses the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the hurricane season, to respond to foodborne illness outbreaks and natural and man-made disasters. In FY 2011, OCM expanded the geospatial capabilities of EON IMS beyond supporting incident preparedness, response and recovery activities to

include risk analysis and research. EON IMS is also used to support preparedness exercises that have included international, federal, state and local partners as well as to manage data related to FDA's response to incidents involving FDA regulated products. In 2011, OCM improved FDA preparedness by conducting exercises and after action reviews to assess response capabilities for foodborne illness outbreaks, major earthquake, and an anthrax terrorist attack. It lead the after action reviews of significant incidents and exercises which identified needed changes/updates to agency and HHS emergency operations policies and procedures. The number of emergency exercises which the agency planned for or participated in more than doubled in the past year, reflecting the Administration's concerns for several types of significant public health threats.

OCM further enhanced FDA's Incident Command System structure and its ability to respond to events such as the Deepwater Horizon Oil Spill and the Japanese Earthquake/Tsunami, by improving response capabilities with incorporation of subject matter expertise into strategic planning and day-to-day operations.

Promoting Efficiency – OCM

OCM continued an Inter-agency Agreement with the Centers for Disease Control and Prevention (CDC) to provide after hours and surge capacity response to the FDA Emergency Phone Line. This produced significant efficiencies such as leveraging CDC's existing infrastructure, contract staff, and equipment to enhance existing emergency response capabilities on a 24 hour basis.

In addition, the existing EON IMS system was enhanced to provide expanded capabilities and provide a mechanism to track notifications of Class 1 Recalls involving FDA regulated products to foreign counterparts. By leveraging existing technologies, the Agency is able to efficiently manage the influx of reports received during a major incident, protecting the public from FDA regulated products that pose a risk to public health.

OCM's Geographic Information System (GIS) proved essential in providing critical data analysis used by Agency officials to determine safe federal and state water re-openings for fish and shellfish during the Deepwater Horizon Oil Spill and radiological monitoring during the Japanese Earthquake/Tsunami. By leveraging existing GIS infrastructure the Agency was able to expand its Geospatial Analysis capability to seafood safety, and risk modeling of high risk food firms.

OCM also partnered with CDC exercise staff to establish common ground for planning, conducting and evaluating exercises, allowing for the sharing of expertise and more meaningful assessment of CDC and FDA roles and responsibilities in protecting the public health from natural and man-made threats. As a result of OCM's enhanced working relationship with HHS/ASPR's Training, Exercises and Lessons Learned staff, national level exercises provide more relevant opportunities for assessment of FDA's capabilities.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	FY 2011: Implemented electronic notifications of Report-able Food Registry Reports to Federal and State Counterparts. In addition OCM conducted training for FDA staff on the implementation of the FDA Emergency Operations Plan and its incident specific annexes. Expanded the geospatial capabilities of EON IMS to increase usage during incident response and recovery by 25%. (Target Met)	Enhance FDA's preparedness capabilities by increasing participation in intra/ interagency exercises by 25%. Emphasize evaluation of FDA responses to incidents and exercises by establishing a formal evaluation program which will include mandatory comprehensive lessons learned and after action reporting. Enhance interoperability of EON IMS with other systems including those administered by other agencies and expand GIS capabilities to an enterprise-wide approach to provide a wider level of access across the Agency.	Enhance FDA's preparedness capabilities by increasing participation in intra/ interagency exercises by 25%. Emphasize evaluation of FDA responses to incidents and exercises by establishing a formal evaluation program which will include mandatory comprehensive lessons learned and after action reporting. Enhance interoperability of EON IMS with other systems including those administered by other agencies and expand GIS capabilities to an enterprise-wide approach to provide a wider level of access across the Agency.	Maintain

Office of Legislation (OL)

Public Health Focus

The Office of Legislation directs and manages FDA's legislative agenda and Congressional relations consistent with the public health mission of the FDA.

Public Health Outcome

OL directs and manages FDA's legislative agenda. OL works with FDA experts and Congressional staff to ensure timely reauthorization of critical programs and review of legislative proposals affecting the Agency. OL manages Congressional relations by providing Congress with timely information on FDA public health programs and policies, and initiatives. For example, OL will continue to educate Members of Congress and staff on key FDA initiatives, such as advancing regulatory science and innovation.

Office of Policy and Planning (OPP)

Public Health Focus

The Office of Policy and Planning supports the public health mission of FDA by providing advice to the Commissioner and other key FDA officials on matters of policy, strategic direction, legislation and regulation, program planning and performance and evaluation. OPP is comprised of the Office of Policy and the Office of Planning. OPP coordinates the publication of FDA rules and notices in the Federal Register, serves as the FDA focal point for policy development, and helps ensure that FDA components adhere to FDA policies and regulations relating to policy development. The Office provides oversight and direction for FDA's rulemaking activities and regulations and guidance development system, including economic analyses that support regulatory impact analyses. In addition, OPP is responsible for the overall agency's strategic direction including the monitoring, analysis, improvement and reporting of the agency's performance results and goals.

Public Health Outcome

OPP achieves its public health outcome through its mission of providing strategic policy direction, planning, and data-driven analysis to more effectively and efficiently promote the agency's public health goals and outcomes. OPP reaches its public health outcome by implementing and monitoring FDA's responsibilities associated with the Government Performance and Results Modernization Act and Executive Orders pertaining to economic analyses of regulatory policies and OMB/HHS directives regarding strategic matters, and by assessing the FDA's performance under the prescription drug, medical device, and animal drug user fee acts.

Promoting Efficiency

OPP is responsible for the ongoing execution and management of FDA-TRACK, the Agency's performance management program. Each of the FDA's 100+ program offices is responsible for using FDA-TRACK to better track, manage and report performance measures and key projects aligned and focused on the office's public health mission. Currently, FDA-TRACK manages performance measures and key projects on over 1,000 key performance indicators and milestones across the Agency. Each quarter, each of the program offices submit monthly performance results on these performance indicators and milestones to OPP. OPP collects, analyzes and prepares the results for face-to-face briefings with the Office Directors and FDA senior leaders. During the briefings, results, accomplishments and roadblocks are discussed; upon completion of the briefings, the briefing summaries as well as performance results are posted to the FDA website at www.fda.gov/fdatrack.

The Office of External Affairs (OEA)

Public Health Focus

The Office of External Affairs advises the Commissioner and other key FDA officials on FDA's communications to the media, other stakeholders and the general public on issues that affect FDA-wide programs, projects, strategies, partnerships and initiatives. OEA also serves as a liaison between FDA and the media, consumers, health professional and patient advocacy organizations, and disseminates information on FDA activities through various programs including medical product safety information distributed through the MedWatch program.

Office of Executive Secretariat (OES)

The Office of the Executive Secretariat provides direct support to the Commissioner and Deputy Commissioners, including preparation of briefing material and background information for meetings, correspondence management and control, and preparation and transmittal of information advisories and alerts to HHS. The office develops and maintains information to monitor the Commissioner's and agency's goals and priorities. OES also serves as the agency liaison to the Government Accountability Office and the HHS Office of the Inspector General.

Office of Women's Health (OWH)

Public Health Focus

The Office of Women's Health provides leadership and policy direction for FDA on women's health issues and ensures that FDA regulatory and oversight functions are responsive to women's health needs. OWH advises key FDA officials on scientific, ethical and policy issues relating to women's health. OWH is responsible for activities related to the participation of women in clinical studies (tracking and data analysis) and

the creation of novel consumer health materials pertinent to FDA regulated products. OWH supports the mission of FDA by providing grants for applied regulatory research, developing focus-group tested consumer health information in English and Spanish, and facilitating dissemination of information to the public through national award-winning partnerships.

Public Health Outcome

In alignment with Congressional priorities, OWH is tasked with promoting the inclusion of historically under-represented populations in clinical trials. Investigational New Drug submission and New Drug Application (NDA) clinical data must be broken out by age, race, and sex. FDA also requires that NDAs include summaries of effectiveness and safety data for important demographic subgroups for age, race and sex.

Promoting Efficiency

OWH utilizes educational consumer health information focus-group tested materials to communicate important public health messages on a variety of health topics. Collaboration, central to the success of this program, enlists other Federal Agencies and over 400 national organizations, health professionals, and businesses to achieve unprecedented levels of community access and dissemination of consumer health information. Materials include fact sheets, brochures, purse cards, and medication discussion guides.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. *(Output)*	FY 2011: 7 Target: 7 (Target Met)	9	10	+1
291303: The number of collaborations and partnerships to maximize Outreach activities. *(Output)*	FY 2011: 350 Target: 350 (Target Met)	400	450	+50

Office of Minority Health (OMH)

Public Health Focus

It is the intent of FDA to establish the Office of Minority Health consistent with the requirements of 42U.S.C 300u-6, Office of Minority Health. The Office of Minority Health advances FDA's regulatory mission in addressing the reduction of racial and ethnic health disparities and in achieving the highest standard of health for all. The Office provides leadership and direction in identifying agency actions that can help reduce health disparities, including the coordination of efforts across the Agency. The Office of Minority Health serves as the principal advisor to the Commissioner on minority health and health disparities.

The Office of Special Health Issues (OSHI)

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	FY 2011: 4 Target: 3 (Target Exceeded)	4	6	+2

Office of the Chief Counsel (OCC)

FY 2012 Enacted Amount: $26,456,754(BA: $14,401,018 / UF: $12,055,736)

The Office of the Chief Counsel provides legal advice and policy guidance and acts as liaison to the Department of Justice and other Federal agencies and programs.

Public Health Focus

OCC provides a broad range of critically important legal services to support FDA's public health mission. For example, OCC will have a key role in developing and implementing new legislation to strengthen FDA's ability to promote and protect the public health. As FDA moves to enhance the transparency of its activities through such actions as better public communications and stakeholder interactions, OCC will provide essential legal analyses and review. OCC will continue to provide prompt, expert legal services crucial to FDA's promulgation of new regulations and guidance to improve the regulatory framework, leading to safer and more effective products. OCC will continue its key role in providing the highest quality legal advice on complex medical product approvals and safety issues, food safety and nutrition issues, animal health issues,

tobacco issues, and public health emergencies. OCC will also continue its important role in enforcing the law through court actions, criminal and civil, and administrative hearings such as civil money penalty proceedings. Finally, OCC will continue to defend FDA in court actions brought to challenge FDA's actions.

Public Health Outcome

OCC provides legal advice and review to FDA and the Department of Health and Human Services on draft and final regulations, draft and final guidance documents, responses to citizen petitions, draft legislation, congressional testimony, press materials, and correspondence. OCC provided key advice on numerous complex legal issues on the implementation of a variety of new laws, including the extensive changes brought about by the Food and Drug Administration Amendments Act of 2007 and the Family Smoking and Prevention and Tobacco Control Act (TCA), on medical product approvals and safety issues, food safety and nutrition issues, animal health issues, and public health emergencies. OCC completed review of over 6,100 requests for legal services, and conducted approximately 600 reviews of draft letters from FDA to firms that were believed to have violated the Federal Food, Drug, and Cosmetic Act. OCC also conducted defensive and enforcement litigation on behalf of FDA. OCC played significant roles in the successful criminal prosecutions for violations of the Federal Food, Drug, and Cosmetic Act

Promoting Efficiency

OCC's legal advice and policy guidance support efficient FDA and industry operations. OCC provides training to agency employees to enable staff to work with a fuller understanding of legal requirements and responsibilities, which produces better work products.

OCC plays a key role in developing and reviewing guidances for industry. Guidances ensure that firms can more efficiently conduct product development and manufacturing by providing valuable information that companies need to market products or comply with the law in the least burdensome, efficient manner. Recent significant guidances for industry address 510(k) submissions for medical devices, risk evaluation and mitigation strategies for drugs and biologics, judicious use of antimicrobials in animals, and nutrition labeling for restaurant menus.

OCC provides key legal advice to the agency on communicating safety information on FDA-regulated products to industry and the public. This OCC input allows health care professionals, patients, consumers, and industry to take efficient, targeted steps to protect the public health.

OCC has a major role in all FDA-industry negotiations on user fee programs, which include human prescription drugs and biologics, human generic drugs, animal prescription and generic drugs, medical devices, and biosimilar biological products.

These important negotiations lead to significant funding for FDA's regulatory programs that allow new medical products to be efficiently developed, reviewed, and marketed.

Office of the Chief Scientist (OCS)
FY 2012 Enacted Amount: $37,498,758 (BA: $32,279,958 / UF: $5,218,800)

Includes the following offices:
Office of Scientific Integrity
Office of Counter Terrorism and Emerging Threats
Office of Regulatory Science and Innovation
Office of Scientific Professional Development

Oversees the following Center:
National Center for Toxicological Research

Public Health Focus

The Office of the Chief Scientist provides strategic FDA-wide leadership, coordination, planning and scientific expertise to support innovation, scientific excellence, and the capacity to achieve FDA's public health mission through advancements in regulatory science. OCS coordinates internal and external outreach to identify critical regulatory science and innovation needs and refines the strategic plan for science at FDA with input from FDA's Science Board and through FDA's internal Science and Innovation Strategic Advisory Council, while coordinating the agency's overall Medical Countermeasures Initiative.

Support of regulatory science, both within FDA and externally, is critical to expanding this vital field. Regulatory science adds value to guidance and policy development and helps to ensure that FDA functions on the best available science. To maintain an active research program, regulatory science must be developed and strengthened to ensure that FDA's reviewers are keeping up with scientific advancements. Many opportunities exist to enhance and expand FDA programs and establish new ones that support robust external and collaborative efforts to advance regulatory science. An FDA-NIH Joint Leadership Council is expanding regulatory science, initially via FDA-NIH scientific collaborations, then through jointly-supported and administered extramural research grants in regulatory science.

OCS supports several academic Centers of Excellence in Regulatory Science (CERS) to carry out applied regulatory science research, both independently and in collaboration with FDA. CERS serve as loci for scientific exchange and training opportunities for both FDA and academic scientists. For example, FDA's goal to develop clear, transparent, and predictable pathways for regulating products that involve nanotechnology and to base FDA's regulatory decisions on scientific evidence involves OCS leading the development of a nanotechnology regulatory science and

research agenda to develop the tools, methods, and expertise that FDA needs to evaluate submissions from industry.[1]
OCS enhances strategic collaboration and coordination with other governmental agencies such as National Institutes of Health, National Institute of Standards and Technology, Center for Disease Control and Prevention, Agency for Healthcare Research and Quality, and the Defense Advanced Research Projects Agency to develop new programs to support regulatory science and innovation. OCS also supports the Critical Path Initiative to advance regulatory science and public health through innovation and modernization of the product development and evaluation processes. In FY 2011, OCS awarded $2.9 million to support six research projects that will help with the diagnosis, treatment, and prevention of tuberculosis (TB). TB remains a major public health challenge and support is urgently needed in TB drug development to shorten therapy and to treat drug-resistant diseases. Additionally, OCS works in conjunction with the Reagan-Udall Foundation on projects in support of regulatory science.

In support of enhancing safety and health through informatics, OCS initiated pilot projects to align its systems to the Health Information Technology standards that are part of the national effort to develop a system to support electronic health records.

OCS supports a culture of, and capacity for, continuous scientific learning and professional development so FDA scientific and technical staff can develop their knowledge about new science and technology to fulfill FDA's public health mission. OCS explores Scientific Exchange Programs with academia, governmental institutions and international regulatory counterparts to enable a better exchange of ideas. OCS also manages the FDA Commissioner's Fellowship Program which recruits and trains promising scientists in key areas of science, innovation and review to make sure the next generation of scientists are ready to help FDA fulfill its public health mission.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	FY 2011: Target set based on data from Pilot Evaluation (Target Met)	50%	50%	Maintain
293206: Promote innovation and predictability in the development of safe and effective nanotechnology- based products by establishing	FY 2011: FDA implemented the Collaborative Opportunities for Research Excellence	Continue regulatory science studies on evaluating nanomaterials	Continue regulatory science studies on evaluating	N/A

[1] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM222536.pdf

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)*	in Science (CORES) Program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. (Target Met)	from 2011.	nanomaterials from 2011.	

The Office of Scientific Integrity (OSI)

The Office of Scientific Integrity provides advice to the Commissioner and other key FDA officials on matters relating to the interaction between offices within FDA as well as with other stakeholders. OSI ensures integrity is maintained in FDA's scientific processes and evaluates scientific differences that are not resolved at Center levels. OSI coordinates FDA's response to, and evaluation of, allegations of improper deviation from established procedures governing FDA's regulatory mandate, including review of pre- and post-market decisions, food-related issues, enforcement actions, and congressional obligations.

The Office of Counterterrorism and Emerging Threats (OCET)

The Office of Counterterrorism and Emerging Threats protects the public health by developing and implementing policies to safeguard medical products from adulteration and prevent disruption of supplies due to terrorist activities. The Office works closely with FDA centers to facilitate the development, evaluation, and availability of safe and effective medical products (i.e., vaccines, drugs, personal protective equipment, and diagnostic tests) to counter threats from, among others, chemical, biological, radioactive, and nuclear agents as well as from emerging infectious diseases. As it did during the government's response to the 2009 H1N1 influenza pandemic, OCET coordinates the provision of critical FDA technical assistance and regulatory expertise to product developers, the scientific community, and governmental partners (e.g., State and local responders, Federal, and international partners) that are developing approaches to expedite deployment of countermeasures during emergencies and protocols for monitoring adverse event reporting during and after an emergency. One of OCET's key responsibilities involves strengthening the nation's ability to prepare and respond to a public health emergency. As part of this effort, OCET coordinates FDA's participation in the HHS Public Health Emergency Medical Countermeasures Enterprise. During FY 2010, OCET worked closely with Federal partners (e.g., Biomedical Advanced Research and Development Authority, NIH, CDC, the Department of Defense) to carefully review the state of U.S. emergency preparedness and

response. The review identified FDA as one of the most critical components of the Nation's medical countermeasure preparedness. Following the review, FDA developed an Action Plan and launched its Medical Countermeasures Initiative (MCM), designed to address key challenges confronting medical countermeasure development and availability. OCET coordinates the MCM initiative.

The MCM mission is to facilitate the development of high-priority medical countermeasures and strengthen the MCM Enterprise. Three key focus areas have been identified: (1) enhance FDA's review process, making it more efficient; (2) advance regulatory science to spur MCM development and evaluation; and (3) modernize the legal, regulatory, and policy framework to enable a quick and effective response to a public health emergency. FDA's MCM initiative will help accelerate the pace and increase the probability of successfully developing medical countermeasures for identified threats. FDA is using its MCM funding to:

- Create and maintain a highly qualified workforce with the appropriate technical training, scientific skill, and subject-matter expertise to fully support MCM activities
- Expand our regulatory science research program to help overcome existing hurdles in MCM development and help translate scientific discoveries into medical countermeasures
- Improve the infrastructure at FDA, including providing the laboratory equipment and information technology researchers and reviewers need to evaluate and approve medical countermeasures
- Establish multidisciplinary Action Teams to identify clear, science-based pathways for evaluation and approval
- Evaluate existing laws, regulations, and policies to identify ways of modernization to make sure FDA's review process is efficient as possible and to ensure that medical countermeasures are made readily available to the public when needed
- Provide FDA subject matter experts who can contribute at various Enterprise partner committees and working groups that set requirements for MCMs, including broad spectrum therapeutics and diagnostics for specific threats (e.g., anthrax, botulinum, smallpox, and other emerging threats)

MCM is proving to be a valuable investment in the future of public health for a number of reasons. Successes in MCM have substantial implications for improving the health and security of the U.S. population beyond countering chemical, biological, radiological, and nuclear threats and emerging infectious disease threats. A continuous and dependable investment to advance regulatory science to support development of medical countermeasures will contribute directly and indirectly in developing products to treat other diseases and conditions and help improve the safety and efficacy of and access to all FDA-regulated products while reducing costs.

The Office of Regulatory Science and Innovation (ORSI)

The Office of Regulatory Science and Innovation builds new programs aimed at supporting regulatory science innovation within FDA and through public private partnerships (PPP). ORSI fosters high quality, mission-targeted FDA collaborative and extramural research to enhance product evaluation tools. ORSI plays a critical role in expanding FDA's efforts through Critical Path and Regulatory Science Initiatives in providing clear pathways to industry for development of novel products.

In addition to ORSI's ongoing collaborations with PPP, ORSI supports and advances major scientific initiatives such as personalized medicine, innovative clinical trial design strategies and scientific computing approaches for data assessment and enables partnerships and consortia to promote transformation in product development and to advance regulatory science as a hub for various partnerships.

ORSI also enhances and supports consistent and collaborative approaches to science and innovation across the entire FDA to help strengthen the US clinical trial enterprise, improve healthcare quality and patient safety, and expand the use of personalized therapies.

Office of Scientific and Professional Development (OSPD)

The Office of Scientific Professional Development supports scientific and technical excellence and the professional development of FDA scientists in all areas. OSPD works with the Centers to implement opportunities, best practices and policies for scientific and technical professional development, facilitates a broad range of collaborative professional development and training opportunities with government agencies, scientific institutions, academia and others, and provides leadership and ongoing evaluation for cross-cutting programs and investments, including the Peer Review Program, Scientific Achievement Awards and Senior Biomedical Research Service. OSPD also manages the Commissioner's Fellowship Program, a two-year fellowship which provides opportunities for health professionals and scientists to receive training and experience at FDA, and the Interagency Oncology Task Force Fellowship Program, a joint Fellowship with the National Cancer Institute at the National Institutes of Health.

National Center for Toxicological Research (NCTR)

The National Center for Toxicological Research is an important research component of FDA that develops, refines and applies current and emerging technologies to improve safety evaluations of FDA-regulated products. NCTR fosters national and international collaborations to improve and protect public health and enhance the quality of life for the American people. Through the training of scientists from around the world, as well as FDA staff, NCTR researchers spread the principles of regulatory science globally. NCTR conducts FDA research to develop a scientifically sound basis for regulatory decisions and reduce risks associated with FDA-regulated products. NCTR

represents the FDA on key committees of the National Toxicology Program (NTP), a program that evaluates the effects of chemicals on health. Over the past 30 years, the NTP and NCTR conducted studies on FDA-nominated compounds, which provided data to support science-based regulatory decisions.

Office of Operations (OO)
FY 2012 Enacted Amount: $84,410,591 (BA: $52,087,444 / UF: $32,323,147)

Includes the following offices:
Office of Equal Employment Opportunity
Office of Finance, Budget and Acquisitions
Office of Information Management
Office of Management

The Office of Operations provides executive direction, leadership, coordination, and guidance for day-to-day operational activities and the interaction and execution of initiatives across all FDA Centers, Field Offices, Regions and Headquarters. OO plans, organizes and carries out annual and multi-year budgeting in support of FDA's public health mission and programs. OO supports the mission of FDA by providing financial management services and IT services across FDA.

Office of Equal Employment Opportunity (OEEO)

The Office of Equal Employment Opportunity (OEEO) is made up of three Divisions: Compliance and Resolution Staff; Diversity Staff; and the Program Evaluation and Executive Support Staff. The Compliance and Resolution Staff is responsible for the laws, policies and regulations that ensure equal opportunity in the workplace irrespective of race, religion, color, gender, sexual orientation, national origin, age, disability or genetic information. In addition to enforcing anti-discrimination law, OEEO pursues the early resolution of disputes whenever possible through its cadre of experienced mediators. OEEO's Diversity Staff proactively seeks to promote an inclusive work environment by fostering a professional culture and empowering individuals through education and training, so they can participate and contribute to the agency's mission to their fullest potential. The Program Evaluation and Executive Support (PES) Staff provides OEEO with leadership and guidance through the management of its administrative, training, marketing and communications functions. PES's technical support allows every facet of OEEO's programmatic activities to support the mission of the agency with maximum effectiveness.

Office of Finance, Budget and Acquisition (OFBA)

The Office of Finance, Budget and Acquisitions supports the public health mission of FDA by providing budget formulation, execution, and acquisition services to the Commissioner and other key FDA, HHS, and OMB officials. OFBA is comprised of the Office of Finance, the Office of Budget and the Office of Acquisitions.

The Office of Finance (OF) supports the mission of FDA by providing financial management services, budget execution and controls, financial policy and compliance, and financial systems support. OF's main objective is to attain operational excellence and accountability. OF continues to apply the Office of Management and Budget's A-123 Appendix A- Internal Controls Over Financial Reporting and continues to achieve major milestones in its corrective action plan (CAP) applications. In order to gain transparency and operational efficiency, FDA documented its end-to-end business processes including the user fee billings and collections processes. OF, in collaboration with the other DHHS Operating Divisions, is revising and re-engineering its IT and financial systems development and implementation strategy following the latest Office of Management and Budget guidelines, OMB Memorandum M-10-26.

The Unified Financial Management System (UFMS) which is fully implemented in FDA, is an integrated system shared by all HHS Operating Divisions (OPDIVs). FDA participates in all other OPDIVs phased implementations and is exploring the effects of moving to a later version of ORACLE Federal Financials which will bring HHS one step closer to Federal Managers Financial Integrity Act compliance. In FY 2011, OF continued to expand its reporting capabilities and started the improvement phase of the end-to-end business processes by participating in four 4 upgrades. In FY 2012, FDA will continue its business intelligence reporting development and UFMS 2012 initiatives towards economies of scale, collaborating with the Department in implementing its OBIEE business intelligence platform and Hyperion Extension Solutions. OF will partner in the implementation of the Department's Data Archiving and Purging Solution pending approval by OMB. In FY 2013 OF will continue participating in the three Department-wide UFMS Initiatives (OBIEE, Hyperion-Extension and Data Archiving and Purging), and will continue to improve its end-to-end business processes to make government business more transparent, robust and efficient with minimum investment.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)*	FY 2011: Expanded FDA's reporting capabilities; defined the TO-BE UFMS processes and developed a comprehensive training program. (Target Met)	1) Continue collaborating with the Department in implementing Department-wide its OBIEE business intelligence platform and Hyperion Extension Solutions. Participate in the	Continue supporting the Department (in the different development phases) with the OBIEE and Hyperion expansions and the Data Archiving and Retrieval System.	N/A

		Department's Solution for Data Management / Data Archiving and Retrieval System Department-wide. 2) Continue to improve FDA's end-to-end business processes and job aids. 3) Continue development of training courses consistent with the CFO Act. 4) Participate in 4 UFMS Planned Point Releases.	Continue with on going improvements with end-to-end business processes and job aids, training efforts, and support UFMS Point Releases as planned.	

The Office of Budget (OB) manages FDA's annual and multi-year budget formulation and presentation processes for its public health programs. OB provides expert advice to top Agency management on complex issues related to the administration of the Agency's total resources, and ensures that the Agency complies with applicable guidelines and statutes. The Office advises senior management on the impact of changes to food and drug laws and regulations on FDA's financial operations and performance.

The Office of Acquisitions (OA) oversees administrative programs and management initiatives related to addressing Presidential, Departmental, and FDA priorities Associated with:

- human capital management programs that include performance management and commercial services management
- pay and compensation policy and flexibilities such as Title 38, Title 42, and Senior Executive Services
- succession and workforce planning, reorganization planning and delegations of authority.

The Office of Acquisitions strives to improve its services by continuously analyzing its contracts and acquisitions processes to ensure adherence to contract and grant

regulations while at the same time remaining flexible enough to acquire the goods and services requested by its customer base.

The Office of Information Management (OIM)

The Office of Information Management manages information technology (IT) and other related services. It also provides technical oversight of system development processes, policies, and methodologies and management of IT infrastructure. This ensures that FDA has a robust IT foundation that enables interoperability across all components of the Agency. These enterprise-wide systems help FDA meet is mission of promoting and protecting public health in an efficient, effective, productive, and timely manner. OIM strives to consistently meet the business needs of its customers by providing the services that adhere to the FDA's IT standards and policies.

Public Health Focus

By enhancing FDA's administrative support structure, public health and safety professionals are better able to focus on their primary roles in protecting, promoting and advancing the public health.

FDA modernized its IT infrastructure to create a robust foundation that enables interoperability across FDA, and allows FDA to develop enterprise-wide systems necessary to transform nearly every aspect of FDA operations, from bioinformatics and scientific computing to adverse event detection. With FDA's increased focus on safety inspections for food, drugs, and medical devices, FDA updated its IT goals to align with and support this direction. FDA's current IT goals support FDA's other public health goals which specifically focus on the following initiatives:

- Transforming the Food Safety and Nutrition
- Advancing Medical Countermeasure
- Protecting Patients
- FDA Regulatory Science and Facilities

OIM works in partnership to support these initiatives by developing and implementing sound technology solutions as well as alternative solution approaches when warranted; overseeing application development efforts; ensuring the security of the FDA's computing environment; creating and implementing processes and procedures for managing the FDA information technology environment; and reporting the status and health of projects.

Public Health Outcome

OIM's focus on strategic investment in information technology will enable FDA to collect, store and analyze large volumes of regulatory, scientific, and risk based information.

The resulting bioinformatics environment will enable FDA to better meet its FDA mission and advance FDA science by:

- providing early risk based information, which will promote proactive decisions and timely responses to issues impacting the public health, including those emanating from beyond our borders
- inserting science-based information into the regulatory review process
- expanding the availability of information across program lines by leveraging internal and external knowledge bases

Expanding the bioinformatics platform to the field and merging laboratory and regulatory data will enable FDA inspectors to make critical decisions based on current information when targeting specific areas for regulatory action. The resulting impact will reduce the risk of adulterated, misbranded or unapproved products entering commerce. Some business drivers for new IT development include the following:

- system obsolescence due to increased number of users, amount of data handled, or unsupported technology
- need for new types of data/document storage
- need for increased or new computation abilities, especially in the areas of high performance computing, scientific computing and data analytics
- need to support globalization and new FDA locations beyond the USA borders.

Promoting Efficiency

OIM will partner with FDA Centers and Offices to provide integrated and collaborative technology support to FDA in 2013 by:

- delivering major program releases in 3 to 6 month increments that provides healthcare stakeholders with early insight into enhanced application capabilities
- using automated program management tools such as Clarity to track risks, schedule, costs, and project deliverables for cross cutting applications and initiatives
- using a risk based project management strategy within integrated project management teams to effectively deliver automated solutions for systems that impact public health
- sharing information across program lines by focusing on data standardization
- facilitating:
    - paperless workflow processes for drug applications and biologic product submissions

- electronic workflows with digital signatures to speed the regulation of drugs, biologics, devices, foods, tobacco products, and pharmaceuticals given to animals
- integrated information and knowledge management systems
- faster and more far reaching public communications via conventional, online and social media
- secure computing and communications for FDA staff
- green computing environment through acquisition of Energy Star designated products; implementing an environmentally friendly disposition; and green configuring of network printers to include duplexing

- continuing the use of server virtualization to minimize the number of physical servers required to support FDA operations; requiring all requests for proposals to support appropriate "green" requirements.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
291405: Percentage of application availability (uptime less non-scheduled emergency outages). *(Output)*	FY 2011: 99.6% Target: 99.9% (Target Not Met)	98.5%	98.5%	Maintain

The Office of Management (OM)

The Office of Management serves as a partner in the support of FDA's mission to promote and protect the public health by providing executive leadership, direction, coordination, and guidance on cross-cutting operations related to FDA's administrative and management programs. OM provides essential services that include administering the FDA Ethics and Integrity program to ensure that all FDA employees are free from conflicts of interest and do not hold prohibited interests; and oversight of FDA-wide Commissioned Corps activities.

Office of Foods (OF)
FY 2012 Enacted Amount: $1,627,450 (BA: $1,407,000 / UF: $220,450)

Oversees the following Centers:
Center for Veterinary Medicine
Center for Food Safety and Applied Nutrition

Public Health Focus

The Office of Foods provides leadership, guidance, and support to the FDA Foods and Veterinary Medicine (FVM) Program to achieve the FDA's public health goals. The FDA FVM Program protects and promotes the health of humans and animals by ensuring the safety of food for humans, including dietary supplements, the safety of animal feed, and the safety and effectiveness of animal drugs. The FVM Program does this by setting science-based standards for preventing food- and feed borne illness and ensuring compliance with these standards; protecting the food and feed supply from intentional contamination; and ensuring that food labels contain reliable information and encouraging product reformulation. The FVM Program also promotes and protects the health of humans and animals by regulating the manufacture and distribution of food additives and drugs that will be given to animals.

Public Health Outcome

OF ensures that FDA has the strategies, scientific and regulatory capacities, and programs to protect consumers from unsafe foods and unsafe or ineffective animal drugs. OF coordinates all elements of FDA's FVM Program to ensure they have the tools they need to work in a closely integrated fashion to prevent food- and feed borne illness, improve the labeling of the food and feed supply, encourage product reformulation to allow consumers to make healthy choices and promote well being, and prevent harm from drugs and additives given to animals.

Promoting Efficiency

OF is the focal point for planning and implementing the recommendations of the President's Food Safety Working Group and the FDA Food Safety Modernization Act (FSMA). Implementation of the FSMA provisions will generate efficiencies for industry, consumers, and FDA because they help anticipate and prevent food and feed safety problems. In addition to protecting public health, preventing such problems reduces the economic impact on individual firms or entire industry sectors from loss of consumer confidence and protracted recalls.

OF is the focal point for activities related to providing consumers with improved information on food and feed labels to encourage more healthful choices, which will reduce costs associated with health care by reducing diet-associated chronic diseases, such as hypertension, heart disease, and cancer.

Office of Medical Products and Tobacco (OMPT)
FY 2012 Enacted Amount: $19,483,804 (BA: $9,726,666 / UF: $9,757,138)

Includes the following office:
Office of Special Medical Programs

Oversees the following Centers:
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Tobacco Products

Office of Special Medical Programs (OSMP)

Public Health Focus

The Office of Special Medical Programs (OSMP) serves as the FDA focal point for special public health programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature. OSMP focuses on the following areas that directly and indirectly affect public health:

- Increasing the availability of medical products for those with rare diseases
- Improving access for children to innovative, safe, and effective medical products
- Ensuring the safety of people participating in clinical trials
- Determining the reliability of clinical trial data used to support research or marketing applications for medical products
- Ensuring timely and appropriate reviews of medical products that combine drugs, devices, and/or biologics
- Ensuring that the FDA has a robust program of expert advisors on public health and medical issues
- Promoting international harmonization of policies and procedures for combination products, pediatric studies, orphan products, advisory committees, and good clinical practice.

Public Health Outcome

OSMP coordinates important cross-cutting FDA public health initiatives, such as human subject protection and greater access to safe and effective medical products for children and for rare disease populations. OSMP also is uniquely positioned to standardize policies and practices across the agency consistent with statutes and regulations. One of OSMP's primary functions is to train and communicate OSMP issues both internally with FDA staff, and externally with the regulated industry, other stakeholders, other Federal agencies, and international regulatory counterparts. OSMP staff members frequently participate at universities, national and international conferences, workshops, and training sessions. OSMP leads the Advisory Committee Oversight and Management Staff (ACOMS), which ensures that FDA's advisory committees comply with relevant statutory requirements, including the Federal Advisory Committee Act (FACA), the Freedom of Information Act, the FDA Amendments Act of 2007 (FDAAA), and the Ethics in Government Act, as well as applicable regulations (U.S. Standards of

Ethical Conduct in 5 CFR §§ 2635 and 2640; 21 CFR Part 14), and pertinent agency policies and guidance. ACOMS oversees advisory committee operations for all FDA centers and FDA Headquarters.
FDA's advisory committees contribute to FDA's mission of protecting the public health by obtaining outside, independent, expert advice and allowing for open public meetings to discuss important health issues. Advisory committees address topics such as product approvals, adverse event reporting, product labeling and manufacturing, communication of public health risk, and reviews of new agency initiatives.

By leveraging the state-of-the-art expertise of external scientific advisors, the FDA has immediate access to the best possible advice to address public health issues as they arise. This enables FDA to assess risk quickly and effectively and make necessary science-based decisions affecting public health and safety. FDA currently has 50 advisory committees and panels with 621 authorized positions. The agency holds approximately 80 meetings per year with the participation of over 1,000 outside experts. ACOMS is also responsible for answering special requests from the Office of the Inspector General (OIG), General Accounting Office (GAO), Office of Government Ethics (OGE), General Services Administration (GSA), Congress, the Department, the press, and public inquiries to the Commissioner on advisory committee issues. Furthermore, ACOMS develops regulations and guidance, establishes new committees, works with external organizations to recruit new candidates for committee vacancies, screens candidates to fill committee vacancies per FACA and FDAAA guidelines, and reviews advisory committee members' financial reports for potential financial conflicts of interest

Promoting Efficiency

OSMP activities foster efficiency and innovative product development, expedite the premarket review process, and enhance the safe and ethical development of therapies by increasing understanding and transparency of the complex regulatory issues raised by medical products. In addition, international harmonization activities promise greater regulatory efficiencies as international standardization of product development is enhanced.

Office of Good Clinical Practice (OGCP)

Public Health Focus

Established in 2000, OGCP serves as the FDA focal point for Good Clinical Practice (GCP) issues related to FDA-regulated clinical trials. OGCP sets priorities for the development of Human Subject Protection (HSP) and Bioresearch Monitoring (BIMO) policy, coordinates the FDA's BIMO program with the Office of Regulatory Affairs, participates in international GCP harmonization activities, and serves as the liaison to other federal agencies and external stakeholders committed to the protection of human research participants. The overarching goals of the HSP/BIMO Programs are to help ensure:

- Protection of the rights, safety, and welfare of subjects involved in FDA-regulated clinical trials
- Accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications
- Compliance with FDA's regulations governing the conduct of clinical trials, including those for informed consent and ethical review.

Public Health Outcome

Through its ongoing HSP/BIMO Modernization Initiative, OGCP is working to modernize and strengthen the agency's oversight and protection of subjects in clinical trials and the integrity of resulting data. The HSP/BIMO Initiative encompasses all FDA-regulated clinical trials that are related to human drugs and biological drug products, devices, foods, and veterinary medicine. In addition, FDA created a dedicated Task Force to specifically address GAO, OIG, and Congressional concerns and recommendations regarding FDA's oversight of clinical trials. The Agency works diligently to develop and issue new regulations and guidance to further improve the conduct of clinical trials and enhance the protection of human subjects. Some of these documents are addressed to study sponsors, clinical investigators, and institutional review boards (IRBs); others focus on FDA's internal procedures. Additional activities are aimed at building quality into the clinical trial process and focus on a risk-based approach. Under these initiatives, the Office is developing key regulations and policy as well as participating in domestic and foreign outreach activities in support of this important effort.

Specifically, in coordination with the Centers and ORA, OGCP is revising its procedures for conducting bioresearch monitoring inspections of institutional review boards, including the development of criteria for enforcement actions. In previous years, inspectional procedures for both sponsors/monitors/contract research organizations and clinical investigators were updated. With completion of this IRB document, all BIMO inspectional programs are complete. In recognition of the globalization of clinical trials, OGCP is drafting guidance to clarify the requirements for FDA acceptance of data from clinical investigations conducted overseas not under an IND, developing a proposed rule to define good clinical practice for studies of medical devices conducted outside the US, and participating in international GCP capacity building activities, such as training of non-US regulators.

As the agency focal point for HSP/BIMO issues, OGCP regularly conducts training for Center review staff as well as field investigators on FDA requirements for clinical trials. The review staff training programs focus on HSP/BIMO issues, such as informed consent for studies involving vulnerable patient populations and, clinical investigator financial disclosure. OGCP also works with HHS' Office for Human Research Protections (OHRP) in sponsoring and conducting several regional conferences each year. These conferences are addressed to clinical investigators and institutional review board members and provide a forum for in-depth discussion of issues related to FDA-regulated research. Finally, OGCP participates in stakeholder (e.g., industry, healthcare providers, and professional organizations) conferences and workshops. All

of the above efforts are aimed at enhancing the protection of human subjects and ensuring the quality of the trial data no matter where the studies are conducted -- domestically or abroad.

Promoting Efficiency

OGCP actively works to harmonize FDA policies and regulations with those of our federal partners, such as OHRP and NIH, whose missions are inter-related with FDA's on issues, such as ensuring equivalent human subject protections in international clinical trials. OGCP routinely collaborates with professional societies, such as the American Medical Association, on issues where we have a mutual interest, for example, improving the informed consent process. As an *ex officio* member to the Secretary's Advisory Committee for Human Research Protections and agency representative to several of its working groups, including the Subcommittee on Harmonization, OGCP provides expert advice on FDA's regulations and policies on specialized topics.

Each year, OGCP receives more than 1,000 inquiries from sponsors, IRBs, the clinical research community, and patients involved in clinical trials. OGCP addresses all of these queries and posts the redacted responses on the Office's website so that other stakeholders can learn from these frequently asked questions. In addition, many of the questions OGCP receives are used as the basis for future guidance or educational outreach activities.

With its sister agencies and through strategic collaborations, OGCP is actively working to better match research oversight with research risk. Such efforts aim to reduce barriers to research, while still ensuring the protection of human subjects participating in FDA-regulated trials. In addition, by harmonizing research regulations and policies with other HHS agencies, OGCP strives to reduce the regulatory burden and confusion due to inconsistent and sometimes conflicting requirements. In July 2011, HHS released an advanced notice of proposed rulemaking (ANPRM) seeking comment on a number of proposals aimed at enhancing human subject protection while reducing regulatory burden. OGCP will be a key player in the review of the comments received on the ANPRM and development of the proposed rule.

Office of Combination Products (OCP)

Public Health Focus

The Office of Combination Products (OCP) is responsible for classifying a product as either a drug, device, biologic, or combination product and assigning the product to a Center for regulation. By submitting a Request for Designation (RFD), a company may obtain a formal FDA determination of the status of its product. OCP must respond to a RFD within 60 days, or the requestor's recommended classification stands. A proper determination by OCP will enable the Agency to assign a particular product to the appropriate agency component for premarket review and postmarket regulation (CDER,

CBER, or CDRH), and also enable the Agency to regulate the product under the proper regulatory authorities (New Drug Application (NDA), Premarket Notification Submission (510(k)), Premarket Approval (PMA), or Biologic License Application (BLA).

Combination products are innovative therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Examples of combination products include drug eluting stents, photodynamic therapy, and implantable drug delivery systems. Because combination products involve articles (drugs, devices, and biological products) that would normally be regulated under different types of regulatory authorities, and frequently by different FDA Centers, they raise challenging scientific, regulatory, policy, and review management challenges.

OCP also serves as a focal point for addressing combination product issues raised by FDA reviewers and industry, and works with the Centers to develop guidance and/or regulations to clarify the regulation of combination products.

In addition, OCP has responsibility for FDA action on all Requests for Designations submitted by industry in accordance with 21 CFR Part 3. This includes requests for classification and assignment of a particular product as a biological product, device, or drug, as well as requests for assignment of combination products.

Public Health Outcome

Although combination products have existed for many years, there is a lack of specific regulations that govern them. For this reason, one of the primary functions of OCP is to develop guidance documents and regulations to ensure combination products are regulated consistently by the FDA. OCP is currently working on two final regulations that will clarify the premarket and post-market requirements for combination products. Streamlining the cGMP and adverse event reporting requirements for combination products will also help promote the development of innovative combination products.

• **Final Rule for Current Good Manufacturing Practice Requirements for Combination Products**. OCP is working with the Centers to codify the current good manufacturing practice (cGMP) requirements applicable to combination products. This final rule is intended to promote the public health by clarifying which cGMP requirements apply when drugs, devices, and biological products are combined to create a combination product. In addition, the final rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with cGMP requirements for ‘‘single-entity’’ and ‘‘co-packaged’’ combination products.

• **Final Rule for Postmarket Safety Reporting for Combination Products**. OCP is working with the Centers to amend the combination product regulations to set forth postmarket safety reporting requirements for combination products. The final rule will clarify the postmarket safety reporting requirements that apply when regulated articles (drugs, devices, and biological products) are combined to create a combination product.

Another primary function of OCP is to make formal determinations on Requests for Designations (RFDs) within the 60 day statutory requirement. RFD is a formal process for obtaining a determination as to whether a particular product in question is a device, drug, biologic, or a combination product; and if it is a combination product, which FDA center should have the lead in its premarket review and postmarket regulation. A formal decision on an RFD is binding on the FDA and the company. As such, these formal decisions are significant to a company because different classification decisions will result in different user fees and different review standards for a particular product. These factors may influence whether a company will be able to continue the development of its medical product.

In order to assist the regulated industry to understand how FDA makes its classification determination, OCP is currently working on three guidance documents which will clarify our decision making process.

• **Guidance Document For Classifying a Product as a Drug or a Medical Device**. FDA has not been transparent in its approach for classifying a product as a drug or a medical device. For this reason, OCP is working with the Centers to develop a guidance document which will provide a general framework for how FDA is making a classification determination as to whether a product is a medical device or a drug. OCP published this draft guidance document in June 2011.

• **Guidance Document on Chemical Action**. This guidance provides information about how FDA interprets the term “chemical action” in the device definition at section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h). FDA’s interpretation of this term can affect whether FDA classifies an article as a medical device. In addition to identifying the types of activity that FDA considers to be chemical action, this guidance also provides illustrative examples of how such chemical action may contribute to the function of regulated articles. OCP published this draft guidance document in June 2011.

• **Guidance Document on Post Approval Changes for Combination Products**. This guidance document provides industry and FDA staff the underlying principles used in determining the type of premarket applications that should be submitted for post approval changes made to a combination product approved under an NDA, PMA, or BLA.

Promoting Efficiency

The purpose of these regulations and guidance documents is to provide a clear understanding to the regulated industry on how FDA classifies products and the regulatory requirements that come with such classification. By having this understanding early in the product development cycle, companies will be better prepared to meet the regulatory and data requirements necessary to get their products on the market. Reducing the time to market for these innovative products will significantly impact public health.

OCP receives hundreds of inquiries every year relating to the regulation of combination products. Many of the inquiries are related to the same topic. By developing regulations and guidance documents, OCP expects to reduce the number of annual inquiries. Reducing this work will give OCP more time to develop additional policies, regulations, and guidance documents that address other significant issues such as cross-labeling, and post approval changes for combination products.

OCP resolves disputes regarding the timeliness of premarket review of combination products, serves as a focal point for combination product and other crosscutting regulatory issues for internal and external stakeholders, and facilitates the intra-center consultative review process for combination products and other medical products. OCP also meets with international counterparts from Canada, the European Union (EU), Australia, Japan, and China to exchange information about regulation of combination products and to develop areas of potential global harmonization. These activities have the potential to improve knowledge about regulation of combination products and streamline product review.

OCP is committed to making formal determinations on every RFD within the 60 day statutory requirement. To date, OCP met its commitment every single year. A timely decision is important since it enables the Agency to appropriately assign the product to the proper Agency component for premarket review and post-market regulation, to regulate the product under the appropriate regulatory provision, and to collect the proper user fees. Each product is properly regulated and the Agency is able to fulfill its mission of protecting and promoting the public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
293205: Percentage of requests for Designations processed within the 60 day statutory requirement. *(Output)*	FY 2011: 100% Target: 95% (Target Exceeded)	95%	95%	Maintain

Office of Orphan Products Development (OOPD)

Public Health Focus

Since its inception in 1982, the public health programs of the Office of Orphan Products Development (OOPD) have been dedicated to promoting and advancing the development of products (drugs, biologics, medical devices, and medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. These are products necessary to treat a patient population that otherwise would be considered too small for profitable research, development, and marketing. These

programs directly support the HHS priority to accelerate scientific advances in lifesaving cures and quality health outcomes. OOPD administers the major provisions of the Orphan Drug Act (ODA) of 1983 which provide incentives for sponsors to develop products for rare diseases.

Public Health Outcome

Since 1983, 394 drugs and biological products for rare diseases have been brought to market. In contrast, the decade prior to 1983 saw fewer than ten such products come to market. OOPD administers the designation of humanitarian use device program under the Food Drug and Cosmetic Act. Fifty-two humanitarian use devices have been approved for very rare diseases and conditions. OOPD interacts with the medical and research communities, professional organizations, academia, and the pharmaceutical industry, as well as rare disease groups. It provides research study design assistance to sponsors of orphan products and encourages well-controlled clinical studies.

Promoting Efficiency

OOPD activities support FDA's strategic public health goals by improving the process of developing promising new product discoveries into safe, effective, and accessible treatments for patients, and by empowering patients and patient groups with vital information and linkages between researchers, patients, and patient advocacy organizations. As more therapies are developed for rare diseases and conditions, and patients and providers become more educated about these therapies, there will be a positive impact on public health.

OOPD has five public health sub-programs:

- orphan product grants, which provide funding for clinical research in rare diseases
- orphan drug designations
- humanitarian use device designations
- pediatric device consortia grants
- outreach activities.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)*	FY 2011: 451 Target: 312 (Target Exceeded)	425	450	+25
293202: The number of medical devices provided development assistance by the Pediatric Device Consortia. (O*utput)*	FY 2011: 90 Target: 90 (Target Met)	100	110	+10

Office of Pediatric Therapeutics (OPT)

Public Health Focus

The Office of Pediatric Therapeutics (OPT) is mandated by Congress to facilitate access for children to innovative, safe and effective medical products. OPT's public health mission cuts across all human product centers at FDA in its efforts to assure that parents and doctors have the information they need to appropriately study and use medical products in the pediatric population. OPT is extensively involved in scientific activities directed at increasing the transparency around knowledge about pediatric trials, failed pediatric studies, and pediatric therapeutic safety issues. OPT's cross-cutting reporting includes postmarket pediatric-focused safety reviews before a public pediatric advisory committee (PAC) as well as oversight responsibilities for pediatric ethics. The safety reviews include drugs, biologics and devices. This is accomplished through collaborations with both internal and external partners such as NIH, Agency for Healthcare Research and Quality (AHRQ), academic hospitals, American Academy of Pediatrics (AAP), CDC, and external scientific experts. New global pediatric initiatives, which provide incentives to conduct pediatric studies, have necessitated regular communication and informational exchanges with many countries on pediatric product development trials. OPT communicates with regulatory authorities from the World Health Organization, European Union, Japan, Canada and Latin America to identify issues, develop data, and arrange information exchanges. OPT also communicates information pertaining to pediatric product development in Europe to the review divisions when these products are discussed at the weekly Pediatric Review Committee (PeRC) meetings to inform the scientific discussion and prevent trial duplication. OPT provides training to international regulators.

Public Health Outcome

OPT is accomplishing its mission through the following programs:

Pediatric Safety Program: OPT coordinates the mandated pediatric-focused safety reviews of drugs, biologics, vaccines, and pediatric Humanitarian Device Exemption (HDE) devices recently studied in the pediatric population for presentation to the

Pediatric Advisory Committee (PAC). Annually, OPT brings over 40 products to a public pediatric-focused safety review. This often results in pediatric-specific safety information either being added to labeling or being communicated to the public in various venues. In addition, OPT coordinates the pediatric device HDE safety review and the profit-making assessment before a public advisory committee. OPT has initiated SAFENET, a pediatric product safety program utilizing CDRH's existing MedSun/KidNet network to address queries from the PAC and internally generated safety questions.

Pediatric Advisory Committee (PAC) Program: OPT coordinates and leads all activities relating to the Pediatric Advisory Committee, the Pediatric Ethics Subcommittee and Part 54 referrals. These activities include all communication and interaction with the pre- and post-market Division staff from CDER, CBER and CDRH for pediatric safety reviews. Further, OPT maintains committee membership, renewal, and meeting logistics to assure that adequate representation and pediatric expertise is present to address the wide array of products and safety reviews covered at each meeting. As required, OPT conducts all conflict of interest screening for each committee member and special government employee (SGEs) prior to each meeting. OPT convenes 3 to 4 advisory committees annually with safety reporting of over 40 products each year.

SAFENET-Pediatric Drugs KidNet Initiative: The KidNet Initiative is an ongoing active surveillance program that interfaces directly between FDA and healthcare professional tertiary care children's hospitals and provides FDA with better quality safety information. This program is tailored to study and better understand pediatric drug use and safety concerns in the neonatal and pediatric ICU settings. It facilitates and promotes the identification and reporting of adverse events and previously unrecognized safety signals. This system pilot study aims to provide important safety information to broaden the view of emerging issues to help focus public health measures, strategies and interventions. Current projects are piloting the utilization of this system to respond to PAC safety inquiries.

Pediatric Ethics Program: This congressionally-mandated program supports FDA efforts to assure that children are only enrolled in clinical studies that are both scientifically and ethically sound. This program provides consultation and education on ethical issues in pediatric product development to CDER, CBER and CDRH. Through such consultation and education, studies presenting an unreasonable risk of harm to children may be identified in a timely manner, and clinical studies can be more easily redesigned in the planning stages thereby preventing exposure of children to unethical and significant risks of harm. The pediatric ethicist is a required member of the internal cross-center committee that reviews all protocols being proposed for pediatric studies. The OPT Ethics Program is integrating ethics education into the initial and continuing education training for FDA reviewers within all three Centers. In addition to informational activities involved in consulting, the program provides internal and external training in ethical issues in pediatric clinical trials. Provision of ethical consults to the technical divisions concerning pediatric proposed and current trials is a major activity. Difficult pediatric ethical trial issues are brought forth for public discussion at FDA advisory

committee meetings and FDA-sponsored workshops. The OPT Ethics Program also participates in guidance and policy development in human subjects protection across FDA, including the Center for Tobacco Products.

Science and Communication Program: OPT works with FDA scientists and reviewers to assure that pediatric studies are rigorously designed and conducted in accord with current scientific knowledge and that "lessons learned" are communicated to the practicing physicians, and caretakers, academicians and industry. FDA is the repository for over 1,000 pediatric studies and can learn from these studies to better inform future pediatric trials. OPT provides analysis of pediatric trials across classes of products, across failed trials, and safety issues, and publishes the results in two to five scientific journals each year. OPT staff also speak at numerous forums in an effort to "get the information out".

Pediatric International Program: OPT facilitates communication and collaboration between FDA and partner regulatory agencies around the world. Pediatric clinical trials are necessarily global, given the incidence and distribution of diseases in the pediatric population. FDA seeks to assure that children are not exposed to unnecessary, duplicative, or poorly designed clinical trials world-wide. OPT leads monthly conferences with the European Medicines Agency (EMA), Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and Health Canada (HC) where information on pediatric trials is exchanged. Since September 2007, information was exchanged on approximately 500 products with discussions on 249 products and 28 general topics. Although the agencies reached consensus on many issues, they continue ongoing discussions related to a number of pediatric scientific and ethical concerns related to products and product classes. Latin America is a prominent participant in the conduct of pediatric trials and informational exchanges have been initiated with regulators in Mexico and Brazil. In addition, investigator level exchanges in Peru, Argentina, Costa Rica, Panama, Colombia, Brazil, Mexico and Chile have occurred. FDA expects this initiative to experience exponential growth in future years.

Promoting Efficiency

FDA developed an efficient centralized approach to communicating new pediatric labeling, safety and ethical information by synthesizing complex new information into compact labeling information and posting this on the web. This information includes post market reviews of the safety of drugs studied in children. Realizing it is critical to educate caregivers on pediatric therapies, OPT leveraged the American Academy of Pediatrics monthly newsletter to provide monthly updates to pediatricians. Other leveraging activities that promote efficient use of existing systems includes OPT's SafeNet, which utilizes CDRH's existing KidNet adverse event reporting system to pilot usage for pediatric drug adverse event enhancement.

OPT utilizes external scientific expertise through mechanisms as diverse as Intergovernmental Personnel Act (IPA) mobility assignments, fellowships, visiting scholars and even summer medical students to address scientific issues. Over the last

five years OPT published almost 40 peer reviewed scientific articles on the safety, ethics and usefulness of new pediatric labeling information that has been obtained through new pediatric studies. In addition, OPT has monthly conferences with Europe, Canada and Japan to identify, discuss and attempt to resolve conflicting or duplicative scientific and ethical issues involving international pediatric clinical trials. In FY2011, the program expanded to Latin America.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
293203: Number of pediatric scientific and ethical, product and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, with Japan and Canada as observers, and through separate collaboration with Latin America. *(Output)*	FY 2011: 70 Target: 36 (Target Exceeded)	36	36	Maintain
293204: Number of new medical products studied in children with labeling changes and safety reviews completed. *(Output)*	FY 2011: 36 Target: 30 (Target Exceeded)	40	45	+5

Office of Global Regulatory Operations and Policy (OGROP)
FY 2012 Enacted Amount: $5,299,288 (BA: $5,193,999 / UF: $105,289)

Includes the following office:
Office of International Programs

Oversees the following Center:
Office of Regulatory Affairs

The Office of Global Regulatory Operations and Policy serves as the agency's lead for providing oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global collaboration, global data-sharing, development and harmonization of standards, field operations, compliance and enforcement activities. OGROP works with agency leaders to enhance FDA's global efforts and strategically implement the Pathway to Global Product Safety and Quality strategy, which is transforming FDA from a regulator of domestic products to one overseeing a worldwide enterprise of food and drug

production and supply, as well as the science that is the foundation of the products FDA regulates.

This office provides broad direction and support to the Office of International Programs and to the Office of Regulatory Affairs, with an agency mandate to make response to the challenges of globalization and import safety a top agency priority.

OIP leads, manages, and coordinates all of FDA's international activities with the primary purpose of providing high quality information that enable FDA Product Centers and border officials to make better decisions regarding the quality, safety, and effectiveness of foreign-made products destined for the U.S. market. ORA is the lead office for all FDA field activities and advises FDA leadership on imports, inspections, and enforcement policy. ORA's field activities support the six FDA Product Centers by assessing industry compliance with applicable laws and regulations to protect public health.

Office of International Programs (OIP)

The Office of International Programs serves as FDA's focal point for all international matters. The Food, Drug and Cosmetic Act (Section 903) mandates, as part of FDA's mission, collaboration with foreign regulatory counterparts to reduce regulatory burdens, harmonize regulatory requirements, and establish appropriate reciprocal arrangements. OIP leads, manages, and coordinates all of FDA's international activities with the primary purpose of providing high quality information that will enable our centers and border officials to make better decisions regarding the quality, safety, and effectiveness of foreign-made products destined for the U.S. market. Also, OIP strives to: effect an affirmative public health agenda in the international arena; enhance and maximize the impact of FDA's communications and interactions globally; help assure they reflect the FDA's policies and best scientific, legal, and policy thinking; help assure that FDA's international communications and interactions are consistent with HHS and administration public health objectives; leverage more effectively the human, financial, and informational resources of trusted foreign counterpart agencies; and collaborate with U.S. Government counterpart agencies with complementary missions in meeting FDA's public health mission and implementation of the Pathway to Global Product Safety and Quality strategy. OIP accomplishes these tasks through offices that are structured geographically to lead and manage these activities.

Collaboration (Bilateral and Multilateral) – OIP carries out and manages daily interactions with a myriad of countries, by providing information on FDA requirements, programs and activities, and obtaining information on foreign activities that are useful for FDA's work. Collaborating on regulatory, scientific and public health matters is a significant component of OIP operations. In addition to the numerous daily interactions, OIP leads annual formal meetings with selected counterpart regulatory authorities, including Canada, China, Mexico, Japan, Singapore, and the European Union, to help assure that our programs and activities are aligned and to agree on the elements of our interactions for the following year. These efforts further FDA's mission and public health

goals by leveraging scientific knowledge and resources. OIP also works regionally and multilaterally through organizations such as the World Health Organization (WHO), Pan American Health Organization (PAHO), Food and Agriculture Organization (FAO), Organization for Economic Co-Operation and Development (OECD), World Organization for Animal Health (OIE) and Asia-Pacific Economic Cooperation.

Harmonization of Requirements and Standards – OIP helps coordinate and support FDA's work with the various international technical standards harmonization initiatives-Codex Alimentarius (food and animal feed), International Conference on Harmonization (ICH) (human drugs and biologics), Veterinary International Conference on Harmonization (VICH) (animal drugs), Global Harmonization Task Force (GHTF) (devices) and International Cooperation on Cosmetic Regulation (ICCR) (cosmetics). These efforts ensure that the FDA's regulatory and scientific resources are used in an efficient way that will improve public health in the U.S. and worldwide.

Capacity Building – OIP manages FDA's capacity building / technical cooperation efforts, including training and outreach, to help improve the regulatory infrastructure, preventive controls and production practices in foreign countries that export FDA-regulated products to the U.S. FDA's efforts to support global and regional harmonization and multilateral engagement are moving beyond scientific contributions in international standard-setting venues. In FY2010, FDA, through OIP, established a series of Cooperative Agreements with key organizations (WHO, OIE, PAHO, IOM, USAID) to catalyze innovative global and regional platforms that address priority global health regulatory issues.

Foreign Offices – OIP established and is maintaining foreign posts in China, India, Europe, Latin America, and in 2011, the Middle East/North Africa and Sub-Saharan Africa Regions to increase interactions with regulatory counterparts, exporting industry, in-country United States Government counterparts, and third party certifiers. These interactions increase the quality of information FDA has to make regulatory decisions at home, especially decisions on the admission of products to the U.S. market. These efforts help ensure that products exported to the U.S. meet FDA's health and safety requirements. FDA employees stationed overseas are engaging with FDA's regulatory counterparts, industry and others, as appropriate, to leverage information, learn more about FDA-regulated products being exported to the U.S., provide information on FDA requirements, conduct capacity building / technical assistance activities, and, in China and India, conduct inspections. These activities help ensure that safety is built into the products from the beginning and that FDA has the necessary information about the safety and quality of imports to make sound decisions to protect consumers from harmful products, e.g. identifying a product that has been produced in violation of FDA's requirements or that has been subjected to conditions that may affect its safety and quality.

Public Health Focus

The primary purpose of OIP's international activities is to help improve the quality, safety, and effectiveness of FDA regulated products exported to the U.S. for consumption or use by the U.S. consumer.

OIP develops and maintains cooperation with its foreign counterpart regulatory agencies and with international organizations in order to meet FDA's domestic mission of protecting and promoting public health in the global environment in which we live and work.

Public Health Outcome

OIP's international activities and presence enables the FDA to increase the number and quality of inspections of foreign manufacturing facilities in China and India; to increase collaboration with and improve the capabilities of foreign regulatory counterparts and industry; and to leverage the knowledge and resources of trusted foreign regulatory counterparts and U.S. Government counterpart agencies with complementary missions to help ensure products exported to the U.S. meet FDA standards. These activities result in a reduction in products shipped to the U.S. that do not meet FDA standards that may possibly end up in the U.S. market. Additionally, the information gained from ongoing interactions with foreign regulatory authorities and industry improve U.S. consumer protection by supporting the ability of FDA to make better-informed decisions about the admissibility of FDA-regulated products offered for import and to target products from countries that represent the highest risk. The outcome of these efforts is increased protection of the health of the U.S. public.

Promoting Efficiency

Collaboration - OIP leads a number of collaborative activities with FDA's foreign counterpart regulatory authorities that provide scientific and technical information exchanges to allow FDA and the foreign authorities to make decisions about the safety, quality and effectiveness of products. One example is "Clusters", which are groups of FDA scientific staff who have regular teleconferences with their counterparts at the European Medicines Agency (EMA) to discuss specific products that they have in common. This is catalyzed by the permanent stationing of an FDA liaison in the European Medicines Agency and the permanent stationing of an EMA liaison at the FDA.

Harmonization - OIP's work with various harmonization bodies such as the Codex Alimentarius (food) and the International Conference on Harmonization (human drugs and biologics) results in standards that allow research by manufacturers and other regulatory and scientific bodies to be conducted in a more efficient manner, and allow the data to be used for marketing application filings in many countries. Manufacturers can use more consistent methods when conducting research globally with harmonized standards, which obviates the need to conduct additional research when submitting

data to different regulatory authorities. This conserves both human and financial research resources.

Capacity Building - OIP manages capacity building activities that improve the regulatory capabilities of foreign counterpart regulatory authorities and industry. Improved capabilities ensure that FDA-regulated products exported to the U.S. meet FDA requirements and that clinical data submitted to FDA in product marketing applications are reliable and come from clinical trials conducted in an ethical manner. For example, FDA recently completed a workshop on food safety in the Middle East and a workshop on Good Clinical Practices (GCP) in Africa. Other GCP workshops have been held in China, India and Russia.

Foreign Offices - The FDA staff in the foreign offices establish strong relationships with their foreign counterparts to learn more thoroughly how products are manufactured and produced in-country and how the local authority helps to assure the quality and safety of such domestic manufactured products. This allows FDA to be more efficient and strategic in its decisions about surveillance and enforcement activities. FDA also provides information to the foreign authorities and industry on FDA requirements, which allows them to better assure that FDA-regulated products exported to the U.S. meet FDA requirements. This conserves industry and FDA resources because fewer products have to be detained at the U.S. border.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
291304: Advance FDA's Pathway to Global Product Safety and Quality strategy by increasing the number of exchanges of confidential information received and shared with foreign counterpart regulatory bodies. *(Output)*	NA	NA	2,100	+2,100

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$123,320,000	$97,606,000	$25,714,000	733
FY 2009 Actual	$159,193,000	$130,020,000	$29,173,000	859
FY 2010 Actual	$178,300,000	$141,321,000	$36,979,000	947
FY 2011 Actual	$186,665,000	$149,477,000	$37,188,000	922
FY 2012 Enacted	$222,811,000	$153,704,000	$69,107,000	972

Budget Request Summary

The FY 2013 budget request for FDA Headquarters is $280, 635,000 supporting 1,089 FTE. This amount is an increase of $57, 824,000 above the FY 2012 Enacted Level with an additional 117 FTE.

The FY 2012 Enacted funding for FDA Headquarters is $222,811,000. This funding allows FDA Headquarters to provide FDA with program direction and administrative services to ensure that FDA's consumer protection efforts are managed effectively and efficiently.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Protect Patients.

Budget Request

Pay Increase (Commissioned Corps: $105,000)

The request for $105,000 in total BA for the FDA Headquarters reflects a pay increase for the Commissioned Corps.

Data Consolidation and IT Savings (Total Program: -$1,358,000)

The request for $163,030 in total budget authority for FDA Headquarters also reflects a contract and administrative savings reduction of -$1,358,000 for FY 2013.

FDA Headquarters will achieve savings by:

- consolidating FDA-wide enterprise data center contract support and reducing redundant IT devices.

Rent Absorption (Total Program: -$720,000)

The request for $163,030,000 in total budget authority for the FDA Headquarters also reflects rent absorption costs of -$720,000 for FY 2013.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings and Rent Absorption affect all sub-programs.

FY 2013 User Fees Increase

FY 2013 increase for user fees:
PDUFA: +$906,000 / -9 FTE
MDUFMA: +$1,246,000 / 5 FTE
ADUFA: +$351,000 / 0 FTE
AGDUFA: +$76,000 / 0 FTE

FY 2013 increase for FSMA user fees:
Food Re-inspection: $154,000 / 0 FTE
Recall: +$30,000 / 0 FTE

FY 2013 increase for proposed user fees:
GDUFA: +$24,196,000 / 50 FTE
Medical Products Re-inspection: +$6,169,000 / 10 FTE
International Courier: +$289,000 / 1 FTE
Food Establishment Registration Fee: +$12,544,000 / 32 FTE
Cosmetic User Fees: $980,000 / 3 FTE
Food Contact Notification User Fee: $267,000 / 1 FTE
Biosimilars User Fee: $1,290,000 / 5 FTE

FY 2013 Initiatives:

China Foods Initiative:
(+$4,112,500 / 8 FTE)

This FDA investment supports a prevention-focused import safety program in China, which is the source of a large and growing volume of imported foods and food ingredients. This initiative will place greater responsibility on Chinese food manufacturers, processors, packers and distributors to assure that food and food ingredients imported to the United States are safe and meet FDA standards.

With this investment, FDA will perform additional foreign inspections in China, focusing on facilities that produce higher risk foods and food ingredients destined for export to the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA food safety, quality and good manufacturing practices.

FDA will expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk foods and manufacturing that originate in China.

China Foods Initiative: Program Support
(+$262,500)

The Transforming Food Safety Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes Include:

- finance and budgeting
- human resource assistance
- contracting, billing, and legal counsel
- communications, ethics, headquarters coordination and related support functions.

China Protecting Patients Initiative:
(+$5,287,500 / 11 FTE)

This FDA investment supports a prevention-focused import safety program in China, which is the source of a large and growing volume of imported drugs and drug ingredients. This initiative will place greater responsibility on Chinese manufacturers to institute measures to assure that drugs and drug ingredients imported to the United States are safe and meet FDA standards.

With this investment, FDA will perform additional foreign inspections in China, focusing on facilities that produce drugs and drug ingredients that pose the greatest risks to patients in the United States. FDA will also conduct outreach and education activities

for Chinese manufacturers on implementing measures to meet FDA manufacturing quality and good manufacturing practices.

FDA will also expand risk modeling and risk analysis to improve FDA's ability to target inspection resources to high-risk drugs and drug ingredients manufactured in China.

China Protecting Patients Initiative: Program Support
(+$337,500)

The Protecting Patients Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes include:

- finance and budgeting
- human resource assistance
- contracting, billing, and legal counsel
- communications, ethics, headquarters coordination and related support functions.

Advancing Medical Countermeasures Initiative:
(+$1,299,000 / 0 FTE)

The Office of Counterterrorism and Emerging Threats will lead, implement, coordinate, manage, track and report on the activities and outcomes associated with the FDA Public Health and Security Action Plan and each of the 3 objectives of the FDA Medical Countermeasures Initiative. FDA will establish Public Health and Security Action Teams (PHSATs) to support enhanced review of the highest priority medical countermeasures, novel approaches to manufacturing, and related technologies to address the most pressing national security requirements. FDA will establish an MCM regulatory science program and robust scientific collaborations with MCM Enterprise partners, including the Department of Defense. FDA will work collaboratively with HHS to examine the legal framework and the regulatory and policy approaches for MCM development and availability to ensure these adequately support emergency preparedness and response. FDA will develop and sustain educational resources for FDA staff to support the objectives of the Medical Countermeasures Initiative, including a dedicated lecture series and targeted threat briefings for reviewers responsible for medical countermeasures.

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

INFRASTRUCTURE
GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

The following table displays funding levels for FY 2011 through FY 2013.

FDA Program Resources Table
Dollars in thousands

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$318,785**	**$307,229**	**$337,111**	**$400,363**	**$63,252**
GSA Rent	$182,746	$178,120	$205,472	$228,420	$22,948
Other Rent	$94,165	$87,235	$87,658	$110,262	$22,604
White Oak	$41,874	$41,874	$43,981	$61,681	$17,700
Budget Authority	**$250,316**	**$250,317**	**$266,490**	**$296,679**	**$30,189**
GSA Rent	$150,762	$150,763	$160,506	$169,374	$8,868
Other Rent	$61,095	$61,095	$65,598	$69,261	$3,663
White Oak	$38,459	$38,459	$40,386	$58,044	$17,658
User Fees					
GSA Rent	**$31,984**	**$27,357**	**$44,966**	**$59,046**	**$14,080**
PDUFA	$19,905	$18,568	$31,928	$21,569	-$10,359
MDUFMA	$4,626	$3,200	$4,308	$5,270	$962
ADUFA	$996	$672	$1,115	$1,556	$441
AGDUFA	$322	$18	$340	$453	$113
Generic Drugs			$0	$13,815	$13,815
Biosimilars User Fee				$1,008	$1,008
Med. Products Reinspection			$0	$1,072	$1,072
Food Establishment Registration Fee			$0	$5,371	$5,371
Tobacco	$6,135	$4,899	$5,503	$5,778	$275
Food Reinspection User Fee			$1,338	$1,399	$61
Recall User Fee			$434	$454	$20
International Courier User Fee			$0	$307	$307
Cosmetics User Fee				$882	$882
Food Contact Notification User Fee				$112	$112
Other Rent	**$33,070**	**$26,140**	**$22,060**	**$41,001**	**$18,941**
PDUFA	$23,253	$23,253	$17,996	$25,130	$7,134
MDUFMA	$1,493	$1,541	$1,390	$1,701	$311
ADUFA	$182	$41	$204	$290	$86
AGDUFA	$76	$26	$80	$100	$20
Generic Drugs [1]			$0	$6,447	$6,447
Biosimilars User Fee [1]				$576	$576
Med. Products Reinspection [1]			$0	$476	$476
Food Registration and Inspection User Fees [1]			$0	$3,031	$3,031
Tobacco	$8,066	$ 1,279	$1,550	$1,628	$78
Voluntary Qualified Importer Program			$0	$0	$0
Food Reinspection User Fee			$592	$619	$27
Recall User Fee			$248	$259	$11
International Courier User Fee [1]			$0	$176	$176
Cosmetics User Fee [1]				$504	$504
Food Contact Notification User Fee [1]				$64	$64
White Oak	**$3,415**	**$3,415**	**$3,595**	**$3,637**	**$42**
PDUFA	$3,415	$3,415	$3,595	$3,637	$42

[1] Proposed User fee; the amount includes associated rent activity

The following are the legal authorities for GSA Rent and Other Rent and Rent Related activities:

- The Public Buildings Act of 1959 (40 USC 601-619)
- Public Buildings Act: Public Buildings Amendments of 1972 (P.L. 92-313, 86 Stat. 216)
- Public Buildings Cooperative Use Act of 1976 (P.L. 94-541, 90 Stat 2505)
- Public Buildings Amendments of 1988 (P.L.100-678, 102 Stat 4049)
- The Federal Property and Administrative Services Act of 1949 (40 USC 486[d] and [e])
- Omnibus Appropriations Act of 2009 (P.L. 111-8, 123 Stat. 524)
- Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

The following are the legal authorities to establish and consolidate FDA facilities at the White Oak Campus:

- The Food and Drug Administration Revitalization Act (21 U.S.C. 379b)
- Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399)
- Treasury, Postal Service and General Government Appropriations Act (5 U.S.C.)

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Infrastructure Program supports FDA's mission of protecting the nation's public health by providing the FDA Programs with secure and cost-effective office and laboratory space to perform mission critical work. The Infrastructure Program consists of:

- General Services Administration (GSA)Rental Payments
- Other Rent and Rent-Related Activities
- The FDA White Oak Consolidation.

GSA Rental Payments
FY 2012 Enacted Amount: $205,472,000 (BA: $160,506,000/ UF: $44,966,000)

The GSA Rental account includes FDA rental payments to cover FDA's office and laboratory facilities.

FDA currently occupies 5.8 million square feet of GSA-owned or -leased office, laboratory, and warehouse space. More than two-thirds of the GSA rent charges for GSA-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for CFSAN's College Park complex and the newly occupied buildings at the White Oak, Maryland campus, now housing most of FDA Headquarters, CDER, and CDRH. In total, FDA occupies GSA space comprising

approximately 285 buildings including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

The GSA Rent program continues to conduct numerous activities to ensure that the FDA workforce has the space and security necessary to carry out FDA's mission of protecting the public health in an efficient and effective manner.

In FY 2011, FDA vacated space in two Headquarter locations in Rockville, MD, but immediately backfilled one of these locations with Office of Criminal Investigations (OCI) staff. After vacating 279,000 rentable square feet (RSF) in FY 2010, the remaining 124,000 RSF occupied by FDA in the Parklawn Building, Rockville, MD, was vacated in FY 2011.

During FY 2011, FDA's OCI opened one new field office and expanded two field offices. In FY 2012, ORA will open one new Resident Post, and one new Border Station, and will acquire expansion space for two Resident Posts and one Border Station. ORA will also relocate nine Resident Posts and acquire expansion space for one District Office.

FDA is working with the Department of Health and Human Services (DHHS) to promote maximum utilization of Federal workspace, consistent with mission requirements, and to maximize its value to the Government. FDA strives to be cost effective and energy efficient when it acquires the necessary space to meet the mission and nationally recognized standards.

Other Rent and Rent-Related Activities

FY 2012 Enacted Amount: $87,658,000 (BA: $65,598,000 / UF: 22,060,000)

The Other Rent and Rent-Related Activities account includes commercial rent and rent-related charges that are not part of the GSA Rent account. These funds cover costs for operating and maintaining FDA and GSA facilities located nationwide. Costs include commercial rent, operation and maintenance contracts, janitorial and grounds maintenance contracts, and above standard security and guard services contract costs. The program also funds standard utilities in FDA owned facilities, essential overtime utilities in laboratories and data centers, and other above-standard level services not provided by GSA in GSA-managed facilities. These accounts directly support the FDA workforce in meeting its public health mission by providing safe, efficient and secure facilities.

FDA is undertaking numerous energy saving projects to decrease long term energy usage and associated operating and maintenance costs while increasing the life span and efficiency of facilities. These efficiencies will help FDA realize significant savings in Other Rent and Rent Related Activities. The implementation of these projects supports Executive Order 13423, Strengthening Federal Environmental, Energy, and Transportation Management, and Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. These projects contribute to meeting the requirements of DHHS' Efficient Energy Management Assessments, the

Energy Policy Act of 2005, the DHHS Sustainable and High Performance Buildings Policy, HHS Sustainable Buildings Plan, and the 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

FDA continues to investigate strategies to save federal funding on overhead while efficiently supporting the FDA mission.

The Jefferson Laboratory Complex in Jefferson, Arkansas is working towards a Utility Energy Savings Contract (UESC) and an Energy Management Service (EMS) Contract with their local Utility Company (Energy of Arkansas). In 2011, Jefferson Labs conducted a preliminary grade audit and identified an Energy Conservation Measure (ECM) to convert Building 26, a large laboratory facility from a constant "outside air" flow rate to a variable flow rate system. This $1.6 million project involves replacing the controls to modulate flow rates within all laboratories for efficient temperature settings. Savings generated by this project will repay the cost in less than 10 years. .

FDA is considering a second energy saving contract for the Muirkirk Road Campus in Laurel, Maryland. Washington Gas and FDA conducted an investment grade audit in March 2011. The estimated capital investment is $2.1 million, with utility cost savings of approximately $275,000 annually in water, sewer, electricity and fuel costs. This change will generate a simple pay back in approximately 7.6 years.

Washington Gas also identified facility improvement measures including electrical upgrades and replacement of the aged switchgear system and HVAC control upgrades. The replacement of this equipment provides the facility reliable power and improves the facility condition index. The HVAC project is planned for FY 2012 and will also improve the facility condition index. Both projects will generate future energy savings.

FDA is also considering an energy saving contract for the ORA District Laboratory and Office in Irvine, California with the Southern California Edison Electric Power Company. If determined to be cost effective and economically feasible, FDA will proceed with awarding the contract. Based on the Preliminary Audit, the estimated capital investment is $1.5 million and cost savings will be about $160,000 per year with a simple pay back of 9.4 years. A detailed analysis of the proposed energy conservation measures was requested and received, and is currently under review.

GSA is currently performing audits in FDA occupied leased facilities, such as the Wiley building in College Park, MD, and in the Queens, NY, lab. UESCs in these GSA leased buildings will, if implemented, provide energy savings.

Awarding additional UESCs and procuring renewable energy will contribute to DHHS sustainability goals established in the DHHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, Federal Leadership in Environmental, Energy and Economic Performance. More specifically, FDA's activities related to UESCs and renewable energy will help reduce Scope 1 and 3 greenhouse gas emissions.

White Oak Consolidation
FY 2012 Enacted Amount: $43,981,000 (BA: $40,386,000 / UF: $3,595,000)

FDA's Headquarters' consolidation to the White Oak complex is replacing and centralizing existing geographically disparate facilities with new, state-of-the art laboratories, office buildings and support facilities into one location. While the GSA appropriation funds the design and construction of the new buildings at White Oak, FDA's appropriation and PDUFA user fees fund building infrastructure fit-out, specialized equipment and move costs. FDA initiated relocation activities to White Oak in FY 2002.

The total number of employees currently working on the White Oak Campus is 5,496. A Child Care Center was completed in December 2011. GSA received $0 funds in FY 2012 for design and construction funding for the FDA project. If adequate GSA construction funds are appropriated in FY 2013 to complete the remaining buildings on the 130-acre White Oak Campus, FDA plans to relocate another approximately 3,393 employees, for a total on Campus of 8,889 and the current phase of the consolidation will conclude in FY 2016.

Completed design plans include:

- The Southeast Parking Garage — plans completed in May 2009 but garage has not been funded for construction — will be constructed pending the FY 2013 or FY 2014 GSA construction appropriation The date of completion is to be determined.
- Buildings 52 and 72 — the Life Sciences-Biodefense Laboratories II and III and the vivarium, and Office Building 71 — to house CBER and CDER staff: Construction began in the fourth quarter of FY 2010 and is anticipated to be completed in FY 2014.
- Building 75 — an office and laboratory support facility intended to house CBER and CDER program requirements and other FDA component staff. Construction began in late FY 2011 and is anticipated to be completed in FY 2014.

GSA received $44 million in FY 2011, short of the $173.77 million in the President's Budget, which was to have completed the Life-Sciences Biodefense Complex. GSA used the $44 million towards the construction of Building 75 (in the Complex) in addition to using $4 million in contingency funds to put toward Building 75. FDA was authorized to use $22 million of its FY 2011 budget for specialized laboratory equipment in the Complex. GSA in turn used its $22 million to fund the shortfall in construction funding for Building 75. Because GSA is not expecting any construction funds in FY 2012 for the White Oak Campus, the design for Buildings 25, 45 (Distribution Facility) and the Communications Facility are on-hold.

GSA considers the FY 2009 Master Plan of the 130-acre White Oak Campus project to be 62 percent complete after considering the availability of the FY 2011 funds. FDA is working with GSA on a strategy to secure GSA construction funds for the remaining

facilities in the 2009 Master Plan. If necessary, FDA will attempt to absorb program growth in existing space until the facilities are available.
FDA White Oak funding will be used for facility-related costs not funded by GSA, including relocation costs. These costs include:

- furniture
- information technology and telecommunications equipment and infrastructure
- internal communications including audiovisual equipment
- security infrastructure and equipment and cabling
- above GSA-standard costs including specialized equipment and associated infrastructure

In addition, funding for operations and logistics functions on the White Oak Campus is required. There are currently 5,496 employees on Campus and as construction and consolidation grow, that number is increasing exponentially. Therefore, services are needed to operate:

- a Campus transportation program including parking management and a Campus Shuttle and Circulator Bus program
- a 1,600-seat Conference Center
- labor and loading dock services
- laboratory maintenance program
- other central services.

As the Campus continues to grow, continued funding will be needed to coordinate and implement activities associated with operations and logistics.

Funding for Campus operations and logistics is critically needed as the Campus has tripled in size over the last five years, and by 2016, the Campus will grow by another 38 percent. To keep pace with this growth and, as a result of its success in service delivery, the central Campus operations budget will continue to grow. As this program continues to expand and FDA capitalizes on opportunities to gain efficiencies, these funds must be included within the FDA budget as a recurring and increasing need.

Promoting Efficiency

FDA's consolidation at White Oak is not only critical to strengthening public health and national security through scientific integration, but also provides an environment that encourages efficiency, creativity and superior performance, while strategically using human capital. The Campus is being built with centrally shared functional spaces such as conference areas, library services, cafeterias, and break areas to make the most effective use of resources and eliminate redundant activities and space across FDA Centers. In addition, FDA is currently exploring the use of centralized document rooms to increase efficiencies. By providing well-organized services on a central basis,

consistent with the design of the facility, FDA gains economies of scale and saves on costs.

FIVE YEAR FUNDING TABLE – GSA RENT

The following table displays funding levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2008 Actual	$145,111,000	$130,611,000	$14,500,000
FY 2009 Actual	$156,399,000	$133,590,000	$22,809,000
FY 2010 Actual	$177,709,000	$145,261,000	$32,448,000
FY 2011 Actual	$178,120,000	$150,763,000	$27,357,000
FY 2012 Enacted	$205,472,000	$160,506,000	$44,966,000

FIVE YEAR FUNDING TABLE – OTHER RENT AND RENT-RELATED ACTIVITIES

The following table displays funding levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2008 Actual	$64,646,000	$50,278,000	$14,368,000
FY 2009 Actual	$77,866,000	$62,533,000	$15,333,000
FY 2010 Actual	$85,668,000	$64,861,000	$20,807,000
FY 2011 Actual	$87,235,000	$61,095,000	$26,140,000
FY 2012 Enacted	$87,658,000	$65,598,000	$22,060,000

FIVE YEAR FUNDING TABLE – WHITE OAK

The following table displays funding levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2008 Actual	$42,726,000	$38,536,000	$4,190,000
FY 2009 Actual	$41,439,000	$38,779,000	$2,660,000
FY 2010 Actual	$38,536,000	$38,536,000	$0
FY 2011 Actual	$41,874,000	$38,459,000	$3,415,000
FY 2012 Enacted	$43,981,000	$40,386,000	$3,595,000

Budget Request

The FY 2013 budget request for the Infrastructure Program is $400,363,000. This amount is an increase of $63,252,000 above the FY 2012 Enacted Level. This request includes $ 296,679,000 in Budget Authority and $103,684,000 in User Fees.

The FY 2012 enacted funding for FDA's Infrastructure Program is $337,111,000 including $266,490,000 in Budget Authority and $70,621,000 in User Fees.

GSA Rental Payments -FY 2012 Enacted Amount: $205,472,000 (BA: $160,506,000/ UF: $44,966,000)

FY 2013 increase above FY 2012 Enacted Level: $22,948,000

The FY 2013 budget request for GSA Rental Payments is $228,420,000. This amount is an increase of $22,948,000 above the FY 2012 Enacted Level. The GSA Rental increase includes $8,868,000 in Budget Authority and $14,080,000 in User Fees. The total request includes $169,374,000 in Budget Authority and $59,046,000 in User Fees.

The rental properties that provide office and laboratory space for FDA's approximately 12,000 employees are essential facilities that allow FDA to perform its vital public health mission. FY 2012 enacted funding for GSA Rental Payments covers the cost of rental payments to GSA for FDA's 5.8 million square feet of GSA rented office and laboratory space, as well as payments to the Department of Homeland Security for guard services and security systems at these facilities.

Other Rent and Rent-Related -FY 2012 Enacted Amount: $87,658,000 (BA: $65,598,000 / UF: $22,060,000)

FY 2013 increase above FY 2012 Enacted Level: $22,604,000

The FY 2013 budget request for Other Rent and Rent-Related is $110,262,000. This amount is an increase of $22,604,000 above the FY 2012 Enacted Level. The Other Rent and Rent-Related increase includes $3,663,000 in Budget Authority and $18,941,000 in User Fees. The total request includes $69,261,000 in Budget Authority and $41,001,000 in User Fees.

It is important that FDA keep its infrastructure up-to-date and efficient to support our staff while executing our regulatory mission. This budget request allows FDA to operate, maintain and secure its facilities in an appropriate and sustainable manner. This budget request will cover the escalating costs in commercial rent, security, service contracts, and utilities without reducing essential FDA programs.

White Oak Consolidation - FY 2012 Enacted Amount: $43,981,000 (BA: $40,386,000 / UF: $3,595,000)

FY 2013 increase above FY 2012 Enacted Level: $17,700,000

The FY 2013 budget request for White Oak Consolidation is $61,681,000.This amount is an increase of $17,700,000 above the FY 2012 Enacted Level. The White Oak Consolidation increase includes $17,658,000 in Budget Authority and $42,000 in User Fees. The total request includes $58,044,000 in Budget Authority and $3,637,000 in User Fees.

The budget request allows FDA to fund furniture, commissioning and equipment outfitting, and decommissioning related to the Life Sciences-Biodefense Complex. The request will fund security, communications network, information technology and telecommunications equipment and infrastructure, AV equipment, and security equipment and cabling. The request also allows the consolidation and operation of the safety program at White Oak to support the critical Bio-Safety Laboratories including infrastructure requirements. The request will also fund security equipment and communications networks for the Auxiliary Support Facilities, such as parking facilities..

The request provides funds for operational and logistical functions on the White Oak Campus to operate a Campus transportation program including parking management, a Campus Shuttle and Circulator Bus program, a 1,600-seat Conference Center, labor and loading dock services, laboratory maintenance program, and other central services.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

BUILDINGS AND FACILITIES

The following table displays funding levels for FY 2011 through FY 2013.

FDA Program Resources Table

(Dollars in thousands)

	FY 2011 Enacted	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request	+/- Enacted
Program Level	**$9,980**	**$12,747**	**$8,788**	**$5,320**	**-$3,468**
Budget Authority	**$9,980**	**$12,747**	**$8,788**	**$5,320**	**-$3,468**
Building and Facilities	$9,980	$12,747	$8,788	$5,320	-$3,468
Natural Products Center	$0	$0	$0	$0	$0

The FDA Building and Facilities program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
Public Health Service Act (42 U.S.C. §238)
Energy Policy Act of 2005 (P.L. 109-058)
Chief Financial Officers Act of 1990 (P.L. 101-576)
Federal Financial Management Act of 1994 (P.L. 103-356)
Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. §§471 *et seq*.)
National Historic Preservation Act of 1966 (P.L. 89-665; 16 U.S.C. 470 *et seq.*)
Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

Allocation Method: Direct Federal; Contract

Program Description and Accomplishments

The Building and Facilities Program (B&F) is a critical element of FDA's real property asset management program and provides direct support to accomplishing FDA's public health mission. B&F supports FDA's strategic goal to transform administrative systems and infrastructure to support FDA operations. Accordingly, funding is provided for new construction of mission critical laboratory, office, and support space as well as for renovations and needed repairs and improvements to 86 existing FDA-owned facilities located at six sites in the U.S. and Puerto Rico where operations critical to FDA's public health mission are being conducted. The majority of FDA's B&F funding is used for renovation as well as repair and improvement projects, which can take multiple years to complete based on project size and complexity. Project design, procurement of construction services and completion of the actual renovations, repairs and/or improvements takes in excess of 18 months on average.

* Authorities under this Act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

The Department of Health and Human Services (HHS) developed a Real Property Asset Management Plan (AMP), which outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets. The AMP contains performance measures and benchmarks that monitor key real property asset management criteria, including mission criticality, utilization, facility condition and operating costs.

The physical condition of FDA's owned assets, which includes a substantial amount of laboratory facilities and site infrastructure, is of critical importance. A safe, suitable and reliable work environment is essential for FDA to protect the Nation's health, security, and economy. Improving and maintaining facilities often results in a positive effect on associated utilization and operating costs. An important component of FDA real property asset management is conducting facility condition assessments on a 3-year cycle. Facility condition assessments evaluate:

- site infrastructure such as utility distribution systems, roads, and sidewalks
- buildings to include physical systems such as architectural, civil, mechanical, and electrical as well as code compliance, life and other safety conditions, and finishes and aesthetics.

The assessments result in a list of maintenance and repair deficiencies with associated costs known as the Backlog of Maintenance and Repair (BMAR) for the site and its facilities, a plant replacement value which is the cost to replace an infrastructure item or a facility, and a Facility Condition Index (FCI) score.

The BMAR identifies and estimates costs associated with addressing needed maintenance, repairs and replacement of equipment and building systems that are approaching, at, or past their useful life. At the end of FY 2011, FDA's total BMAR for its six owned sites, including renewals, was approximately $100,503,000. BMAR information is used to identify and prioritize short- and long-term projects using B&F Program funding. The FCI score is calculated using the BMAR and plant replacement value. HHS established an FCI goal of 90 percent or greater for all owned facilities. Currently, approximately 65 percent of FDA's owned assets have an FCI score below the HHS established goal and require significant repairs and improvements.

FDA utilized B&F Program funding provided in FY 2011 and plans to utilize appropriated funds in FY2012 to accomplish several mission and BMAR driven projects at each of its six owned sites. The goals of these projects are to improve the condition of these assets and the site infrastructure as well as to ensure the suitability and reliability of owned assets for conducting FDA's mission. The descriptions below are representational and not comprehensive.

FDA's Gulf Coast Seafood Laboratory site located in Dauphin Island, AL is used by the Center for Food Safety and Applied Nutrition (CFSAN) to conduct research programs related to seafood safety, especially seafood harvested from the Gulf of Mexico. During FY 2011, FDA initiated projects to ensure the continued functionality of this facility

including replacing worn electrical switchgear, replacing an air conditioning unit for critical IT equipment, and installing water and electric meters in the main laboratory building. In FY 2012 FDA plans to replace the hazardous/radioactive waste storage building, paint the building exteriors, repair the sea wall, and replace and insulate corroded chilled water supply and return lines.

The FDA Muirkirk Road Complex (MRC) located in Laurel, MD, is a campus shared by CFSAN and the Center for Veterinary Medicine (CVM) to conduct research programs related to food and animal drug safety, toxicology, microbiology, and molecular biology. In addition, laboratories at this site are used as part of the Laboratory and Food Emergency Response Networks. FDA initiated projects to repair the site substation and an underground storage tank, replace electrical switchgear in critical laboratory facilities, install an asphalt access road to an emergency generator, and replace two aged, inefficient compressors. These projects support FDA's ability to establish science-based regulatory standards and rapid responses to outbreaks.

In FY 2012 FDA plans to complete projects in mission critical laboratory space at the MRC including replacing water fountains contaminated with lead; renovating space to install safety equipment including eyewashes, hand washing sinks and chemical storage units; testing and balancing several buildings; and replacing electrical switchgear, a substation, two large air handling units. FDA also plans to replace two undersized chillers with larger capacity chillers to support mission critical aquaculture research, repair miscellaneous facility deficiencies, and replace pneumatic HVAC controls with upgraded controls.

The Jefferson Laboratories Complex (JLC) located in Jefferson, AR, houses the National Center for Toxicological Research (NCTR) and Office of Regulatory Affairs' (ORA) Arkansas Regional Laboratory (ARL). NCTR conducts research at this site that focuses on risk assessment, investigates toxicity, and studies the extrapolation of data from animal studies to humans, all in support of promulgating FDA regulatory policies. The ARL provides analytical laboratory support to ORA's regulatory mission in the Southwest Region. In FY 2011 FDA initiated projects to significantly improve an aged electrical infrastructure, install water meters, and complete the installation of cage and rack washing equipment in an animal processing area. In FY 2012 FDA plans to initiate additional site and building infrastructure projects including continued repair of the site electrical infrastructure, replacing the HVAC controls in one building, installing an emergency generator, replacing a sterilizer and bedding vacuum system to support animal research, repairing fire alarm systems, and designing future repair, improvement and mission support projects.

The assets at FDA's San Juan District Office located in San Juan, PR, are primarily used for specialized human drug testing and analysis. FDA initiated projects to correct miscellaneous electrical deficiencies in the main laboratory building and make needed repairs to the boathouse. In FY 2012 projects are planned that will replace chemical fume hoods, install roof access ladders needed for maintenance purposes, and modify or replace access ramps to ensure American's with Disabilities Act compliance.

FDA's Pacific Regional Laboratory Southwest is located in Irvine, CA. This space provides analytical laboratory support to ORA's regulatory mission in the Pacific Region. The facility also houses the Los Angeles District Office, which serves as ORA's inspection and compliance activity in the Los Angeles area. In FY 2011, FDA initiated projects to perform building and parking lot waterproofing and to repair excessive soil erosion beneath the parking area. In FY 2012, FDA plans to continue repairing the excessive soil erosion beneath the parking area, fund improvements to the site security gate and emergency call stations, and, if determined to be a feasible economic investment, award a Utility Energy Service Contract (UESC) to complete energy conservation measures in the laboratory to improve energy efficiency and sustainability.

The Winchester Engineering and Analytical Center (WEAC) located in Winchester, MA, is an ORA specialty laboratory used to test the safety and performance of medical devices, microwaves, and radiopharmaceuticals; to conduct radionuclide testing with food samples; and to ensure seafood freshness. FDA initiated projects in the main laboratory building to upgrade the laboratory HVAC system and associated controls, improve the fire alarm system, provide emergency power to chemical fume hoods, and repair doors. In FY 2012 FDA plans to install additional HVAC control points and replace urinals and water closets with low flow fixtures.

FDA initiated a project to perform facility condition and sustainability assessments for its owned assets in accordance with HHS policy.

Five Year Funding Table

The following table displays funding levels from FY 2008 through FY 2012.

Fiscal Year	Program Level	Budget Authority
FY 2008 Actual [1]	$7,534,000	$7,534,000
FY 2009 Actual	$5,871,000	$5,871,000
FY 2010 Actual[2]	$22,111,000	$22,111,000
FY 2011 Actual	$12,747,000	$12,747,000
FY 2012 Enacted	$8,788,000	$8,788,000

[1] FY 2008 includes $3,724,000 under FY 2008 Omnibus Appropriations Act General Provision Sec. 734 to the National Center for Natural Products Research for construction and renovation.
[2]FY 2010 includes $6,994,000 to the National Center for Natural Products Research for construction and renovation.

Summary of the Budget Request

The FY 2013 budget request for the Buildings and Facilities Program is $5,320,000. This amount is a decrease of $3,468,000 below the FY 2012 Enacted Level.

FDA will use the requested resources to fund various projects at its six mission critical owned sites, facilitating FDA's ability to achieve its mission, provide a safe and productive work environment, and sustain and improve the condition of its owned sites and associated buildings.

FDA prioritized a multitude of renovation, repair and improvement projects for both site infrastructure and buildings, driven by mission requirements and the Backlog of Maintenance and Repair. FDA will utilize the FY 2013 funding to complete a portion of these priority projects. Conditions and mission needs at FDA sites may change after the prioritization process that may require FDA to modify its planned projects for FY 2013, including a modification to funding allocations per site. Such flexibility is critical to ensure the highest level of support for the programs carrying out the FDA mission.

FDA plans to use FY 2013 B&F funding at its Jefferson Labs Complex (JLC) site to:

- continue to repair the electrical distribution system on the campus
- upgrade the control system in one laboratory building that will result in more reliable operation, a safer working environment, and energy savings
- refurbish a sterilizer in a processing area that supports critical research
- repair the fire alarm and reporting system in one building
- replace the roof of one building.

These projects are critical to ensure adequate, reliable site infrastructure and building operations in support of FDA's mission. This site provides analytical laboratory support to ORA's regulatory mission in the Southwest Region and houses ORA's only nanotechnology laboratory. JLC is also the home base for ORA's two mobile laboratories, and supports numerous analytical testing capabilities including dioxin testing and gulf oil spill testing.

The National Center for Toxicological Research also employs this site to support integrated research vital to regulatory decisions on products using new technologies such as nanomaterials and to increase understanding of the interaction between genetics, metabolism, nutrition, and disease susceptibility to develop dietary recommendations and individualized therapy regimens. This laboratory directly benefits public health by enabling enhanced and more efficient regulatory laboratory operations and providing the necessary environment to develop regulatory tools that facilitate premarket review, postmarket safety assurance, and rapid detection of food contamination.

Repairs and improvement projects planned for FY 2013 at the Muirkirk Road Complex (MRC) include:

- reworking the emergency power distribution system at the site to include increasing emergency power capacity to meet growing demands
- repairing and enhancing emergency egress lighting in MOD1
- replacing obsolete pneumatic mechanical system controls with direct digital controls in MOD1 and BRF laboratory buildings
- upgrading aged relay switch controls to digital solid state controls on all elevators in MOD1
- modifying the steam vent distribution piping to prevent steam loss at vents and in turn, save energy
- replacing the asphalt roadway and sidewalk in front of MOD1 as well as installing curbs and gutters where needed
- renovating and repairing the BRF laboratory to meet CVM mission needs and address masonry, door, window and plumbing deficiencies.

The MRC provides laboratory support to assure the safety of animal food, animal-derived food and the safety and efficacy of animal health products. Maintenance repairs and improvements allow the facility to accommodate state of the art instrumentation and the laboratory processes currently required to apply quick, innovative, and decisive science to animal health and food safety problems to better protect the public health. Repairs to the facility enable CFSAN and CVM scientists to meet the current and anticipated demand for applied research to support the regulatory needs of FDA.

B&F funding will be used at FDA's Irvine, CA, site in FY 2013 for site infrastructure improvements to include such projects as replacing entrance walkway lighting or repairing cracked and damaged walkways campus-wide.

The Irvine site provides analytical laboratory support to ORA's regulatory mission in the Pacific Region and houses the Los Angeles District Office, which supports ORA's inspection and compliance activity in the Los Angeles area.

Improvements planned for the main laboratory at the Winchester, MA site include:

- replacing electrical distribution panel boards and switchgear
- replacing exhaust fans in the ashing room
- upgrading the building management system
- installing light controls and occupancy sensors throughout the building
- replacing four chemical fume hoods and balancing the associated HVAC system

- replacing the air conditioning and heating units in three rooms
- replacing the aged and energy inefficient front entrance.

WEAC provides specialized analytical services in engineering and medical devices and is the only field laboratory providing radiation analyses for both the foods and medical products programs. The site supports comprehensive evaluation of medical devices and radiation emitting appliances and recently played a critical role regarding polonium testing in beef. It is the primary field laboratory that FDA's Center for Device and Radiological Health (CDRH) relies on for analytical services and temperature-critical laboratory testing.

FDA plans to improve assets at the San Juan, PR site by:

- replacing corroded direct-expansion (DX) HVAC units for multiple buildings,
- repairing or replacing roofs on three buildings,
- replacing the existing domestic water tanks to increase capacity,
- installing a new electric substation for the main laboratory building,
- repairing exterior wall cracks on one building,
- repairing 100 linear feet of sidewalk throughout the site, and
- repairing or replacing site security fencing.

This facility is the National Servicing Laboratory in PR and specializes in pharmaceutical testing and analyses. It is strategically located since Puerto Rico has a large concentration of pharmaceutical manufacturers that produce approximately 30 percent of the world's pharmaceuticals and about 60 percent of the human drugs consumed in the U.S. These improvements and repairs are essential to the infrastructure of this mission critical site and necessary to ensure continued optimal asset functionality.

FDA will complete miscellaneous building and site infrastructure repairs and improvements at the Dauphin Island, AL site in FY 2013.

The Gulf Coast Seafood Laboratory located at this site is CFSAN's sole marine laboratory. Scientific staff at this location represents 80 percent of FDA research capacity for addressing seafood issues. The B&F project planned at this facility supports work on existing, emerging, and potential seafood safety issues, including continuing recovery efforts and research related to the 2010 Deepwater Horizon oil spill.

The following table provides an allocation plan by site for use of the FY 2013 funds.

FY 2013 Buildings and Facilities Allocation Plan

Site	*Total*
Jefferson Laboratories Complex (NCTR & ARL) - Jefferson, AR	$2,660,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$2,020,400
ORA Pacific Regional Laboratory SW – Irvine, CA	$15,000
Winchester Engineering and Analytical Center – Winchester, MA	$287,300
San Juan District Office – San Juan, PR	$287,300
CFSAN Gulf Coast Seafood Laboratory	$50,000
B&F PROJECT TOTAL	**$5,320,000**

FDA's B&F Program funding for FY 2013 will continue to make sustaining and improving the condition of owned real property assets a priority. Completion of these projects enhances FDA's ability to achieve its critical mission of protecting and promoting the health of the American public. In addition, several of these projects will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Performance Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2013 projects will help reduce Scope 1, 2 and 3 greenhouse gas emissions by replacing aged, inefficient HVAC controls and equipment at several locations; modifying the steam vent distribution system at MOD1; installing light controls and occupancy sensors in the main laboratory at WEAC; and replacing the energy inefficient front entrance of the main laboratory at WEAC.

Buildings and Facilities Program Activity Data[1]

Facility	Average FCI Score		
	FY 2011 Actual	FY 2012 Enacted	FY 2013 Request
Gulf Coast Seafood Laboratory[2]	96	98	98
Jefferson Laboratory Complex[3]	80	82	82
Muirkirk Road Complex[4]	89	89	90
Pacific Regional Laboratory Southwest[5]	100	100	100
San Juan District Office and Laboratories[6]	84	85	86
Winchester Engineering and Analytic Center[7]	70	72	73

[1]The Backlog of Maintenance and Repairs (BMAR) at each site is significant. Funding is allocated to projects at each site in an effort to reduce the BMAR and improve the average Facility Condition Index (FCI) for the site. Without ongoing repair and improvement projects, the increase in BMAR each year would result in no change or a decrease in the FCI rather than an increase. Improvements may not be realized in the fiscal year the funds are received due to timing and complexity of the project.
[2]Based on funding levels in FY 2012 and FY 2013, the remaining BMAR for this site is approximately $71K.
[3]Based on funding levels in FY 2012 and FY 2013 the BMAR for this site will decrease by approximately $5.5M. Remaining BMAR total will be approximately $66.5M.
[4]Based on funding levels in FY 2012 and FY 2013 the BMAR for this site will decrease by approximately $1.5M. Remaining BMAR total will be approximately $11.5M.
[5]Based on funding levels in FY 2012 and FY 2013, the remaining BMAR for this site is approximately $47K..
[6]Based on funding levels in FY 2012 and FY 2013 the BMAR for this site will decrease by approximately $370K. Remaining BMAR total will be approximately $2.5M.
[7]Based on funding levels in FY 2012 and FY 2013, the BMAR for this site will decrease by approximately $473K. Remaining BMAR total will be approximately $4.0M.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

FOOD AND DRUG ADMINISTRATION
Table of Estimates and Appropriations
S&E and Rental Payments to GSA

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation*
2000	1,305,869,000[1]	1,218,384,000[2]	1,180,972,000[3]	1,183,095,000[4]
2001	1,359,481,000[5]	1,240,178,000[6]	1,216,796,000[7]	1,215,446,000[8]
2002	1,377,160,000[9]	1,342,339,000[10]	1,344,386,000[11]	1,496,486,000[12]
2003	1,633,605,000[13]	1,599,602,000[14]	1,628,895,000[15]	1,621,739,000[16]
2004	1,678,632,000[17]	1,675,713,000[18]	1,670,692,000[19]	1,665,258,000[20]
2005	1,820,849,000[21]	1,788,849,000[22]	1,791,599,000[23]	1,776,784,000[24]
2006	1,849,676,000[25]	1,837,928,000[26]	1,841,959,000[27]	1,843,751,000[28]
2007	1,916,329,000[29]	1,914,382,000[30]	1,941,646,000[31]	1,790,368,000[32]
2008	2,051,801,000[33]	1,683,405,000[34]	2,276,262,000[35]	2,235,876,000[36]
2009	2,638,197,000[37]	[38]	3,168,794,000[39]	2,622,267,000[40]
2010	3,371,218,000[41]	3,230,218,000[42]	3,230,218,000	3,237,218,000[43]
2011	3,989,507,000[44]		3,720,044,000[45]	3,660,763,000[46]
2012	4,256,673,000[47]	3,599,871,000[48]	3,599,871,000[49]	3,801,706,000[50]
2013	4,454,603,000[51]			

* Appropriation contains salaries and expenses (S&E), PDUFA, MDUFMA, ADUFA, AGDUFA and Tobacco.

[1] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent), $15,128,000 for MQSA fee collections, $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification, $4,492,000 for Certification fund, and $19,483,000 for proposed new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[2] Includes $1,090,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent). This does not include $15,128,000 for MQSA fee collections.

[3] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in S&E, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). Excludes $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[4] Includes rescission of $2,351,000, S&E of $1,066,173,000 (including $98,876,000 of GSA Rent), and $149,273,000 for PDUFA (of which 5,860,000 is GSA rent). Excludes $14,947,000 for MQSA fee collections, $1,500,000 for Export Certification, or $22,950,000 million for drug importation that is not available until requested by the President. Also does not include $1,750,000 funded from PHSSEF for physical security counter-terrorism measures.

[5] Includes $1,156,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent), $15,128,000 for MQSA fee collections, $12,700,000 for Seafood Transfer User Fees, $1,500,000 for Export Certification, $4,492,000 for Certification fund, and $19,483,000 for proposed new user fees (Food Additive $8,400,000; Premarket Medical Devices $5,833,000; Foods Export Certification $5,250,000).

[6] Includes $1,090,905,000 (including $99,094,000 of GSA Rent) in S&E, $149,273,000 for PDUFA ($5,860,000 is GSA rent). This does not include $15,128,000 for MQSA fee collections.

[7] Includes $1,067,523,000 (including $99,094,000 of GSA Rent) in S&E, and $149,273,000 for PDUFA ($5,860,000 is GSA rent). Excludes $15,128,000 for MQSA fee collections, and $5,992,000 in Export Certification.

[8] Includes rescission of $2,351,000, S&E of $1,066,173,000 (including $98,876,000 of GSA Rent), and $149,273,000 for PDUFA (of which 5,860,000 is GSA rent). Excludes $14,947,000 for MQSA fee collections, $1,500,000 for Export Certification, or $22,950,000 million for drug importation that is not available until requested by the President. Also does not include $1,750,000 funded from PHSSEF for physical security counter-terrorism measures.

[9] Includes $1,173,673,000 (including $98,876,000 of GSA Rent) in S&E, $161,716,000 for PDUFA ($6,240,000 is GSA rent), $15,590,000 for MQSA fee collections, $1,500,000 for Export Certification, $4,681,000 for Certification fund, and $20,000,000 for proposed new user fees. Excludes $2,950,000 million for drug importation that is not available until requested by the President.

[10] Includes $1,180,623,000 (including $98,876,000 of GSA Rent) in S&E, and $161,716,000 for PDUFA ($6,240,000 is GSA rent). This does not include $15,590,000 for MQSA fee collections. This does not include the $2,950,000 the House provided for MEDSA.

[11] Includes $1,182,670,000 (including $98,876,000 of GSA Rent) in S&E, and $161,716,000 for PDUFA ($6,240,000 is GSA rent) Excludes $15,590,000 for MQSA fee collections, and $6,181,000 in Export Certification and Color Certification.

[12] Includes $1,183,670,000 (including $98,876,000 of GSA Rent) in S&E, $161,716,000 for PDUFA ($6,240,000 is GSA rent). Excludes $15,590,000 for MQSA fee collections, or $6,181,000 in Export Certification and Color Certification. Includes an additional $151,100,000 provided in the FY 2002 counter-terrorism supplemental.

[13] Includes $1,369,385,000 (including $98,556,000 of GSA Rent) in S&E, $264,220 in proposed PDUFA fees ($7,140,000 is GSA rent). Excludes $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $4,878,000 in Color Certification.

[14] Includes $1,376,702,000 (including $98,876,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent). Excludes $16,112,000for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[15] Includes $1,383,505,000 (including $98,556,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent) and $22,490,000 for MDUFMA. Excludes $16,112,000 for MQSA fee collections, and $6,378,000 in Export Certification and Color Certification.

[16] Includes $1,373,714,000 (including $98,233,000 of GSA Rent) in S&E, and $222,900,000 for PDUFA ($7,802,000 is GSA rent), and $25,125 in MDUFMA fees ($1,591,000 is GSA rent). Excludes $16,112,000 in MQSA fee collections, $1,500,000 in Export Certification, and $5,237,000 in Color Certification.

[17] Includes $1,394,617,000 (including $108,876,000 of GSA Rent) in S&E, $249,825,000 in proposed PDUFA fees ($8,646,000 is GSA rent) and $29,190,000 in MDUFMA fees ($2,273,000 is GSA rent) and $5,000,000 in proposed Animal Drug User Fees ($250,000 is GSA Rent). Excludes $16,576,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[18] Includes $1,389,234,000 (including $108,876,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA) ($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[19] Includes $1,384,213,000 (including $108,233,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification.

[20] Includes $1,378,779,000 (including $107,594,000 of GSA Rent) in S&E, and $249,825,000 for PDUFA ($8,646,000 is GSA rent), $31,654,000 in MDUFMA fees ($2,465,000 is GSA rent), and $5,000,000 in proposed Animal Drug User Fees (ADUFA)($250,000 is GSA Rent). Excludes $16,575,000 in MQSA fee collections, $1,570,000 in Export Certification, and $5,079,000 in Color Certification. A$8,224,000 rescission is included.

[21] Includes $1,494,517,000 (including $107,594,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[22] Includes $1,462,517,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[23] Includes $1,465,267,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,000,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[24] Includes $1,450,098,000 (including $114,394,000 of GSA Rent) in S&E, and $284,394,000 for PDUFA ($12,407,000 is GSA rent), $33,938,000 in MDUFMA fees ($2,643,000 is GSA rent), and $8,354,000 in proposed Animal Drug User Fees (ADUFA) ($371,000 is GSA Rent). Excludes $16,919,000 in MQSA fee collections, $1,615,000 in Export Certification, and $5,223,000 in Color Certification.

[25] Includes $1,492,726,000 (including $117,579,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,203,000 is GSA rent), and $11,318,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[26] Includes $1,480,978,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, $11,318,000 in proposed ADUFA fees, $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[27] Includes $1,486,009,000 in S&E, and $305,332,000 for PDUFA, $40,300,000 in MDUFMA fees, $11,318,000 in proposed ADUFA fees, $124,598,000 in GSA Rental Payments (Budget Authority), $12,700,000 in GSA Rent (PDUFA), $3,203,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[28] Includes $1,486,801,000 (including $116,403,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent), $40,300,000 in MDUFMA fees ($3,230,000 is GSA rent), and $11,318,000 in Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,173,000 in MQSA fee collections, $1,639,000 in Export Certification, and $6,001,000 in Color Certification.

[29] Includes $1,540,399,000 (including $126,871,000 of GSA Rent) in S&E, and $320,600,000 for PDUFA ($14,501,000 is GSA rent), $43,726,000 in MDUFMA fees ($3,323,000 is GSA rent), and $11,604,000 in proposed Animal Drug User Fees (ADUFA) ($1,371,000 is GSA Rent). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[30] Includes $1,538,452,000 in S&E, and $320,600,000 for PDUFA fees, $43,726,000 in MDUFMA fees, $11,604,000 in ADUFA fees, $126,871,000 in GSA Rental Payments (Budget Authority), $14,501,000 in GSA Rent (PDUFA), $3,270,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[31] Includes $1,565,716,000 in S&E, and $320,600,000 for PDUFA fees, $43,726,000 for MDUFMA fees, $11,604,000 for ADUFA fees, $126,871,000 in GSA Rental Payments (Budget Authority), $14,501,000 in GSA Rent (PDUFA), $3,270,000 in GSA Rent (MDUFMA), and $1,371,000 in GSA Rent (ADUFA). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[32] Reflects FY2007 Continuing Resolution. Includes $1,485,036,000 (including $116,403,000 of GSA Rent) in S&E, and $305,332,000 for PDUFA ($12,700,000 is GSA rent). Excludes $17,522,000 in MQSA fee collections, $2,300,000 in Export Certification, and $6,181,000 in Color Certification.

[33] Includes $1,635,709,000 (including $131,533,000 of GSA Rent) in S&E, and $339,195,000 for PDUFA ($21,901,000 is GSA Rent), $47,500,000 in MDUFMA fees ($3,552,000 is GSA rent), $13,696,000 in ADUFA fees ($1,441,000 is GSA), and $15,701,000 in proposed Generic Drug User Fees ($987,000 is GSA rent). Excludes $18,389,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,000,000 in Color Certification.

[34] Includes $1,669,709,000 in S&E, and $13,696,000 in ADUFA fees, $131,533,000 in GSA Rental Payments (Budget Authority), $23,498,000 in GSA Rental Payments (PDUFA), $3,622,000 in GSA Rental Payments (MDUFMA), and $1,441,000 in GSA Rental Payments (ADUFA). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[35] Includes $1,755,135,000 in S&E, and $459,000,000 for PDUFA fees, $48,431,000 for MDUFMA fees, $13,696,000 for ADUFA fees, $160,544,000 in GSA Rental Payments (Budget Authority), $23,498,000 in GSA Rental Payments (PDUFA), $3,622,000 in GSA Rental Payments (MDUFMA), and $1,441,000 in GSA Rental Payments (ADUFA). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[36] Includes $1,726,422,000 (including $130,612,000 in GSA Rent) in S&E (minus a 0.7% rescission), and $459,412,000 for PDUFA ($23,498,000 is GSA rent), $48,431,000 for MDUFMA ($3,622,000 is GSA rent), $13,696,000 for ADUFA ($1,441,000 is GSA rent). Excludes $18,398,000 in MQSA fee collections, $2,500,000 in Export Certification, and $7,500,000 in Color Certification.

[37] Includes $2,038,964,000 (including $134,351,000 of GSA Rent) in S&E, and $510,665,000 for PDUFA ($16,000,000 is GSA Rent), $52,547,000 for MDUFMA ($3,930,000 is GSA Rent), $15,260,000 for ADUFA ($839,000 is GSA Rent), $4,831,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,600,000 in Export Certification, and $7,700,000 in Color Certification.

[38] The House did not report an FY 2009 Appropriations Bill.

[39] Includes $2,603,879,000 in S&E (including 151,381,000 in GSA Rent), and $497,108,000 for PDUFA fees (including $18,691,000 in GSA Rent), $52,547,000 for MDUFMA fees (including $839,000 in GSA

Rent), $15,260,000 for ADUFA fees (including $3,930,000 in GSA Rent). Excludes MQSA fee collections, Export Certification, and Color Certification.

[40] Includes $2,038,964,000 in S&E (including $134,351,000 of GSA Rent) in S&E, and $510,665,000 for PDUFA ($16,000,000 is GSA Rent), $52,547,000 for MDUFMA ($3,930,000 is GSA Rent), $15,260,000 for ADUFA ($839,000 is GSA Rent), $4,831,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,600,000 in Export Certification, and $7,700,000 in Color Certification.

[41] Includes $2,337,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $36,000,000 for GDUFA ($2,263,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[42] Includes $2,337,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[43] Includes $2,344,656,000 (including $146,022,000 of GSA Rent) in S&E, and $235,000,000 for Family Smoking Prevention and Tobacco Control Act (including $2,798,000 of GSA Rent), and $578,162,000 for PDUFA ($17,252,000 is GSA Rent), $57,014,000 for MDUFMA ($4,264,000 is GSA Rent), $17,280,000 for ADUFA ($885,000 is GSA Rent), $5,106,000 for AGDUFA ($305,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[44] Includes $2,808,695,000 (including $172,205,000 of GSA Rent) in S&E, and $235,000,000 for Tobacco Program (including $5,491,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $38,015,000 for GDUFA ($1,841,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[45] Includes $2,516,282,000 (including $153,999,000 of GSA Rent) in S&E, and $450,000,000 for Tobacco Program (including $6,135,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,080,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[46] Includes $2,487,001,000 (including $150,762,000 of GSA Rent) in S&E, and $450,000,000 for Tobacco Program (including $6,135,000 of GSA Rent), and $667,057,000 for PDUFA ($19,905,000 is GSA Rent), $61,860,000 for MDUFMA ($4,626,000 is GSA Rent), $19,448,000 for ADUFA ($996,000 is GSA Rent), $5,397,000 for AGDUFA ($322,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[47] Includes $2,730,910,000 (including $167,826,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $71,006,000 for Voluntary Qualified Importer Program ($3,920,000 is GSA Rent), $1,267,000 for Food Export Certification User Fee ($82,000 is GSA Rent),

$14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,346,000 for Recall User Fee ($434,000 is GSA Rent) $40,122,000 for GDUFA ($1,943,000 is GSA Rent), $14,108,000 for Medical Products Re-inspection User Fee ($1026,000 is GSA Rent), $5,338,000 for International Courier User Fee ($294,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[48] Includes $2,172,238,000 (including $156,007,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $36,006,000 for Voluntary Qualified Importer Program ($1,986,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,364,000 for Recall User Fee ($434,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[49] Includes $2,172,238,000 (including $156,007,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $856,041,000 for PDUFA ($25,544,000 is GSA Rent), $67,118,000 for MDUFMA ($5,019,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $36,006,000 for Voluntary Qualified Importer Program ($1,986,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,364,000 for Recall User Fee ($434,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $2,700,000 in Export Certification, and $7,700,000 in Color Certification.

[50] Includes $2,505,809,000 (including $160,506,000 of GSA Rent) in S&E, and $477,000,000 for Tobacco Program (including $5,503,000 of GSA Rent), and $702,172,000 for PDUFA ($31,928,000 is GSA Rent), $57,605,000 for MDUFMA ($4,308,000 is GSA Rent), $21,768,000 for ADUFA ($1,115,000 is GSA Rent), $5,706,000 for AGDUFA ($340,000 is GSA Rent), $14,700,000 for Food Re-inspection User Fee ($1,338,000 is GSA Rent), $12,346,000 for Recall User Fee ($434,000 is GSA Rent) Excludes $19,318,000 in MQSA fee collections, $3,337,000 in Export Certification, $4,582 Priority Review Vouchers, and $7,843,000 in Color Certification.

[51] Includes $2,517,311,000 (including $169,374,000 of GSA Rent) in S&E, and $505,000,000 for Tobacco Program (including $5,778,000 of GSA Rent), and $712,808,000 for PDUFA ($21,569,000 is GSA Rent), $69,700,000 for MDUFMA ($5,270,000 is GSA Rent), $30,530,000 for ADUFA ($1,556,000 is GSA Rent), $7,595,000 for AGDUFA ($453,000 is GSA Rent), $15,367,000 for Food Re-inspection User Fee ($1,399,000 is GSA Rent), $12,925,000 for Recall User Fee ($454,000 is GSA Rent) $299,000,000 for GDUFA ($13,815,000 is GSA Rent), $14,746,000 for Medical Products Re-inspection User Fee ($1,072,000 is GSA Rent), $5,580,000 for International Courier User Fee ($307,000 is GSA Rent), $220,200,000 for Food Establishment Registration User Fee ($5,371,000 is GSA Rent), $18,698,000 for Cosmetics User Fee ($882 is GSA Rent), $4,901,000 for Food Contact Notification User Fee ($112,000 is GSA Rent), $20,242,000 for Biosimilars User Fee ($1,008,000 is GSA Rent). Excludes $19,318,000 in MQSA fee collections, $4,604,000 in Export Certification, and $7,843,000 in Color Certification.

FOOD AND DRUG ADMINISTRATION
Table of Estimates and Appropriations
Buildings and Facilities

Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2000	31,750,000 [1]	31,750,000	8,350,000	11,350,000
2001	31,350,000 [2]	11,350,000	31,350,000	31,350,000
2002	34,281,000 [3]	34,281,000	34,281,000	34,281,000
2003	8,000,000 [4]	8,000,000	11,000,000 [5]	7,948,000 [6]
2004	11,500,000 [7]	6,000,000	7,948,000	6,959,000 [8]
2005	6,959,000 [9]	-6,959,000	-6,959,000	-6,959,000
2006	7,000,000	5,000,000	7,000,000	7,920,000
2007	4,950,000	4,950,000	4,950,000	4,950,000 [10]
2008	4,950,000	4,950,000	4,950,000	2,433,000
2009	2,433,000	12,433,000	12,433,000	12,433,000
2010	12,433,000	12,433,000	12,433,000	12,433,000
2011	12,433,000	9,980,000	9,980,000	9,980,000
2012	13,055,000	8,788,000	8,788,000	8,788,000
2013	5,320,000			

[1] Includes $20,400,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.

[2] Includes $20,000,000 for construction of Phase I of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.

[3] Includes $23,000,000 for construction of Phase II of the new Los Angeles Laboratory and $3,000,000 for continuing modernization of the ARL.

[4] Reflects a reduction of $26,281,000 to centralize of B&F construction activities at the Department.

[5] Includes $3,000,000 to complete ARL.

[6] Includes $8,000,000 in Appropriated funds with a rescission of $52,000.

[7] Includes $3,500,000 to complete ARL.

[8] Includes Final Conference amount of $7,000,000 with a $41,000 rescission.

[9] Includes a $6,959,000 decrease to fund high priority programs.

[10] Reflects FY 2007 current rate.

Food and Drug Administration Budget Authority by Object Dollars in thousands				
	FY2011	FY 2012	FY 2013	
	Actual	Enacted	Estimate	+/- FY 2012 Enacted
Personnel compensation:				
Full-time permanent (11.1)	$748,684	$758,467	$762,049	$3,582
Other than full-time permanent (11.3)	$104,948	$106,319	$106,821	$502
Other personnel compensation (11.5)	$58,993	$59,764	$60,046	$282
Military personnel (11.7)	$58,658	$60,768	$61,769	$1,001
Special personnel services payments (11.8)	$354	$359	$361	$2
Subtotal personnel compensation	**$971,637**	**$985,677**	**$991,046**	**$5,368**
Civilian benefits (12.1)	$260,198	$263,598	$264,843	$1,245
Military benefits (12.2)	$29,372	$30,428	$30,929	$501
Benefits to former personnel (13.0)	$1,486	$1,506	$1,513	$7
Total Pay Costs	**$1,262,693**	**$1,281,209**	**$1,288,331**	**$7,122**
Travel and transportation of persons (21.0)	$50,358	$51,209	$50,994	-$216
Transportation of things (22.0)	$5,385	$5,476	$5,453	-$23
Rental payments to GSA (23.1)	$150,763	$160,506	$169,374	$8,868
Rent payments to others (23.2)	$2,122	$2,158	$2,149	-$9
Communication, utilities, and misc. charges (23.3)	$54,897	$55,826	$55,591	-$235
Printing and reproduction (24.0)	$2,150	$2,186	$2,177	-$9
Other Contractual Services:				
Advisory and assistance services (25.1)	$41,997	$42,707	$42,527	-$180
Other services (25.2)	$426,470	$433,685	$431,857	-$1,829
Purchase of goods and svcs from Govt Acts. (25.3)	$112,136	$114,033	$113,553	-$481
Operation and maintenance of facilities (25.4)	$105,498	$107,283	$106,831	-$452
Research and Development Contracts (25.5)	$33,547	$34,115	$33,971	-$144
Medical care (25.6)			$0	
Operation and maintenance of equipment (25.7)	$30,400	$30,914	$30,784	-$130
Subsistence and support of persons (25.8)				
Subtotal Other Contractual Services	**$750,049**	**$762,738**	**$759,522**	**-$3,216**
Supplies and materials (26.0)	$45,421	$46,190	$45,994	-$196
Equipment (31.0)	$54,851	$55,779	$55,544	-$235
Land and Structures (32.0)	$5,515	$5,609	$5,585	-$24
Investments and Loans (33.0)				
Grants, subsidies, and contributions (41.0)	$75,383	$76,658	$76,335	-$323
Insurance claims and indemnities (42.0)	$251	$255	$254	-$1
Interest and dividends (43.0)	$10	$10	$10	$0
Receivables Collected (61.7)				
Total Non-Pay Costs	**$1,197,154**	**$1,224,600**	**$1,228,980**	**$4,380**
Total Budget Authority by Object Class	**$2,459,847**	**$2,505,809**	**$2,517,311**	**$11,502**

Food and Drug Administration
User Fee by Object
Dollars in thousands

	FY2011	FY 2012	FY 2013	
	Actual	Enacted	Estimate	+/- FY 2012 Enacted
Personnel compensation:				
Full-time permanent (11.1)	$299,980	$452,441	$686,723	$234,283
Other than full-time permanent (11.3)	$40,348	$60,854	$92,366	$31,512
Other personnel compensation (11.5)	$22,126	$33,372	$50,652	$17,281
Military personnel (11.7)	$22,418	$33,812	$34,386	$575
Special personnel services payments (11.8)	$280	$423	$642	$219
Subtotal personnel compensation	**$385,152**	**$580,901**	**$864,770**	**$283,869**
Civilian benefits (12.1)	$101,979	$153,809	$233,454	$79,645
Military benefits (12.2)	$11,208	$16,905	$17,530	$625
Benefits to former personnel (13.0)	$622	$939	$1,425	$486
Total Pay Costs	**$498,962**	**$752,553**	**$1,117,179**	**$364,625**
Travel and transportation of persons (21.0)	$7,985	$11,960	$17,928	$5,969
Transportation of things (22.0)	$500	$749	$1,123	$374
Rental payments to GSA (23.1)	$27,357	$44,966	$59,046	$14,080
Rent payments to others (23.2)	$248	$372	$558	$186
Communication, utilities, and misc. charges (23.3)	$8,817	$13,205	$19,796	$6,591
Printing and reproduction (24.0)	$1,012	$1,515	$2,272	$756
Other Contractual Services:				
Advisory and assistance services (25.1)	$40,773	$61,068	$91,546	$30,478
Other services (25.2)	$89,134	$133,497	$200,126	$66,629
Purchase of goods and svcs from Govt Acts. (25.3)	$123,989	$185,704	$278,387	$92,683
Operation and maintenance of facilities (25.4)	$39,410	$59,026	$88,485	$29,459
Research and Development Contracts (25.5)	$19,652	$29,433	$44,123	$14,690
Medical care (25.6)				
Operation and maintenance of equipment (25.7)	$3,828	$5,733	$8,594	$2,861
Subsistence and support of persons (25.8)				
Subtotal Other Contractual Services	**$316,785**	**$474,461**	**$711,261**	**$236,800**
Supplies and materials (26.0)	$7,309	$10,948	$16,411	$5,463
Equipment (31.0)	$10,285	$15,405	$23,093	$7,688
Land and Structures (32.0)	$0	$0	$0	$0
Investments and Loans (33.0)	$0	$0	$0	$0
Grants, subsidies, and contributions (41.0)	$67	$100	$149	$50
Insurance claims and indemnities (42.0)	$107	$160	$240	$80
Interest and dividends (43.0)	$0	$0	$0	$0
Receivables Collected (61.7)				
Total Non-Pay Costs	**$380,471**	**$573,842**	**$851,878**	**$278,036**
Total Budget Authority by Object Class	**$879,434**	**$1,326,395**	**$1,969,057**	**$642,662**

Food and Drug Administration
Total Program by Object
Dollars in thousands

	FY2011	FY 2012	FY 2013	
	Actual	Enacted	Estimate	+/- FY 2012 Enacted
Personnel compensation:				
Full-time permanent (11.1)	$1,048,664	$1,210,907	$1,448,772	$237,865
Other than full-time permanent (11.3)	$145,296	$167,173	$199,187	$32,014
Other personnel compensation (11.5)	$81,120	$93,136	$110,699	$17,563
Military personnel (11.7)	$81,076	$94,579	$96,155	$1,576
Special personnel services payments (11.8)	$635	$782	$1,002	$221
Subtotal personnel compensation	**$1,356,789**	**$1,566,578**	**$1,855,815**	**$289,238**
Civilian benefits (12.1)	$362,178	$417,407	$498,297	$80,890
Military benefits (12.2)	$40,580	$47,333	$48,460	$1,127
Benefits to former personnel (13.0)	$2,109	$2,444	$2,938	$493
Total Pay Costs	**$1,761,655**	**$2,033,762**	**$2,405,510**	**$371,747**
Travel and transportation of persons (21.0)	$58,343	$63,169	$68,922	$5,753
Transportation of things (22.0)	$5,885	$6,225	$6,576	$351
Rental payments to GSA (23.1)	$178,120	$205,472	$228,420	$22,948
Rent payments to others (23.2)	$2,370	$2,530	$2,706	$177
Communication, utilities, and misc. charges (23.3)	$63,714	$69,031	$75,387	$6,355
Printing and reproduction (24.0)	$3,162	$3,702	$4,449	$747
Other Contractual Services:				
Advisory and assistance services (25.1)	$82,770	$103,775	$134,073	$30,298
Other services (25.2)	$515,604	$567,182	$631,982	$64,800
Purchase of goods and svcs from Govt Acts. (25.3)……	$236,125	$299,737	$391,940	$92,202
Operation and maintenance of facilities (25.4)	$144,908	$166,309	$195,316	$29,007
Research and Development Contracts (25.5)	$53,199	$63,548	$78,094	$14,546
Medical care (25.6)				
Operation and maintenance of equipment (25.7)	$34,228	$36,647	$39,378	$2,731
Subsistence and support of persons (25.8)				
Subtotal Other Contractual Services	**$1,066,834**	**$1,237,199**	**$1,470,783**	**$233,584**
Supplies and materials (26.0)	$52,729	$57,138	$62,405	$5,267
Equipment (31.0)	$65,136	$71,184	$78,637	$7,453
Land and Structures (32.0)	$5,515	$5,609	$5,585	-$24
Investments and Loans (33.0)				
Grants, subsidies, and contributions (41.0)	$75,449	$76,757	$76,484	-$274
Insurance claims and indemnities (42.0)	$358	$415	$494	$79
Interest and dividends (43.0)	$10	$10	$10	$0
Receivables Collected (61.7)				
Total Non-Pay Costs	**$1,577,625**	**$1,798,442**	**$2,080,858**	**$282,416**
Total Budget Authority by Object Class	**$3,339,281**	**$3,832,204**	**$4,486,368**	**$654,164**

Food and Drug Administration
Salaries and Expenses
Dollars in thousands

	FY2011	FY 2012	FY 2013	
	Actual	Enacted	Estimate	+/- FY 2012 Enacted
Personnel compensation:				
Full-time permanent (11.1)	$748,684	$758,467	$762,049	$3,582
Other than full-time permanent (11.3)	$104,948	$106,319	$106,821	$502
Other personnel compensation (11.5)	$58,993	$59,764	$60,046	$282
Military personnel (11.7)	$58,658	$60,768	$61,769	$1,001
Special personnel services payments (11.8)	$354	$359	$361	$2
Subtotal personnel compensation	**$971,637**	**$985,677**	**$991,046**	**$5,369**
Civilian benefits (12.1)	$260,198	$263,598	$264,843	$1,245
Military benefits (12.2)	$29,372	$30,428	$30,929	$501
Benefits to former personnel (13.0)	$1,486	$1,506	$1,513	$7
Total Pay Costs	**$1,262,693**	**$1,281,209**	**$1,288,331**	**$7,122**
Travel and transportation of persons (21.0)	$50,358	$51,209	$50,994	-$216
Transportation of things (22.0)	$5,385	$5,476	$5,453	-$23
Rent payments to others (23.2)	$2,122	$2,158	$2,149	-$9
Communication, utilities, and misc. charges (23.3)	$54,897	$55,826	$55,591	-$235
Printing and reproduction (24.0)	$2,150	$2,186	$2,177	-$9
Other Contractual Services:				
Advisory and assistance services (25.1)	$41,997	$42,707	$42,527	-$180
Other services (25.2)	$426,470	$433,685	$431,857	-$1,829
Purchase of goods and svcs from Govt Acts. (25.3)	$112,136	$114,033	$113,553	-$481
Operation and maintenance of facilities (25.4)	$105,498	$107,283	$106,831	-$452
Research and Development Contracts (25.5)	$33,547	$34,115	$33,971	-$144
Medical care (25.6)				$0
Operation and maintenance of equipment (25.7)	$30,400	$30,914	$30,784	-$130
Subsistence and support of persons (25.8)				$0
Subtotal Other Contractual Services	**$750,049**	**$762,738**	**$759,522**	**-$3,216**
Supplies and materials (26.0)	$45,421	$46,190	$45,994	-$196
Total Non-Pay Costs	$910,381	$925,783	$921,879	-$3,905
Rental payments to GSA (23.1)	$150,763	$160,506	$169,374	$8,868
Grand Total, Salaries & Expenses and Rent	$2,323,837	$2,367,498	$2,379,584	$12,085
Direct FTE	9,794	9,927	9,939	12

Food and Drug Administration
Distribution of Full-Time Equivalent (FTE) Employment
Program Level

Project[1]	FY 2011 Actual			FY 2012 Enacted			FY 2013 Estimate		
	Civilian	Military	Total FY 2011 Actual	Civilian	Military	Total FY 2012 Enacted	Civilian	Military	Total FY 2013 President's Request
Center for Food Safety and Applied Nutrition	841	35	876	898	35	933	1,047	35	1,082
Center for Drug Evaluation and Research	2,894	370	3,264	2,911	370	3,281	3,233	370	3,603
Center for Biologics Evaluation and Research	994	61	1,055	994	61	1,055	1,013	61	1,074
Center for Veterinary Medicine	505	4	509	504	4	508	515	4	519
Center for Devices and Radiological Health	1,309	97	1,406	1,277	97	1,374	1,316	97	1,413
National Center for Toxological Research	272	-	272	272	-	272	270	-	270
Office of Regulatory Affairs	4,265	305	4,570	4,380	305	4,685	4,763	305	5,068
Headquarters and Office of the Commissioner	872	50	922	922	50	972	1,039	50	1,089
Export Certification	15	-	15	15	-	15	22	-	22
Color Certification	37	-	37	37	-	37	37	-	37
Family Smoking Prevention and Tabacco Control Act	211	14	225	352	14	366	457	14	471
TOTAL	**12,215**	**936**	**13,151**	**12,560**	**936**	**13,496**	**13,712**	**936**	**14,648**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2008	12.3
FY 2009	12.3
FY 2010	12.2
FY 2011	12.3
FY 2012	12.3

[1] *FY 2011, FY 2012 and FY 2013 do not include an estimated 114 reimbursable, 22 PEPFAR, and 44 IDDA FTE.*

FOOD AND DRUG ADMINISTRATION
DISTRIBUTION OF FTE BY GRADE

	FY 2011 Actuals	FY 2012 Enacted	FY 2013 Request
Executive Level I			
Executive Level II			
Executive Level III			
Executive Level IV	1	1	1
Executive Level V			
Total, Exec. Level	1	1	1
ES	55	57	62
Total ES	55	57	62
GS-15	1,231	1,265	1,380
GS-14	2,433	2,501	2,727
GS-13	3,387	3,482	3,796
GS-12	1,814	1,864	2,033
GS-11	836	859	937
GS-10	31	32	35
GS-9	766	787	858
GS-8	130	133	145
GS-7	460	473	516
GS-6	58	59	65
GS-5	93	96	105
GS-4	92	95	103
GS-3	43	44	48
GS-2	19	20	21
GS-1	2	2	2
Subtotal, GS	11,395	11,712	12,771
AL	0	0	0
ST/SL	1	1	2
RS	34	35	39
CC - 08/07/06	229	229	229
CC - Other	707	707	707
Subtotal, CC	936	936	936
AD (includes Title 42)	858	882	961
Wage Grade	36	37	40
Consultants	15	15	16
Total FTE (End of Year) [1]	13,331	13,676	14,828
Average ES Level	-		-
Average ES Salary	$170,315	$170,315	$171,167
Average GS grade	12	12	12
Average GS salary	$95,074	$95,074	$95,549

[1] *FY 2011, FY 2012, and FY 2013 include an estimated 114 reimbursable, 22 PEPFAR, and 44 IDDA FTE.*

PROGRAMS PROPOSED FOR ELIMINATION

FDA has no programs proposed for elimination.

FY 2013 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

OPDIV Allocation Statement:

The **FDA** will use **$1,192,950.00** of its **FY 2013** budget to support Department-wide enterprise information technology and government-wide E-Government initiatives. Operating Divisions help to finance specific HHS enterprise information technology programs and initiatives, identified through the HHS Information Technology Capital Planning and Investment Control process, and the government-wide E-Government initiatives. The HHS enterprise initiatives meet cross-functional criteria and are approved by the HHS IT Investment Review Board based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability.

Of the amount specified above, **$594,037.00** is allocated to developmental government-wide E-Government initiatives for **FY 2013**. This amount supports these government-wide E-Government initiatives as follows:

FY 2013 Developmental E-Gov Initiatives*	
Lines of Business - Human Resources Management	$23,054.00
Lines of Business - Grants Management	$571.00
Lines of Business - Financial Management	$18,064.00
Lines of Business - Budget Formulation and Execution	$13,263.00
Disaster Assistance Improvement Plan	$0.00
Lines of Business - Federal Health Architecture	$535,100.00
Integrated Acquisitions Environment Loans and Grants (IAE)	$3,985.00
Line of Business - Geospatial	$0.00
FY 2013 Developmental E-Gov Initiatives Total	**$594,037.00**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Prospective benefits from these initiatives are:

Lines of Business-Human Resources Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital.

Lines of Business-Grants Management: Supports end-to-end grants management activities promoting improved customer service, decision making, financial management processes, efficiency of reporting procedure, and post-award closeout actions. The

Administration for Children and Families (ACF) is a GMLOB consortia lead, which has allowed ACF to take on customers external to HHS. These additional agency users have allowed HHS to reduce overhead costs for internal HHS users. Additionally, NIH is an internally HHS-designated Center of Excellence. This effort has allowed HHS agencies using the NIH system to reduce grants management costs. Both efforts have allowed HHS to achieve economies of scale and efficiencies, as well as streamlining and standardization of grants processes, thus reducing overall HHS costs for grants management systems and processes.

Lines of Business –**Financial Management:** Supports efficient and improved business performance while ensuring integrity in accountability, financial controls, and mission effectiveness by enhancing process improvements, achieving cost savings, standardizing business processes and data models, promoting seamless data exchanges between Federal agencies, and strengthening internal controls.

Lines of Business-Budget Formulation and Execution: Allows sharing across the Federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Lines of Business-Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) Solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and to provide appropriate patient access to improved health data. HHS works closely with federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

In addition, **$598,913.00** is allocated to ongoing government-wide E-Government initiatives for **FY 2013**. This amount supports these government-wide E-Government initiatives as follows:

FY 2013 Ongoing E-Gov Initiatives*	
E-Rule Making	$330,564.00
GovBenefits	$0.00
Integrated Acquisition Environment	$225,758.00
Grants.gov	$42,591.00
FY 2013 Ongoing E-Gov Initiatives Total	**$598,913.00**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

Physicians' Comparability Allowance (PCA) Worksheet

[Department: Food and Drug Administration]

Table 1

		PY 2011 (Actual)	CY 2012 (Estimates)	BY 2013* (Estimates)
1) Number of Physicians Receiving PCAs		9	0	0
2) Number of Physicians with One-Year PCA Agreements		0	0	0
3) Number of Physicians with Multi-Year PCA Agreements		9	0	0
4) Average Annual PCA Physician Pay (without PCA payment)		$ 139,764	0	0
5) Average Annual PCA Payment		$ 19,111	0	0
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position	0	0	0
	Category II Research Position	9	0	0
	Category III Occupational Health	0	0	0
	Category IV-A Disability Evaluation	0	0	0
	Category IV-B Health and Medical Admin.	0	0	0

*FY 2013 data will be approved during the FY 2014 Budget cycle.

7) If applicable, list and explain the necessity of any additional physician categories designated by your agency (for categories other than I through IV-B). Provide the number of PCA agreements per additional category for the PY, CY and BY.

FDA will not have a need for additional physician categories other than those listed above.

8) Provide the maximum annual PCA amount paid to each category of physician in your agency and explain the reasoning for these amounts by category.

FDA utilizes the Category 2 to hire physicians that are not eligible for Title 38. The maximum annual PCA for this category for FY 11 was $30,000 for the 9 employees receiving PCA. The amounts were determined based upon the qualifications of the physicians.

9) Explain the recruitment and retention problem(s) for each category of physician in your agency (this should demonstrate that a current need continues to persist).

(*Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)*
FDA made a decision in 2008 to convert all eligible physicians to Title 38 which is useful in allowing the agency to effectively recruit and retain medical officers across the FDA. The minimal continued use of PCA allows FDA the ability to recruit physicians who are not eligible for Title 38.

10) Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior fiscal year.

(*Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)*
FDA did not experience recruitment or retention problems as we use PCA sparingly across the agency. FDA would use PCA as a means to recruit candidates that are not eligible for Title 38.

11) Provide any additional information that may be useful in planning PCA staffing levels and amounts in your agency.

FDA uses PCA as an additional authority to hire physicians that are not eligible for Title 38. We plan to convert those in PCA to Title 38 once eligible.

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

BLANK PAGE

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2011 Actual	PREMARKET														POSTMARKET															
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION DOMESTIC		OUTREACH COORDINATION FOREIGN		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		TOTAL		OUTREACH COORDINATION COMPLIANCE		APPLIED RESEARCH		LABORATORY ANALYSIS DOMESTIC		LABORATORY ANALYSIS IMPORTS		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		INSPECTIONS IMPORTS		TOTAL		FDA	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS																																
Center for Food Safety & Applied Nutrition	17,839	98	9,102	26	13,996	77	4,399	30					45,336	231	108,155	394	62,989	152	13,096	30	10,997	25	3,869	15	5,098	23	3,000	6	207,204	645	252,540	876
Field Activities	-												-	-	147,848	609	1,099	5	*89,671*	352	81,265	408	111,539	640	27,049	113	126,233	602	583,704	2,729	583,704	2,729
Export Certification User Fee: (non-add):Center	-												-	-															-	-	-	-
Field	-												-	-															-	-	-	-
Reinspection User Fee (non-add)	-												-	-															-	-	-	-
Recall User Fee(non-add): Center	-												-	-															-	-	-	-
Field	-												-	-															-	-	-	-
Proposed International Courier User Fee (non-add): Center	-												-	-															-	-	-	-
Proposed Food VQIP user fee (non-add): Center	-												-	-															-	-	-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-															-	-	-	-
FOODS TOTAL	**17,839**	**98**	**9,102**	**26**	**13,996**	**77**	**4,399**	**30**	**-**	**-**	**-**	**-**	**45,336**	**231**	**256,003**	**1,003**	**64,088**	**157**	**102,767**	**382**	**92,262**	**433**	**115,408**	**655**	**32,147**	**136**	**128,233**	**608**	**790,908**	**3,374**	**836,244**	**3,605**
HUMAN DRUGS																																
Center for Drug Evaluation & Research	453,455	2,042	45,505	88	29,810	124	10,377	43	10,358	50	9,106	43	558,611	2,390	211,207	680	18,592	78	3,006	14	596	3	10,935	55	7,123	35	1,799	9	*253,258*	*874*	811,869	3,264
Field Activities									24,510	140	18,005	103	42,515	243	28,743	176			14,575	76	3,715	22	29,950	173	10,812	71	7,466	36	*95,261*	*554*	137,776	797
PDUFA (non-add): Center	*293,338*	*1,353*	*18,207*	*55*	*19,573*	*85*	*7,287*	*30*	*7,098*	*35*	*5,018*	*24*	350,521	1,582	*115,154*	*398*													*115,154*	*398*	*465,675*	*1,980*
Field	-								*4,269*	*33*	*2,199*	*18*	6,468	51															-	-	*6,468*	*51*
Proposed GDUFA (non-add): Center	-												-	-															-	-	-	-
Field	-												-	-															-	-	-	-
Proposed Reinspection user fee (non-add): Field	-												-	-															-	-	-	-
Proposed International Courier User Fee (non-add): Center	-												-	-															-	-	-	-
HUMAN DRUGS TOTAL	**453,455**	**2,042**	**45,505**	**88**	**29,810**	**124**	**10,377**	**43**	**34,868**	**190**	**27,111**	**146**	**601,126**	**2,633**	**239,950**	**856**	**18,592**	**78**	**17,581**	**90**	**4,311**	**25**	**40,885**	**228**	**17,935**	**106**	**9,265**	**45**	**348,519**	**1,428**	**949,645**	**4,061**
BIOLOGICS																																
Center for Biologics Evaluation & Research	176,411	674	24,709	152	24,390	93	928	3	2,490	10			228,928	932	27,332	110	250	2					2,919	11					30,501	123	259,429	1,055
Field Activities									4,642	20	191	1	4,833	21	7,279	45							26,881	159	2,280	9	1,318	7	37,758	220	*42,591*	*241*
PDUFA (non-add): Center	*67,560*	*301*			*9,530*	*42*			*983*	*4*			78,073	347	*1,673*	*8*													1,673	8	*79,746*	*355*
Field									*1,719*	*5*			1,719	5															-	-	*1,719*	*5*
MDUFMA (non-add): Center	*7,341*	*30*			*742*	*3*	*15*	-	*140*	*2*			8,238	35	*104*	*1*													104	1	*8,342*	*36*
Field	-								*423*	*1*			423	1															-	-	*423*	*1*
Proposed Reinspection user fee (non-add): Field	-												-	-															-	-	-	-
BIOLOGICS TOTAL	**176,411**	**674**	**24,709**	**152**	**24,390**	**93**	**928**	**3**	**7,132**	**30**	**191**	**1**	**233,761**	**953**	**34,611**	**155**	**250**	**2**	**-**	**-**	**-**	**-**	**29,800**	**170**	**2,280**	**9**	**1,318**	**7**	**68,259**	**343**	**302,020**	**1,296**
ANIMAL DRUGS & FEEDS																																
Center for Veterinary Medicine	55,598	271	3,590	18	924	5			1,758	8	816	4	60,112	295	33,571	165	11,134	50					18,656	121	1,264	17	7,184	27	44,705	215	104,817	510
Field Activities													2,574	12	16,926	77			6,057	35	1,293	7							51,380	284	53,954	296
ADUFA (non-add): Center	*14,992*	*67*											14,992	67															-	-	*14,992*	*67*
Field									*277*	*2*			277	2															-	-	*277*	*2*
AGDUFA (non-add): Center	*4,326*	*23*											4,326	23															-	-	*4,326*	*23*
Field	-								*151*	*1*			151	1															-	-	*151*	*1*
Reinspection user fee (non-add):	-												-	-															-	-	-	-
Recall User Fee(non-add): Center	-												-	-															-	-	-	-
Field	-												-	-															-	-	-	-
Proposed Food Inspection and Facility Registration user fee (non-add): Center	-												-	-															-	-	-	-
Field	-												-	-															-	-	-	-
Export Certification User Fee(non-add): Center	-												-	-															-	-	-	-
ANIMAL DRUGS & FEEDS TOTAL	**55,598**	**271**	**3,590**	**18**	**924**	**5**	**-**	**-**	**1,758**	**8**	**816**	**4**	**62,686**	**307**	**50,497**	**242**	**11,134**	**50**	**6,057**	**35**	**1,293**	**7**	**18,656**	**121**	**1,264**	**17**	**7,184**	**27**	**96,085**	**499**	**158,771**	**806**
DEVICES AND RADIOLOGICAL HEALTH																																
Center for Devices & Radiological Health	136,559	740	16,677	63	11,980	64	2,810	15					*168,026*	*882*	97,069	451	2,598	12	18,284	61									117,951	524	285,977	1,406
Field Activities	-								7,722	47	522	2	*8,244*	*49*	23,459	133			4,721	20	2,711	15	38,142	185	8,461	38	6,794	56	84,288	447	92,532.45	496
MOSA (non-add): Center	-												-	-	4,912	*31*													4,912	31	*4,912*	*31*
Field	-												-	-	5,225	*5*							*4,234*	*3*					9,459	8	*9,459*	*8*
MDUFMA (non-add): Center	*27,456*	*182*	*2,135*	*9*	*2,392*	*16*	*561*	*4*					*32,544*	*211*	*7,171*	*33*	*20*	-	*635*	*4*									7,826	37	*40,370*	*248*
Field	-								*1,514*	*12*			*1,514*	*12*	-	-							*72*	-					72	-	*1,586*	*12*
Proposed Reinspection user fee (non-add): Field	-												-	-															-	-	-	-
Proposed International Courier User Fee (non-add): Center	-												-	-															-	-	-	-
DEVICES TOTAL	**136,559**	**740**	**16,677**	**63**	**11,980**	**64**	**2,810**	**15**	**7,722**	**47**	**522**	**2**	**176,270**	**931**	**120,528**	**584**	**2,598**	**12**	**23,005**	**81**	**2,711**	**15**	**38,142**	**185**	**8,461**	**38**	**6,794**	**56**	**202,239**	**971**	**378,509**	**1,902**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**39,373**	**177**									**39,373**	*177*			**21,190**	**95**											**21,190**	95	**60,563**	**272**
Proposed Reinspection user fee (non-add): Center													-	-															-	-	-	-
CENTER FOR TOBACCO PRODUCTS													-	-															**132,274**	**230**	**135,708**	**236**
Center for Tobacco Products			3,434	6									*3,434*	*6*	60,947	102	34,216	57	738	1			34,810	59					**130,711**	**219**	*134,145*	225
Field													-	-	*784*	*4*					425	3					354	3	1,563	10	1,563	10
HEADQUARTERS / OFFICE OF THE COMMISSIONER																																
Headquarters / Office of the Commissioner	**38,672**	**228**	**20,500**	**230**	**5,297**	**22**	**1,209**	**5**	**3,363**	**16**	**1,871**	**9**	**70,913**	**510**	**45,828**	**175**	**21,372**	**26**	**9,808**	**35**	**6,570**	**29**	**18,139**	**84**	**4,056**	**19**	**9,980**	**44**	**115,753**	**412**	**186,665**	**922**
USER FEES (non-add): PDUFA	*18,893*	*137*	*953*	*4*	*1,524*	*10*	*381*	*2*	*737*	*6*	*378*	*3*	**22,866**	**162**	*6,116*	*33*	-	-	-	-	-	-	-	-	-	-	-	-	*6,116*	*33*	*28,982*	*195*
MOSA (NO / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*189*	*2*	-	-	-	-	-	-	*79*	-	-	-	-	-	*268*	*2*	*268*	*2*
MDUFMA	*2,605*	*21*	*160*	-	*234*	*1*	*43*	-	*155*	-	-	-	**3,197**	**22**	*544*	*2*	*1*	-	*48*	-	-	-	*5*	-	-	-	-	-	*598*	*4*	*3,795*	*26*
ADUFA	*639*	*4*	-	-	-	-	-	-	*12*	-	-	-	**651**	**4**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	651	*4*
Proposed GDUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AGDUFA	*159*	*1*	-	-	-	-	-	-	*6*	-	-	-	**165**	**1**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*165*	*1*
TOBACCO	-	-	*85*	*1*	-	-	-	-	-	-	-	-	**85**	**1**	*1,513*	*10*	*849*	*5*	*18*	-	-	-	*863*	*5*	-	-	-	-	*3,243*	*20*	*3,328*	*21*
Food Reinspection user fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Recall User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed Reinspection User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed International Courier User Fee	-												-	-															-	-	-	-
Proposed Food VQIP User Fee													-	-															-	-	-	-
HEADQUARTERS / OC TOTAL	**38,672**	**228**	**20,500**	**230**	**5,297**	**22**	**1,209**	**5**	**3,363**	**16**	**1,871**	**9**	**3,197**	**22**	**45,828**	**175**	**21,372**	**26**	**9,808**	**35**	**6,570**	**29**	**18,139**	**84**	**4,056**	**19**	**9,980**	**44**	**115,753**	**412**	**186,665**	**922**
SUB-TOTAL:	**878,534**	**4,053**	**123,517**	**584**	**86,397**	**385**	**19,723**	**96**	**54,843**	**291**	**30,511**	**162**	**1,125,809**	**5,083**	**809,148**	**3,121**	**152,250**	**382**	**159,956**	**624**	**107,572**	**512**	**261,030**	**1,443**	**66,143**	**325**	**163,128**	**790**	**1,775,227**	**7,352**	**3,008,125**	**13,100**
Total Center	878,534	4,053	162,890	761	86,397	385	19,723	96	16,211	76	10,977	52	1,174,732	5,423	584,109	2,077	172,341	472	44,932	141	18,163	57	70,672	224	16,277	77	14,779	59	921,273	3,107	2,096,005	8,530
Total Field	-	-	-	-	-	-	-	-	38,632	215	19,534	110	58,166	325	225,039	1,044	1,099	5	115,024	483	89,409	455	225,168	1,278	49,866	248	148,349	731	853,954	4,245	912,120	4,570
(PDUFA, MOSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees User Fees - non add)	*437,308*	*2,120*	*24,974*	*75*	*33,995*	*157*	*8,287*	*36*	*17,484*	*101*	*7,595*	*45*	*529,643*	*2,337*	*203,548*	*625*	*35,086*	*62*	*86,203*	*5*	*40,063*	*67*	-	-	-	-	-	-	*364,900*	*493*	879,434	3,357
Plus:																																
Other Rent and Rent-Related (incl. White Oak Relocation)																															**129,109**	-
White Oak Relocation PDUFA (non-add)																															*3,415*	-
White Oak Relocation Reinspection User Fee (non-add)																																-
White Oak Relocation Proposed Reinspection User Fee (non-add)																																-
Other Rent and Rent Related MDUFMA (non-add)																															1,541	-
Other Rent and Rent Related PDUFA (non-add)																															23,253	-
Other Rent and Rent Related ADUFA (non-add)																															41	-
Other Rent and Rent Related for Proposed GDUFA (non-add)																																-
Other Rent and Rent Related AGDUFA (non-add)																															26	-
Other Rent and Rent Related Food Reinspection User Fee (non-add)																																-
Other Rent and Rent Related Proposed Reinspection User Fee (non-add)																																-
Other Rent and Rent Related for Center of Tobacco (non-add)																															1,279	-
Other Rent and Rent Related for Recall User Fee (non-add)																																-
Other Rent and Rent Related for Proposed International Courier User Fee (non-add)																																-
Other Rent and Rent Related for Proposed Food VQIP User Fee (non-add)																																-
GSA Rent																															**178,120**	-
GSA Rent PDUFA (non-add)																															18,568	-
GSA Rent MDUFMA (non-add)																															3,200	-
GSA Rent ADUFA (non-add)																															672	-
GSA Rent for Proposed GDUFA (non-add)																																-
GSA Rent AGDUFA (non-add)																															18	-
GSA Rent Food Reinspection User Fee (non-add)																																-
GSA Rent Proposed Reinspection User Fee (non-add)																																-
GSA Rent Proposed Food VQIP User Fee (non-add)																																-
GSA Rent for Center of Tobacco (non-add)																															4,899	-
GSA Rent for Recall User Fee (non-add)																																-
GSA Rent for Proposed International Courier User Fee (non-add)																																-
Export Certification User Fee																															**3,337**	**15**
Colors Certification User Fee																															**7,843**	**37**
Buildings and Facilities																															**12,747**	-
TOTAL S&E PROGRAM:																															**3,339,281**	**13,151**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2012 Enacted Budget	PREMARKET														POSTMARKET																	
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION				INSPECTIONS				TOTAL		OUTREACH COORDINATION		APPLIED RESEARCH		LABORATORY ANALYSIS				INSPECTIONS						TOTAL		FDA	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN				COMPLIANCE				DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS																																
Center for Food Safety & Applied Nutrition	17,681	98	9,021	26	13,872	77	4,360	30					44,934	231	121,655	451	62,430	152	12,980	30	10,900	25	3,835	15	5,053	23	2,973	6	219,826	702	264,760	932.6
Field Activities													-	-	155,760	591	1,098	5	89,619	352	81,217	408	127,695	711	27,033	113	135,565	644	617,987	2,824	617,987	2,824
Export Certification User Fee: (non-add):Center															-	-													-	-	*0*	*0*
Field													-	-															-	-	*0*	*0*
Reinspection User Fee (non-add): Field													-	-									*6,825*	*48*					*6,825*	*48*	*6,825*	*48*
Food Feed Recall User Fee(non-add): Center															*464*	*2*													*464*	*2*	*464*	*2*
Field																							*9,397*	*23*					*9,397*	*23*	*9,397*	*23*
Proposed International Courier User Fee (non-add): Field																											-	-	-	-	*0*	*0*
Proposed Food VQIP user fee (non-add): Center															*232*	*1*													-	-	*0*	*0*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-													-	-	-	-	*0*	*0*
FOODS TOTAL	**17,681**	**98**	**9,021**	**26**	**13,872**	**77**	**4,360**	**30**	**-**	**-**	**-**	**-**	**44,934**	**231**	**277,415**	**1,042**	**63,528**	**157**	**102,599**	**382**	**92,117**	**433**	**131,530**	**726**	**32,086**	**136**	**138,538**	**650**	**837,813**	**3,526**	**882,747**	**3,757**
HUMAN DRUGS																																
Center for Drug Evaluation & Research	470,069	2,054	45,995	88	31,009	124	10,800	43	10,852	50	9,444	43	578,169	2,402	218,474	685	18,592	78	3,006	14	596	3	10,935	55	7,123	35	1,799	9	*260,525*	*879*	838,694	3,281
Field Activities									25,317	140	18,527	103	43,844	243	28,251	169			14,881	76	3,793	22	30,580	173	11,039	71	7,623	36	*96,167*	*547*	140,011	790
PDUFA (non-add): Center	*306,596*	*1,353*	*18,697*	*55*	*20,772*	*85*	*7,710*	*30*	*7,592*	*35*	*5,356*	*24*	366,723	1,582	*124,154*	*398*													*124,154*	*398*	*490,877*	*1,980*
Field									*6,634*	*33*	*3,384*	*18*	10,018	51															-	-	*10,018*	*51*
Proposed GDUFA (non-add): Center	-	-											-	-	-	-													-	-	*0*	*0*
Field									-	-	-	-	-	-															-	-	*0*	*0*
Proposed Reinspection user fee (non-add): Field													-	-									-	-					-	-	*0*	*0*
Proposed International Courier User Fee (non-add): Center													-														-	-	-	-	*0*	*0*
HUMAN DRUGS TOTAL	**470,069**	**2,054**	**45,995**	**88**	**31,009**	**124**	**10,800**	**43**	**36,169**	**190**	**27,971**	**146**	**622,013**	**2,645**	**246,725**	**854**	**18,592**	**78**	**17,887**	**90**	**4,389**	**25**	**41,515**	**228**	**18,162**	**106**	**9,422**	**45**	**356,692**	**1,426**	**978,705**	**4,071**
BIOLOGICS																																
Center for Biologics Evaluation & Research	194,960	673	24,871	153	26,948	91	1,017	3	2,751	9			250,547	929	29,911	112	251	2					3,195	12					33,357	126	283,904	1,055
Field Activities									5,095	20	204	1	5,299	21	7,421	43							28,674	159	2,432	9	1,406	7	39,933	218	45,232	239
PDUFA (non-add): Center	*85,576*	*301*			*12,072*	*42*	-	-	*1,244*	*4*			98,892	347	*2,118*	*8*	-	-											2,118	8	*101,010*	*355*
Field									*4,207*	*5*			4,207	5															-	-	*4,207*	*5*
MDUFMA (non-add): Center	*9,842*	*25*			*994*	*2*	*22*	-	*186*	-			11,044	27	*139*	*1*													139	1	*11,183*	*28*
Field									*512*	*1*			512	1															-	-	*512*	*1*
Proposed Reinspection user fee (non-add): Field													-	-									-	-					-	-	*0*	*0*
BIOLOGICS TOTAL	**194,960**	**673**	**24,871**	**153**	**26,948**	**91**	**1,017**	**3**	**7,846**	**29**	**204**	**1**	**255,846**	**950**	**37,332**	**155**	**251**	**2**	**-**	**-**	**-**	**-**	**31,869**	**171**	**2,432**	**9**	**1,406**	**7**	**73,290**	**344**	**329,136**	**1,294**
ANIMAL DRUGS & FEEDS																																
Center for Veterinary Medicine	60,094	267	3,556	18	915	5							64,565	290	33,776	168	11,038	50											*44,814*	*218*	109,379	508
Field Activities									1,810	8	820	4	2,630	12	16,552	74			6,085	35	1,299	7	21,932	141	1,270	17	7,218	27	*54,356*	*301*	56,986	313
ADUFA (non-add): Center	*19,261*	*66*											19,261	66															-	-	*19,261*	*66*
Field									*315*	*2*			315	2															-	-	*315*	*2*
AGDUFA (non-add): Center	*4,898*	*20*											4,898	20															-	-	*4,898*	*20*
Field									*160*	*1*			160	1															-	-	*160*	*1*
Food Reinspection user fee (non-add): field													-	-									*2,550*	*18*					*2,550*	*18*	*2,550*	*18*
Food Feed Recall User Fee(non-add): Center															*521*	*2*													*521*	*2*	*521*	*2*
Field																							*639*	*2*					*639*	*2*	*639*	*2*
													-	-															-	-	*0*	*0*
Medical Reinspection user fee (non-add): field													-	-									-	-					-	-	*0*	*0*
Field													-	-															-	-	*0*	*0*
Export Certification User Fee(non-add): Center													-	-	-	-													-	-	*0*	*0*
ANIMAL DRUGS & FEEDS TOTAL	**60,094**	**267**	**3,556**	**18**	**915**	**5**	**-**	**-**	**1,810**	**8**	**820**	**4**	**67,195**	**302**	**50,328**	**242**	**11,038**	**50**	**6,085**	**35**	**1,299**	**7**	**21,932**	**141**	**1,270**	**17**	**7,218**	**27**	**99,170**	**519**	**166,365**	**821**
DEVICES AND RADIOLOGICAL HEALTH													-	-																		
Center for Devices & Radiological Health	133,356	722	16,292	62	11,461	62	2,688	14					163,797	860	96,130	441	2,699	13	18,029	60									116,858	514	280,655	1,374
Field Activities									7,946	47	542	2	8,488	49	23,676	129			4,903	20	2,816	15	39,608	185	8,787	38	7,056	56	86,846	443	95,334	492
MQSA (non-add): Center													-	-	*6,003*	*26*													6,003	26	*6,003*	*26*
Field													-	-	*7,223*	*5*							*5,854*	*3*					13,077	8	*13,077*	*8*
MDUFMA (non-add): Center	*22,564*	*153*	*1,755*	*8*	*1,966*	*14*	*461*	*3*					26,746	178	*5,893*	*28*	*16*	-	*522*	*3*									6,431	31	*33,177*	*209*
Field									*1,012*	*12*			1,012	12									*48*	-					48	-	*1,060*	*12*
Proposed Reinspection user fee (non-add): Field													-	-									-	-					-	-	*0*	*0*
Proposed International Courier User Fee (non-add): Field													-	-									-	-					-	-	*0*	*0*
DEVICES TOTAL	**133,356**	**722**	**16,292**	**62**	**11,461**	**62**	**2,688**	**14**	**7,946**	**47**	**542**	**2**	**172,285**	**909**	**119,806**	**570**	**2,699**	**13**	**22,932**	**80**	**2,816**	**15**	**39,608**	**185**	**8,787**	**38**	**7,056**	**56**	**203,704**	**957**	**375,989**	**1,866**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**34,715**	**147**									**34,715**	**147**	**-**	**-**	**25,324**	**125**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	25,324	125	**60,039**	**272**
Proposed Reinspection user fee (non-add): Center													-	-		-			-	-	-	-	-	-	-	-	-	-	-	-	0	0
CENTER FOR TOBACCO PRODUCTS													-	-															**443,346**	**383**	**454,751**	**392**
Center for Tobacco Products			11,405	9									*11,405*	*9*	202,440	161	113,649	95	2,451	2			118,556	99					**437,096**	**357**	*448,501*	366
Field													-	-	2,062	9			2,090	8							2,098	9	6,250	26	6,250	26

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2012 Enacted Budget	PREMARKET														POSTMARKET															
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION DOMESTIC		OUTREACH COORDINATION FOREIGN		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		TOTAL		OUTREACH COORDINATION COMPLIANCE		APPLIED RESEARCH		LABORATORY ANALYSIS DOMESTIC		LABORATORY ANALYSIS IMPORTS		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		INSPECTIONS IMPORTS		TOTAL		FDA	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
HEADQUARTERS / OFFICE OF THE COMMISSIONER																																
Headquarters / Office of the Commissioner	**64,731**	**184**	**20,500**	**230**	**5,936**	**16**	**1,330**	**4**	**3,790**	**12**	**2,082**	**7**	**98,369**	**453**	**51,571**	**128**	**20,500**	**230**	**10,538**	**26**	**7,093**	**21**	**18,782**	**65**	**4,422**	**14**	**11,535**	**35**	**124,442**	**519**	**222,811**	**972**
USER FEES (non-add): PDUFA	*27,523*	*137*	*1,312*	*4*	*2,305*	*10*	*541*	*2*	*1,381*	*6*	*613*	*3*	**33,675**	**162**	*8,866*	*33*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*8,866*	*33*	*42,541*	*195*
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*4,215*	*16*	*228*	*1*	*385*	*1*	*63*	-	*222*	*1*	-	-	**5,113**	**19**	*785*	*2*	*2*	-	*69*	-	-	-	*6*	-	-	-	-	-	*862*	*2*	*5,975*	*21*
ADUFA	*859*	*4*	-	-	-	-	-	-	*14*	-	-	-	**873**	**4**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*873*	*4*
Proposed GDUFA													-	-															-	-	*0*	*0*
AGDUFA	*221*	*1*	-	-	-	-	-	-	*7*	-	-	-	**228**	**1**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*228*	*1*
TOBACCO	*2*	-	*386*	*1*	-	-	-	-	-	-	-	-	**388**	**1**	*6,859*	*15*	*3,851*	*9*	*83*	-	-	-	*4,017*	*9*	-	-	-	-	*14,810*	*33*	*15,198*	*34*
Food Reinspection user fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*3,395*	*7*	-	-	-	-	*3,395*	*7*	*3,395*	*7*
Food Feed Recall User Fee			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*661*	*2*	-	-	-	-	*661*	*2*	*661*	*2*
Proposed Medical Products Reinspection User Fee			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*0*	*0*
Proposed International Courier User Fee			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-							-	-	*0*	*0*
Proposed Food VQIP User Fee			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-							-	-	*0*	*0*
HEADQUARTERS / OC TOTAL	**64,731**	**184**	**20,500**	**230**	**5,936**	**16**	**1,330**	**4**	**3,790**	**12**	**2,082**	**7**	**5,113**	**19**	**51,571**	**128**	**20,500**	**230**	**10,538**	**26**	**7,093**	**21**	**18,782**	**65**	**4,422**	**14**	**11,535**	**35**	**124,442**	**519**	**222,811**	**972**
SUB-TOTAL:	**940,891**	**3,997**	**131,640**	**586**	**90,141**	**375**	**20,195**	**94**	**57,561**	**286**	**31,619**	**160**	**1,178,791**	**5,064**	**987,679**	**3,161**	**230,257**	**625**	**162,492**	**615**	**107,714**	**501**	**285,236**	**1,516**	**67,159**	**320**	**177,273**	**830**	**2,163,781**	**7,801**	**3,470,543**	**13,445**
Total Center	940,891	3,997	120,235	577	90,141	375	20,195	94	17,393	71	11,526	50	1,102,012	4,711	551,517	1,985	115,510	525	44,553	130	18,589	49	36,747	147	16,598	72	16,307	50	799,822	2,958	2,508,743	8,760
Total Field	-	-	-	-	-	-	-	-	40,168	215	20,093	110	60,261	325	231,660	1,006	1,098	5	115,488	483	89,125	452	248,489	1,369	50,561	248	158,868	770	895,289	4,334	961,800	4,685
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees	*448,737*	*1,918*	*20,452*	*63*	*35,804*	*143*	*8,193*	*33*	*21,862*	*93*	*8,740*	*42*	*543,788*	*2,292*	*147,592*	*475*	*16*	-	*2,612*	*11*	-	-	*8,452*	*21*	-	-	*2,098*	*9*	*160,770*	*517*	$1,326,395	3,570
User Fees - non add)																																
Plus:																																
Other Rent and Rent-Related (incl. White Oak Relocation)																															**131,639**	**0**
White Oak Relocation PDUFA (non-add)																															3,595	**0**
White Oak Relocation Reinspection User Fee (non-add)																															0	**0**
White Oak Relocation Proposed Reinspection User Fee (non-add)																															0	**0**
Other Rent and Rent Related MDUFMA (non-add)																															1,390	0
Other Rent and Rent Related PDUFA (non-add)																															17,996	0
Other Rent and Rent Related ADUFA (non-add)																															204	0
Other Rent and Rent Related for Proposed GDUFA (non-add)																															0	0
Other Rent and Rent Related AGDUFA (non-add)																															80	0
Other Rent and Rent Related Food Reinspection User Fee (non-add)																															592	0
Other Rent and Rent Related Proposed Reinspection User Fee (non-add)																															0	0
Other Rent and Rent Related for Center of Tobacco (non-add)																															1,550	0
Other Rent and Rent Related for Food Feed Recall User Fee (non-add)																															248	0
Other Rent and Rent Related for Proposed International Courier User Fee (non-add)																															0	0
Other Rent and Rent Related for Proposed Food VQIP User Fee (non-add)																															0	0
GSA Rent																															**205,472**	**0**
GSA Rent PDUFA (non-add)																															31,928	0
GSA Rent MDUFMA (non-add)																															4,308	0
GSA Rent ADUFA (non-add)																															1,115	0
GSA Rent for Proposed GDUFA (non-add)																															0	0
GSA Rent AGDUFA (non-add)																															340	0
GSA Rent Food Reinspection User Fee (non-add)																															1,338	0
GSA Rent Proposed Reinspection User Fee (non-add)																															0	0
GSA Rent Proposed Food VQIP User Fee (non-add)																															0	0
GSA Rent for Center of Tobacco (non-add)																															5,503	0
GSA Rent for Food Feed Recall User Fee (non-add)																															434	0
GSA Rent for Proposed International Courier User Fee (non-add)																															0	0
Export Certification User Fee																															**3,337**	**15**
Colors Certification User Fee																															**7,843**	**37**
Priority Review Voucher User Fee																															**4,582**	**0**
Buildings and Facilities																															**8,788**	**0**
TOTAL S&E PROGRAM:																															**3,832,204**	**13,496**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2013 PB	PREMARKET														POSTMARKET															
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION				INSPECTIONS				TOTAL		OUTREACH COORDINATION		APPLIED RESEARCH		LABORATORY ANALYSIS				INSPECTIONS						TOTAL		FDA	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN				COMPLIANCE				DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS																																
Center for Food Safety & Applied Nutrition	21,920	105	8,909	26	13,700	77	4,306	30					48,835	238	178,916	542	93,574	175	12,819	30	10,769	28	10,462	31	9,315	35	2,936	6	318,787	844	367,622	1,082
Field Activities													-	-	153,711	591	1,084	5	88,921	354	81,589	414	229,111	838	26,678	113	135,223	693	716,317	2,965	716,317	2,965
Export Certification User Fee: (non-add):Center													-	-	-	-													-	-	0	0
Field													-	-															-	-	0	0
Reinspection User Fee (non-add): Center													-	-															-	-	0	0
Field													-	-															-	-	0	0
Food and Feed Recall User Fee(non-add): Center													-	-	485	2													485	2	485	2
Field													-	-									9,823	23					9,823	23	9,823	23
Proposed International Courier User Fee (non-add): Center													-	-															-	-	0	0
Field													-	-													721	3	721	3	721	3
Proposed Food Registration and Inspection User Fee (non-add): Field													-	-									100,269	120					100,269	120	100,269	120
Center															46,736	49	31,919	23					6,498	16	4,325	12			89,478	100	89,478	100
Proposed Cosmetics User Fee(Non-add) : Center													-	-	12,012	42													12,012	42	12,012	42
Field													-	-					480	2	1,440	6	1,680	7			720	3	4,320	18	4,320	18
Proposed Food Contact Notification User Fee: (non-add) : Center	4,458	7											4,458	7															-	-	4,458	7
Field													-	-															-	-	0	0
Proposed Food VQIP user fee (non-add): Center													-	-	-	-													-	-	0	0
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-															-	-	0	0
FOODS TOTAL	**21,920**	**105**	**8,909**	**26**	**13,700**	**77**	**4,306**	**30**	**-**	**-**	**-**	**-**	**48,835**	**238**	**332,627**	**1,133**	**94,658**	**180**	**101,740**	**384**	**92,354**	**439**	**239,573**	**869**	**35,993**	**148**	**138,159**	**698**	**1,035,104**	**3,809**	**1,083,939**	**4,047**
HUMAN DRUGS																																
Center for Drug Evaluation & Research	659,881	2,324	46,123	88	31,228	124	10,879	43	10,943	50	9,492	43	768,546	2,672	254,031	737	18,421	78	2,975	14	589	3	10,660	55	6,848	35	1,799	9	295,323	932	1,063,869	3,603
Field Activities									25,891	143	35,172	151	61,063	294	27,900	169			14,679	76	3,741	22	32,913	191	46,389	175	8,000	38	133,682	671	194,745	965
PDUFA (non-add): Center	*314,589*	*1,361*	*18,898*	*65*	*21,057*	*85*	*7,811*	*30*	*7,709*	*35*	*5,436*	*24*	375,493	1,590	*125,881*	*400*													*125,881*	*400*	501,374	1,990
Field									*6,777*	*33*	*3,454*	*18*	10,231	51															-	-	10,231	51
Proposed GDUFA (non-add): Center	*166,938*	*200*											166,938	200	*35,793*	*50*													*35,793*	*50*	*202,731*	*250*
Field											*16,311*	*46*	16,311	46											*35,500*	*104*			*35,500*	*104*	*51,811*	*150*
Proposed Medical Product s Reinspection User Fee (Non-add) Field													-	-									*2,749*	*18*					*2,749*	*18*	*2,749*	*18*
Proposed BSUFA (non-add): Center	*15,304*	*59*											15,304	59															-	-	*15,304*	*59*
Field									*774*	*3*	*516*	*2*	1,290	5															-	-	*1,290*	*5*
Proposed International Courier User Fee (non-add): Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-															*481*	*2*	*481*	*2*
HUMAN DRUGS TOTAL	**659,881**	**2,324**	**46,123**	**88**	**31,228**	**124**	**10,879**	**43**	**36,834**	**193**	**44,664**	**194**	**829,609**	**2,966**	**281,931**	**906**	**18,421**	**78**	**17,654**	**90**	**4,330**	**25**	**43,573**	**246**	**53,237**	**210**	**9,799**	**47**	**429,005**	**1,602**	**1,298,614**	**4,568**
BIOLOGICS																																
Center for Biologics Evaluation & Research	192,983	686	24,871	103	29,796	97	795	3	2,591	9			251,036	948	33,689	113	251	2					2,357	12					36,297	127	287,333	1,075
Field Activities									5,226	21	201	1	5,427	22	7,351	43							28,857	162	2,400	9	1,387	7	39,995	220	45,422	242
PDUFA (non-add): Center	*86,067*	*306*			*13,683*	*49*	-	-	*947*	*3*			100,697	358	*2,466*	*9*													*2,466*	*9*	*103,163*	*367*
Field									*4,297*	*5*			4,297	5															-	-	4,297	5
Proposed Medical Product s Reinspection User Fee (Non-add) Field													-	-									*561*	*3*					*561*	*3*	*561*	*3*
Proposed BSUFA (non-add): Center	*774*	*3*											774	3																	774	*3*
Field													-	-																	0	*0*
MDUFMA (non-add): Center	*11,707*	*31*			*1,498*	*4*	*13*		*12*				13,223	35	*292*	*1*													*292*	*1*	13,515	*36*
Field									*619*	*1*			619	1															-	-	*619*	*1*
BIOLOGICS TOTAL	**192,983**	**686**	**24,871**	**103**	**29,796**	**97**	**795**	**3**	**7,817**	**30**	**201**	**1**	**256,463**	**970**	**41,041**	**156**	**251**	**2**	**-**	**-**	**-**	**-**	**31,214**	**174**	**2,400**	**9**	**1,387**	**7**	**76,293**	**347**	**332,756**	**1,317**
ANIMAL DRUGS & FEEDS																																
Center for Veterinary Medicine	68,949	267	3,507	18	903	5							73,359	290	37,550	176	12,443	53											49,993	229	123,352	519
Field Activities									1,985	8	809	4	2,794	12	16,367	74			6,003	35	1,282	7	25,727	152	1,253	17	7,121	27	57,753	312	60,547	334
ADUFA (non-add): Center	*26,996*	*66*											26,996	66																	26,996	*66*
Field									*464*	*2*			464	2															-	-	464	*2*
AGDUFA (non-add): Center	*6,527*	*20*											6,527	20															-	-	6,527	*20*
Field									*211*	*1*			211	1															-	-	*211*	*1*
Reinspection user fee (non-add): Center													-	-															-	-	0	*0*
Field													-	-									2,666	*18*					2,666	*18*	2,666	*18*
Proposed Food Registration and Inspection User Fee (Non-add) Field													-	-	-	-	-	-					3,805	*10*					3,805	*10*	3,805	*10*
Center															4,155	*8*	1,547	*3*											5,702	*11*	5,702	*11*
Proposed Medical Product s Reinspection User Fee (Non-add) Field													-	-									*140*	*1*					*140*	*1*	*140*	*1*
Export Certification User Fee (Non-add) Center													-	-	-	-													-	-	0	*0*
Food and Feed Recall User Fee(non-add): Center													-	-	545	*2*													545	*2*	545	*2*
Field													-	-									*668*	*2*					*668*	*2*	*668*	*2*
ANIMAL DRUGS & FEEDS TOTAL	**68,949**	**267**	**3,507**	**18**	**903**	**5**	**-**	**-**	**1,985**	**8**	**809**	**4**	**76,153**	**302**	**53,917**	**250**	**12,443**	**53**	**6,003**	**35**	**1,282**	**7**	**25,727**	**152**	**1,253**	**17**	**7,121**	**27**	**107,746**	**541**	**183,899**	**843**
DEVICES AND RADIOLOGICAL HEALTH																																
Center for Devices & Radiological Health	137,138	749	16,582	64	11,615	63	2,724	15					168,069	891	96,391	449	2,791	13	17,927	60									117,109	522	285,168	1,413
Field Activities									8,057	47	535	2	8,592	49	23,435	129			4,841	20	2,781	15	42,700	209	8,676	38	10,573	71	93,006	482	101,598	531
MQSA (non-add): Center													-	-	*6,003*	*31*													6,003	31	*6,003*	*31*
Field													-	-	*7,223*	*5*							*5,854*	*3*					13,077	8	13,077	*8*
MDUFMA (non-add): Center	*27,430*	*183*	*2,115*	*9*	*2,255*	*15*	*529*	*4*					32,329	211	*7,113*	*33*	*20*	-	*631*	*4*									7,764	37	40,093	*248*
Field									*1,222*	*12*			1,222	12									*59*	-					59	-	*1,281*	*12*
Proposed Medical Product s Reinspection User Fee (Non-add) Field													-	-									*3,579*	*24*					*3,579*	*24*	*3,579*	*24*
Proposed International Courier User Fee (non-add): Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-													*3,606*	*15*	*3,606*	*15*	*3,606*	*15*
DEVICES TOTAL	**137,138**	**749**	**16,582**	**64**	**11,615**	**63**	**2,724**	**15**	**8,057**	**47**	**535**	**2**	**176,661**	**940**	**119,826**	**578**	**2,791**	**13**	**22,768**	**80**	**2,781**	**15**	**42,700**	**209**	**8,676**	**38**	**10,573**	**71**	**230,116**	**1,004**	**386,766**	**1,944**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2013 PB	PREMARKET														POSTMARKET															
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION DOMESTIC		OUTREACH COORDINATION FOREIGN		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		TOTAL		OUTREACH COORDINATION COMPLIANCE		APPLIED RESEARCH		LABORATORY ANALYSIS DOMESTIC		LABORATORY ANALYSIS IMPORTS		INSPECTIONS DOMESTIC		INSPECTIONS FOREIGN		INSPECTIONS IMPORTS		TOTAL		FDA	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**34,354**	**157**									**34,354**	**157**	-	-	**24,877**	**113**		-	-	-	-	-	-	-	**24,877**	113	**59,231**	**270**
Proposed Reinspection user fee (non-add): Center													-	-			-			-	-	-	-	-	-	-	-	-	-	0
CENTER FOR TOBACCO PRODUCTS													-	-													**470,370**	**500**	**482,398**	**512**
Center for Tobacco Products			12,028	12									*12,028*	*12*	213,497	212	119,857	119	2,585	3			125,031	125					460,970	459	*472,998*	471
Field													-	-	2,092	9			2,090	8							5,248	24	9,400	41	9,400	41
HEADQUARTERS / OFFICE OF THE COMMISSIONER																																
Headquarters / Office of the Commissioner	**96,815**	**176**	**27,450**	**195**	**5,900**	**32**	**1,265**	**8**	**3,699**	**24**	**3,125**	**18**	**138,254**	**453**	**56,093**	**213**	**25,400**	**102**	**10,020**	**52**	**6,814**	**43**	**25,888**	**119**	**6,868**	**37**	**11,297**	**71**	**142,380**	**636**	**280,635**	**1,089**
USER FEES (non-add): PDUFA	*28,139*	*129*	*1,925*	*4*	*2,438*	*10*	*548*	*2*	*1,385*	*6*	*624*	*3*	**34,439**	**154**	*9,008*	*32*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*9,008*	*32*	*43,447*	*186*
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*5,090*	*19*	*275*	*1*	*487*	*2*	*72*	-	*241*	*1*	-	-	**6,184**	**23**	*963*	*3*	*3*	-	*83*	-	-	-	*8*	-	-	-	-	-	*1,057*	*3*	*7,221*	*26*
ADUFA	*1,208*	*4*	-	-	-	-	-	-	*21*	-	-	-	**1,234**	**4**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*1,234*	*4*
AGDUFA	*294*	*1*	-	-	-	-	-	-	*10*	-	-	-	**304**	**1**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*304*	*1*
Proposed GDUFA	*15,869*	*25*	-	-	-	-	-	-	-	-	*1,550*	*6*	**17,419**	**31**	*3,402*	*6*	-	-	-	-	-	-	-	-	*3,375*	*13*	-	-	*6,777*	*19*	*24,196*	*50*
TOBACCO	-	-	*386*	*1*	-	-	-	-	-	-	-	-	**386**	**1**	*6,859*	*15*	*3,851*	*9*	*83*	-	-	-	*4,017*	*9*	-	-	-	-	*14,810*	*33*	*15,196*	*34*
Food Reinspection (Indefinite) user fee																							*3,549*	*7*	-	-	-	-	*3,549*	*7*	*3,549*	*7*
Food and Feed Recall User Fee																							*691*	*2*	-	-	-	-	*691*	*2*	*691*	*2*
Proposed Medical Product s Reinspection User Fee																							*6,169*	*10*	-	-	-	-	*6,169*	*10*	*6,169*	*10*
Proposed Cosmetics User Fee																							*980*	*3*					*980*	*3*	*980*	*3*
Proposed Food Contact Notification User Fee																							*267*	*1*					*267*	*1*	*267*	*1*
Proposed International Courier User Fee																							-		-	-	*289*	*1*	*289*	*1*	*289*	*1*
Proposed Food Registration Inspection User Fee																							*12,544*	*32*					*12,544*	*32*	*12,544*	*32*
Proposed BSUFA User Fee																							*1,290*	*5*					*1,290*	*5*	*1,290*	*5*
Proposed Food VQIP User Fee																							-	-	-	-	-	-	-	-	*0*	*0*
HEADQUARTERS / OC TOTAL	**96,815**	**176**	**27,450**	**195**	**5,900**	**32**	**1,265**	**8**	**3,699**	**24**	**3,125**	**18**	**6,164**	**23**	**56,093**	**213**	**25,400**	**102**	**10,020**	**52**	**6,814**	**43**	**25,888**	**119**	**6,868**	**37**	**11,297**	**71**	**142,380**	**636**	**280,635**	**1,089**
SUB-TOTAL:	**1,177,686**	**4,307**	**139,470**	**556**	**93,142**	**398**	**19,969**	**99**	**58,392**	**302**	**49,334**	**239**	**1,405,993**	**5,451**	**1,101,054**	**3,457**	**273,821**	**547**	**160,770**	**644**	**107,961**	**529**	**408,675**	**1,770**	**103,427**	**457**	**183,584**	**902**	**2,495,890**	**8,551**	**4,068,237**	**14,590**
Total Center	1,177,686	4,307	127,442	544	93,142	398	19,969	99	17,233	83	12,617	61	1,315,998	5,062	656,670	2,230	152,880	423	43,741	196	18,168	71	49,367	217	23,031	106	16,032	86	999,890	3,288	2,940,208	9,521
Total Field	-	-	-	-	-	-	-	-	41,159	219	36,717	198	77,876	377	228,834	1,006	1,084	6	114,444	486	89,393	488	359,308	1,553	85,396	352	162,304	788	1,040,753	4,651	1,128,029	5,089
User Fee (PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP and proposed user fees (Non - add)	$711,335	$2,414	$35,010	$82	$41,411	$165	$8,972	$36	$24,689	$102	$27,891	$99	$849,308	$2,898	$484,660	$911	$157,197	$154	$5,952	$17	$1,440	$6	$300,104	$487	$43,200	$129	$11,065	$48	$1,003,618	$1,752	$1,969,057	4,709
Plus:																																
Other Rent and Rent-Related (incl. White Oak Relocation)																															**171,943**	**0**
White Oak Relocation PDUFA (non-add)																															3,637	**0**
White Oak Relocation for Proposed Medical Product s Reinspection User Fee																															0	**0**
White Oak Relocation for Proposed BSUFA User Fee																															0	
Other Rent and Rent Related MDUFMA (non-add)																															1,701	0
Other Rent and Rent Related PDUFA (non-add)																															25,130	0
Other Rent and Rent Related ADUFA (non-add)																															290	0
Other Rent and Rent Related for Proposed GDUFA (non-add)																															6,447	0
Other Rent and Rent Related AGDUFA (non-add)																															100	0
Other Rent and Rent Related Food Reinspection (Indefinite) User Fee (non-add)																															619	0
Other Rent and Rent Related for Center of Tobacco (non-add)																															1,628	0
Other Rent and Rent Related for Food and Feed Recall User Fee (non-add)																															259	0
Other Rent and Rent Related for Proposed International Courrier User Fee (non-add)																															176	0
Other Rent and Rent Related for Proposed Cosmetics User Fee (non-add)																															504	0
Other Rent and Rent Related for Proposed Food Contact Notification User Fee (non-add)																															64	0
Other Rent and Rent Related for Proposed Medical Product s Reinspection User Fee																															476	0
Other Rent and Rent Related for Proposed Food Registration and Inspection User Fee																															3,031	0
Other Rent and Rent Related for Proposed Food VQIP User Fee (non-add)																															0	0
Other Rent and Rent Related for Proposed BSUFA User Fee (non-add)																															576	
GSA Rent																															**228,420**	**0**
GSA Rent PDUFA (non-add)																															21,969	0
GSA Rent MDUFMA (non-add)																															5,270	0
GSA Rent ADUFA (non-add)																															1,556	0
GSA Rent for Proposed GDUFA (non-add)																															13,815	0
GSA Rent AGDUFA (non-add)																															453	0
GSA Rent Food Reinspection User Fee (non-add)																															1,399	0
GSA Rent Proposed Food VQIP User Fee (non-add)																															0	0
GSA Rent for Center of Tobacco (non-add)																															5,778	0
GSA Rent for Food and Feed Recall User Fee (non-add)																															454	0
GSA Rent for Proposed Cosmetics User Fee (non-add)																															882	0
GSA Rent for Proposed Food Contact Notification User Fee (non-add)																															112	0
GSA Rent for Proposed Medical Product s Reinspection User Fee																															1,072	0
GSA Rent for Proposed Food Registration and Inspection User Fee																															5,371	0
GSA Rent for Proposed International Courrier User Fee (non-add)																															307	0
GSA Rent for Proposed BSUFA User Fee (non-add)																															1,008	0
Export Certification User Fee																															**4,604**	**22**
Colora Certification User Fee																															**7,843**	**37**
Buildings and Facilities																															**5,320**	**0**
TOTAL S&E PROGRAM:																															**4,486,368**	**14,648**

Food and Drug Administration
HIV/AIDS
(Dollars in Thousands)

Program	FY 2009 Actual	FY 2010 Actual	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
Human Drugs	*$36,643*	*$33,443*	*$36,572*	*$37,303*	*$37,444*
Biologics	*$32,045*	*$33,387*	*$33,189*	*$33,189*	*$33,189*
Medical Devices	*$2,506*	*$1,846*	*$1,697*	*$1,697*	*$1,697*
Toxicological	*$102*	*$235*	*$132*		
Other Activities	*$3,355*	*$3,529*	*$3,469*	*$3,469*	*$3,469*
Field Activity	*$30,810*	*$36,256*	*$38,586*	*$40,710*	*$42,480*
Total HIV/AIDS	**$ 105,461**	**$ 108,696**	**$ 113,645**	**$ 116,368**	**$ 118,279**

FOOD AND DRUG ADMINISTRATION
User Fee History

(Dollars in Thousands)

USER FEES: Appropriations

	FY 2010 Actual		FY 2011 Actual		FY 2012 Enacted		FY 2013 Estimate	
	FTE	$	FTE	$	FTE	$	FTE	$
Definite Appropriations:								
PDUFA								
- Human Drugs	*1,849*	*$414,877*	*1,980*	*$456,222*	*1,980*	*$490,877*	*1,990*	*$501,334*
- Biologics	*341*	*$76,781*	*355*	*$87,443*	*355*	*$101,010*	*367*	*$103,163*
- Office of Regulatory Affairs	*54*	*$8,024*	*56*	*$9,943*	*56*	*$14,225*	*56*	*$14,528*
- Headquarters and Office of the Commissioner	*172*	*$28,953*	*195*	*$28,982*	*195*	*$42,541*	*186*	*$43,447*
- GSA Rent		*$25,632*		*$18,568*		*$31,928*		*$21,569*
- Other Rent and Rent Related Activities		*$18,991*		*$23,253*		*$17,996*		*$25,130*
- FDA Consolidation at White Oak		*$0*		*$3,415*		*$3,595*		*$3,637*
Subtotal, PDUFA	**2,416**	**$573,258**	**2,587**	**$627,826**	**2,587**	**$702,172**	**2,599**	**$712,808**
MDUFMA								
- Medical Devices and Radiological Health	*232*	*$41,283*	*248*	*$39,987*	*209*	*$33,177*	*248*	*$40,093*
- Biologics	*30*	*$7,039*	*36*	*$8,531*	*28*	*$11,183*	*36*	*$13,515*
- Office of Regulatory Affairs	*13*	*$1,825*	*13*	*$2,015*	*13*	*$1,572*	*13*	*$1,900*
- Headquarters and Office of the Commissioner	*23*	*$3,592*	*26*	*$3,983*	*21*	*$5,975*	*26*	*$7,221*
- GSA Rent		*$2,361*		*$3,200*		*$4,308*		*$5,270*
- Other Rent and Rent Related Activities		*$1,087*		*$1,541*		*$1,390*		*$1,701*
Subtotal, MDUFMA	**298**	**$57,187**	**323**	**$59,257**	**271**	**$57,605**	**323**	**$69,700**
ADUFA								
- Animal Drugs and Feeds	*65*	*$14,644*	*67*	*$14,967*	*66*	*$19,261*	*66*	*$26,996*
- Office of Regulatory Affairs	*2*	*$546*	*2*	*$302*	*2*	*$315*	*2*	*$464*
- Headquarters and Office of the Commissioner	*4*	*$631*	*4*	*$651*	*4*	*$873*	*4*	*$1,224*
- GSA Rent		*$659*		*$672*		*$1,115*		*$1,556*
- Other Rent and Rent Related Activities		*$121*		*$41*		*$204*		*$290*
Subtotal, ADUFA	**71**	**$16,601**	**73**	**$16,633**	**72**	**$21,768**	**72**	**$30,530**
AGDUFA								
- Animal Drugs and Feeds	*22*	*$4,225*	*23*	*$4,321*	*20*	*$4,898*	*20*	*$6,527*
- Office of Regulatory Affairs	*1*	*$144*	*1*	*$156*	*1*	*$160*	*1*	*$211*
- Headquarters and Office of the Commissioner	*1*	*$158*	*1*	*$165*	*1*	*$228*	*1*	*$304*
- GSA Rent		*$105*		*$18*		*$340*		*$453*
- Other Rent and Rent Related Activities		*$105*		*$26*		*$80*		*$100*
Subtotal, AGDUFA	**24**	**$4,737**	**25**	**$4,686**	**22**	**$5,706**	**22**	**$7,595**
TOBACCO								
- Tobacco Products	84	$62,355	*225*	*$135,027*	366	$448,501	471	$472,998
- Office of Regulatory Affairs	6	$2,063	*10*	*$1,198*	26	$6,250	41	$9,400
- Headquarters and Office of the Commissioner	23	$3,375	*21*	*$2,810*	34	$15,196	34	$15,196
- GSA Rent		$3,691		*$4,899*		$5,503		$5,778
- Other Rent and Rent Related Activities		$503		*$1,279*		$1,550		$1,628
Subtotal, TOBACCO	**113**	**$71,987**	**256**	**$145,213**	**426**	**$477,000**	**546**	**$505,000**
REINSPECTION:								
- Office of Regulatory Affairs					***66***	***9,375***	***66***	***9,800***
Foods Program Estimate					*48*	*$6,825*	*48*	*$7,134*
Human Drugs Program Estimate					*18*	*$2,550*	*18*	*$2,666*
- Headquarters and Office of the Commissioner					*7*	*$3,395*	*7*	*$3,549*
- GSA Rent						*$1,338*		*$1,399*
- Other Rent and Rent Related Activities						*$592*		*$619*
Subtotal, Reinspection User Fee					***73***	***14,700***	***73***	***15,367***
RECALL								
- Foods					*2*	*$464*	*2*	*$485*
- Animal Drugs and Feeds					*2*	*$521*	*2*	*$545*
- Office of Regulatory Affairs					*25*	*$10,036*	*25*	*$10,491*
- Headquarters and Office of the Commissioner					*2*	*$661*	*2*	*$691*
- GSA Rent						*$434*		*$454*
- Other Rent and Rent Related Activities						*$248*		*$259*
Subtotal, Recall					**31**	**$12,364**	**31**	**$12,925**
Proposed Definite Appropriations:								
Generic Prescription Drug User Fee (GDUFA):								
- Human Drugs							*250*	*$202,731*
- Office of Regulatory Affairs							*150*	*$51,811*
- Headquarters and Office of the Commissioner							*50*	*$24,196*
- GSA Rent								*$13,815*
- Other Rent and Rent Related Activities								*$6,447*
Subtotal, Generic Prescription Drug							***450***	***$299,000***
Medical Products Reinspection User Fee:								
- Office of Regulatory Affairs							***46***	***7,029***
-Human Drug Program							*18*	*2,749*
- Biologics Program							***3***	***561***
-Animal Drugs Program							*1*	*$140*
-Devices and Radiological Health Program							*24*	*$3,579*
- Headquarters and Office of the Commissioner							*10*	*$6,169*
- GSA Rent								*$1,072*
- Other Rent and Rent Related Activities								*$476*
Subtotal, Medical Products Reinspection							***56***	***14,746***
International Courier User Fee:								
- Office of Regulatory Affairs							***20***	***4,808***
-Foods Program							*3*	*721*
- Human Drugs Program							***2***	***481***
-Devices and Radiological Health Program							*15*	*$3,606*
- Headquarters and Office of the Commissioner							*1*	*$289*

FOOD AND DRUG ADMINISTRATION
User Fee History

(Dollars in Thousands)

- GSA Rent								*$307*
- Other Rent and Rent Related Activities								*$176*
Subtotal, Medical Products Reinspection							***21***	***5,580***
Food Establishment Registration Fee								
- Foods							*100*	*$89,478*
- Animal Drugs and Fees							*11*	*$5,702*
- Office of Regulatory Affairs							*130*	*$104,074*
- Headquarters and Office of the Commissioner							*32*	*$12,544*
- GSA Rent								*$5,371*
- Other Rent and Rent Related Activities								*$3,031*
Subtotal							**273**	**$220,200**
Cosmetic User Fee								
- Foods							*42*	*$12,012*
- Office of Regulatory Affairs							*18*	*$4,320*
- Headquarters and Office of the Commissioner							*3*	*$980*
- GSA Rent								*$882*
- Other Rent and Rent Related Activities								*$504*
Subtotal							**63**	**$18,698**
Food Contact Notification User Fee								
- Foods							*7*	*$4,458*
- Office of Regulatory Affairs							*0*	*$0*
- Headquarters and Office of the Commissioner							*1*	*$267*
- GSA Rent								*$112*
- Other Rent and Rent Related Activities								*$64*
Subtotal							**8**	**$4,901**
Biosimilar User Fee								
- Human Drugs							*59*	*$15,304*
- Biologics							*3*	*$774*
- Office of Regulatory Affairs							*5*	*$1,290*
- Headquarters and Office of the Commissioner							*5*	*$1,290*
- GSA Rent								*$1,008*
- Other Rent and Rent Related Activities								*$576*
Subtotal BSUFA							**72**	**$20,242**
Indefininate Appropriations:								
MQSA								
- Devices and Radiological Health	*23*	*$4,284*	*31*	*$4,912*	*26*	*$6,003*	*31*	*$6,003*
- Office of Regulatory Affairs	*8*	*$9,510*	*8*	*$9,459*	*8*	*$13,077*	*8*	*$13,077*
- Headquarters and Office of the Commissioner	*2*	*$270*	*2*	*$268*	*2*	*$238*	*2*	*$238*
Subtotal, MQSA	**33**	**$14,064**	**41**	**$14,639**	**36**	**$19,318**	**41**	**$19,318**
Export Certification	**20**	**$3,663**	**15**	**$3,337**	**15**	**$3,337**	**22**	**$4,604**
Certification Fund	**38**	**$6,768**	**37**	**$7,843**	**37**	**$7,843**	**37**	**$7,843**
Priority Review Vouchers						**$4,582**		
Total, User Fees	**3,013**	**748,265**	**3,358**	**879,434**	**3,569**	**1,326,395**	**4,709**	**1,969,057**

FOOD AND DRUG ADMINISTRATION
User Fee History
(Dollars in Thousands)

USER FEES: Obligations

	FY 2008 Actual		FY 2009 Actual		FY 2010 Actual		FY 2011 Actual	
	FTE	$	FTE	$	FTE	$	FTE	$
PDUFA:								
- Human Drugs	*1,252*	*$321,282*	*1,636*	*$351,021*	*1,849*	*$409,029*	*1,980*	*$456,222*
- Biologics	*304*	*$70,890*	*326*	*$79,122*	*341*	*$80,664*	*355*	*$87,443*
- Office of Regulatory Affairs	*40*	*$7,259*	*55*	*$9,905*	*54*	*$9,988*	*56*	*$9,943*
- Headquarters and Office of the Commissioner	*166*	*$21,936*	*166*	*$35,018*	*172*	*$28,954*	*195*	*$28,982*
- GSA Rent		*$11,821*		*$16,886*		*$25,632*		*$18,568*
- Other Rent and Rent Related Activities		*$13,409*		*$20,099*		*$18,991*		*$23,253*
- White Oak		*$4,190*		*$0*		*$0*		*$3,415*
Subtotal, PDUFA	**1,762**	**$450,787**	**2,183**	**$512,051**	**2,416**	**$573,258**	**2,587**	**$627,826**
MDUFMA								
- Medical Devices and Radiological Health	*164*	*$23,289*	*176*	*$32,462*	*232*	*$41,256*	*248*	*$39,987*
- Biologics	*28*	*$6,005*	*29*	*$7,227*	*30*	*$6,990*	*36*	*$8,531*
- Office of Regulatory Affairs	*8*	*$1,230*	*9*	*$1,352*	*13*	*$1,901*	*13*	*$2,015*
- Headquarters and Office of the Commissioner	*21*	*$2,967*	*22*	*$3,389*	*23*	*$3,592*	*26*	*$3,983*
- GSA Rent		*$2,081*		*$1,982*		*$2,361*		*$3,200*
- Other Rent and Rent Related Activities		*$850*		*$892*		*$1,087*		*$1,541*
Subtotal, MDUFMA	**221**	**$36,422**	**236**	**$47,304**	**298**	**$57,187**	**323**	**$59,257**
ADUFA								
- Animal Drugs and Feeds	*59*	*$12,260*	*64*	*$11,792*	*65*	*$14,926*	*67*	*$14,967*
- Office of Regulatory Affairs	*0*	*$0*	*2*	*$250*	*2*	*$264*	*2*	*$302*
- Headquarters and Office of the Commissioner	*4*	*$563*	*4*	*$594*	*4*	*$631*	*4*	*$651*
- GSA Rent		*$598*		*$628*		*$659*		*$672*
- Other Rent and Rent Related Activities		*$109*		*$115*		*$121*		*$41*
Subtotal, ADUFA	**63**	**$13,530**	**70**	**$13,379**	**71**	**$16,601**	**73**	**$16,633**
AGDUFA								
- Animal Drugs and Feeds			*11*	*$1,854*	*22*	*$4,225*	*23*	*$4,321*
- Office of Regulatory Affairs			*2*	*$54*	*1*	*$144*	*1*	*$156*
- Headquarters and Office of the Commissioner			*1*	*$17*	*1*	*$158*	*1*	*$165*
- GSA Rent				*$100*		*$105*		*$18*
- Other Rent and Rent Related Activities				*$100*		*$105*		*$26*
Subtotal, AGDUFA			**14**	**$2,125**	**24**	**$4,737**	**25**	**$4,686**
TOBACCO								
- Tobacco Products					*84*	*$62,355*	*225*	*$135,027*
- Office of Regulatory Affairs					*6*	*$2,063*	*10*	*$1,198*
- Headquarters and Office of the Commissioner					*23*	*$3,375*	*21*	*$2,810*
- GSA Rent						*$3,691*		*$4,899*
- Other Rent and Rent Related Activities						*$503*		*$1,279*
Subtotal, TOBACCO					**113**	**$71,987**	**256**	**$145,213**
MQSA	31	$13,537	31	$13,731	33	$14,064	41	$14,639
Export Certification	17	$2,707	10	$1,651	20	$3,663	15	$3,337
Certification Fund	39	$7,379	38	$7,407	38	$6,768	37	$7,843
Subtotal	**87**	$23,623	**79**	$22,789	**91**	$24,495	**93**	$25,819
Total, FDA	**2,133**	**$524,362**	**2,582**	**$597,648**	**3,013**	**$748,265**	**3,358**	**$879,434**

USER FEES: Collections

	FY 2010 Actual	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
	$	$	$	$
PDUFA Collections	$572,614	$627,826	$702,172	$712,808
MDUFMA Collections	$64,865	$59,257	$57,605	$69,700
ADUFA Collections	$15,441	$16,633	$21,768	$30,530
AGDUFA Collections	$4,521	$4,686	$5,706	$7,595
Tobacco Collections 1/	$193,114	$145,213	$477,000	$505,000
MQSA Collections	$15,485	$14,639	$19,318	$19,318
Export Certification	$3,225	$3,337	$3,337	$4,604
Certification Fund	$7,811	$7,843	$7,843	$7,843
FSMA Reinspection	$0	$0	$14,700	$15,367
FSMA Recall	$0	$0	$12,364	$12,925
GDUFA Collections	$0	$0	$0	$299,000
Medical Products	$0	$0	$0	$14,746
International Courier				$5,580
Food Establishment				$220,200
Cosmetics				$18,698
Food Contact				$4,901
BsUFA Collections				$20,242
Priority Review Voucher	$0	$0	$4,582	$0
Total, User Fees Collections	**$877,076**	**$879,434**	**$1,326,395**	**$1,969,057**

1/ The Family Smoking Prevention and Tobacco Control Act authorizes quarterly collection of industry user fees. As required by law, FDA bills and collects Tobacco user fees at the end of each quarter, which means that the fourth quarter collections are not available for obligation until the first quarter of the following fiscal year.

Food and Drug Administration

FY 2011 - FY 2013 Crosscutting Information

(Program Level in Millions)

	FY 2011 Actual	FY 2012 Enacted	FY 2013 Estimate
Antimicrobial Resistance	**30.825**	**30.034**	**28.509**
Budget Authority (non-add)	*27.733*	*26.849*	*25.223*
Biosimilars	**7.900**	**8.158**	**40.379**
Budget Authority (non-add)	*7.900*	*8.158*	*20.137*
Bioterrorism	**324.965**	**342.487**	**345.771**
Food Defense	*217.490*	*217.489*	*217.489*
Medical Countermeasures	*100.504*	*118.027*	*121.311*
Physical Security	*6.971*	*6.971*	*6.971*
Budget Authority (non-add)	*312.529*	*332.709*	*335.941*
Blood Safety	**114.464**	**122.370**	**125.458**
Budget Authority (non-add)	*89.114*	*88.907*	*88.344*
BSE (Prion Disease)	**25.639**	**26.381**	**27.036**
Budget Authority (non-add)	*23.999*	*24.298*	*24.855*
Dietary Supplements	**17.704**	**18.902**	**19.451**
Budget Authority (non-add)	*17.704*	*18.902*	*19.451*
Drug Marketing, Advertising, and Communication Activities	**17.854**	**17.133**	**16.967**
Budget Authority (non-add)	*15.279*	*14.433*	*14.182*
Drug Safety	**915.751**	**974.885**	**1,153.219**
Pre-market	*529.559*	*573.077*	*680.021*
Post-market	*386.192*	*401.808*	*473.198*
Office of Surveillance & Epidemiology (non-add)	*83.700*	*85.500*	*87.892*
Budget Authority (non-add)	*541.522*	*552.938*	*537.326*
Food Labeling	**10.876**	**11.243**	**11.549**
Budget Authority (non-add)	*10.876*	*11.243*	*11.549*
Food Safety	**1,175.377**	**1,171.771**	**1,425.130**
Food Defense (non-add)	*217.490*	*217.489*	*217.489*
Budget Authority (non-add)	*1,175.377*	*1,144.707*	*1,150.725*
Human Generic Drugs Program	**104.034**	**105.736**	**407.005**
Office of Generic Drugs (non-add)	*55.324*	*56.714*	*98.384*
Field Drug Program (for Generic Drugs (non-add)	*8.097*	*8.029*	*59.840*
Budget Authority (non-add)	*104.034*	*105.736*	*108.005*
Immunization	**23.269**	**26.118**	**26.417**
Budget Authority (non-add)	*16.189*	*16.219*	*16.062*
Medical Countermeasures Initiative (MCMi)	**$0.000[1]**	**$20.038**	**$23.548**
Budget Authority	*$0.000*	*$20.038*	*$23.548*
Medical Device Surveillance	**27.704**	**27.784**	**27.511**
Budget Authority (non-add)	*22.336*	*22.408*	*21.970*
Over-the-Counter Drugs	**17.584**	**18.311**	**18.369**
Budget Authority (non-add)	*8.202*	*8.609*	*8.534*
Pandemic Influenza	**43.557**	**44.070**	**44.237**
Budget Authority (non-add)	*33.831*	*34.292*	*34.407*
Pre-Market Human Drug Review	**841.823**	**882.777**	**1,087.785**
Budget Authority (non-add)	*398.523*	*396.100*	*387.564*
Tissues	**17.653**	**18.150**	**18.105**
Budget Authority (non-add)	*17.172*	*16.972*	*16.902*
Women's Health	**59.665**	**66.915**	**67.747**
Budget Authority (non-add)	*25.194*	*25.606*	*25.902*
Office of Women's Health (non-add)	*6.040*	*6.040*	*6.040*
Breast Cancer (MQSA) (non-add)	*20.516*	*25.195*	*25.195*

Summary of Central Account

FDA uses the Central Account to pay a variety of costs that FDA pays for centralized services and assessments. It is generally more efficient to purchase services that have FDA-wide benefit when FDA purchases these services centrally from one account. The savings that result allow FDA components to have more resources available for public health programs.

There are four main categories of expenditures from the central account: Program Support Center (PSC), facilities, information technology, and support services.

If the charge universally benefits FDA centers, ORA and offices, charges are based on Full-Time Equivalent (FTE). In certain cases, charges are limited to the specific FDA centers, ORA and offices that benefit from the services.

Program Support Center (PSC)

- PSC assessments are for centralized services that PSC provides to FDA. These funds provide various administrative and program support services, including financial management services, human resources services, building operations, Federal Occupational Health Services, HHS University, payroll systems, and enterprise applications.

Facilities

- The Facilities category includes the NIH Management Fund that supports lab and office space occupied by CBER and CDER at the NIH campus and rent-related costs such as utilities, maintenance, and janitorial and guard services incurred by NCTR in support of the Arkansas Regional lab. In addition, this subcategory includes recurring costs for maintenance of alarm systems, lock work for FDA headquarters, x-ray machines and explosive detection devices for FDA sites across the nation. This subcategory also includes non-recurring services such as one-time security system installations to meet minimum security standards as required by the Department of Homeland Security and Presidential directives.

Information Technology

- The IT expenditures include five subcategories: IT security, telecommunications costs, operations and maintenance of agency-wide systems (AIMS, EASE, FDA Internet/intranet, etc.), enterprise agreements (including enterprise information management), and miscellaneous IT costs, such as Departmental tap for consolidated grants management system and NIH computer charges.

Support Services

- The support services category includes: TAPS/Assessments for HHS Department-wide initiatives, Secretary Priorities, Joint Funding Arrangements with other HHS agencies, mail and courier services for mail rooms, General Service Administration Fleet Mail vehicles, Piney Bowes equipment and maintenance, records storage at the National Archives and Records Administration; interpreting services, ethics review, A-123 activities, A-76 studies, succession planning, Equal Employment Opportunity settlements, and other employee services, such as background investigations.

The following tables reflect program level expenditures by budget authority and user fees from the FDA Central Account for FY 2010 actual and estimated FY 2011, FY 2012.

FY 2011 Actuals

	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	3,412		1,499		4,065		1,662		10,638	-
Field Activities	8,006		3,518		9,540		3,898		24,962	-
FOODS TOTAL	11,418	-	5,017	-	13,605	-	5,560		35,600	-
HUMAN DRUGS										
Center for Drug Evaluation & Research	8,724	14,580	3,833	6,406	10,395	19,265	4,248	7,100	27,200	47,351
Field Activities	2,193	338	963	148	2,613	446	1,068	165	6,837	1,097
HUMAN DRUGS TOTAL	10,917	14,918	4,796	6,554	13,008	19,711	5,316	7,265	34,037	48,448
BIOLOGICS										
Center for Biologics Evaluation & Research	4,639	3,402	2,039	1,495	5,528	4,645	2,259	1,657	14,465	11,199
Field Activities	707	85	311	37	842	121	344	42	2,204	285
BIOLOGICS TOTAL	5,346	3,487	2,350	1,532	6,370	4,766	2,603	1,699	16,669	11,484
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,254	156	551	68	1,494	778	611	76	3,910	1,078
Field Activities	878		386		1,047		428		2,739	-
ANIMAL DRUGS & FEEDS TOTAL	2,132	156	937	68	2,541	778	1,039	76	6,649	1,078
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	3,425	933	1,505	410	4,081	1,896	1,668	454	10,679	3,693
Field Activities	1,426	50	626	22	1,698	102	694	24	4,444	198
DEVICES TOTAL	4,851	983	2,131	432	5,779	1,998	2,362	478	15,123	3,891
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	486	-	214	-	580	-	237	-	1,517	-
HEADQUARTERS/OFFICE OF THE COMMISSIONER	4,861	-	2,136	-	5,792	-	2,367	-	15,156	-
TOTAL BA and UF:	40,011	19,544	17,581	8,586	47,675	27,253	19,484	9,518	124,751	64,901

FY 2012 Estimate

	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	3,381		1,486		4,028		1,647		10,542	-
Field Activities	7,934		3,486		9,454		3,863		24,737	-
FOODS TOTAL	11,315	-	4,972	-	13,483	-	5,510		35,280	-
HUMAN DRUGS										
Center for Drug Evaluation & Research	8,645	14,449	3,799	6,348	10,301	19,092	4,210	7,036	26,955	46,925
Field Activities	2,173	335	954	147	2,589	442	1,058	164	6,775	1,087
HUMAN DRUGS TOTAL	10,819	14,784	4,753	6,495	12,891	19,534	5,268	7,200	33,731	48,012
BIOLOGICS										
Center for Biologics Evaluation & Research	4,597	3,371	2,021	1,482	5,478	4,603	2,239	1,642	14,335	11,098
Field Activities	701	84	308	37	834	120	341	42	2,184	282
BIOLOGICS TOTAL	5,298	3,456	2,329	1,518	6,313	4,723	2,580	1,684	16,519	11,381
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,243	155	546	67	1,481	771	606	75	3,875	1,068
Field Activities	870		383		1,038		424		2,714	-
ANIMAL DRUGS & FEEDS TOTAL	2,113	155	929	67	2,518	771	1,030	75	6,589	1,068
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	3,394	925	1,491	406	4,044	1,879	1,653	450	10,583	3,660
Field Activities	1,413	50	620	22	1,683	101	688	24	4,404	196
DEVICES TOTAL	4,807	974	2,112	428	5,727	1,980	2,341	474	14,987	3,856
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	482	-	212	-	575	-	235	-	1,503	-
HEADQUARTERS/OFFICE OF THE COMMISSIONER	4,817	-	2,117	-	5,740	-	2,346	-	15,020	-
TOTAL BA and UF:	39,651	19,368	17,423	8,509	47,246	27,008	19,309	9,432	123,628	64,317

Note: Reduction of .009% representing contract savings of $22M based on agency BA

FY 2013 Estimate

	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	3,381		1,486		4,028		1,647		10,542	-
Field Activities	7,934		3,486		9,454		3,863		24,737	-
FOODS TOTAL	11,315	-	4,972	-	13,483	-	5,510		35,280	-
HUMAN DRUGS										
Center for Drug Evaluation & Research	8,645	14,449	3,799	6,348	10,301	19,092	4,210	7,036	26,955	46,925
Field Activities	2,173	335	954	147	2,589	442	1,058	164	6,775	1,087
HUMAN DRUGS TOTAL	10,819	14,784	4,753	6,495	12,891	19,534	5,268	7,200	33,731	48,012
BIOLOGICS										
Center for Biologics Evaluation & Research	4,597	3,371	2,021	1,482	5,478	4,603	2,239	1,642	14,335	11,098
Field Activities	701	84	308	37	834	120	341	42	2,184	282
BIOLOGICS TOTAL	5,298	3,456	2,329	1,518	6,313	4,723	2,580	1,684	16,519	11,381
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,243	155	546	67	1,481	771	606	75	3,875	1,068
Field Activities	870		383		1,038		424		2,714	-
ANIMAL DRUGS & FEEDS TOTAL	2,113	155	929	67	2,518	771	1,030	75	6,589	1,068
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	3,394	925	1,491	406	4,044	1,879	1,653	450	10,583	3,660
Field Activities	1,413	50	620	22	1,683	101	688	24	4,404	196
DEVICES TOTAL	4,807	974	2,112	428	5,727	1,980	2,341	474	14,987	3,856
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	482	-	212	-	575	-	235	-	1,503	-
HEADQUARTERS/OFFICE OF THE COMMISSIONER	4,817	-	2,117	-	5,740	-	2,346	-	15,020	-
TOTAL BA and UF:	39,651	19,368	17,423	8,509	47,246	27,008	19,309	9,432	123,628	64,317

FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services Charges and Assessments
Fiscal Year 2011

ASSESSMENTS: $1,161,109

Interagency Council Funds $87,351
Funding to support government wide financial, information technology, procurement, human capital, and other management activities.

NIH eRA Grants Management System $153,693
Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System

Capital Security Cost sharing $212,784
Department of State charge for a "Head Tax" (Capital Security Cost Sharing)

Office of Commissioned Corps Force Management $73,213
SGLI reimbursement

Department Ethics Program $633,550
The Office of General Counsel provides legal and related support services to the FDA.

Federal Audit Clearinghouse $518

FEE FOR SERVICE:

$30,928,374

Program Support Center/FOH/OS ($13,338,939):

Provides various services to the FDA, including some Information and Systems Management Services. The following is a breakdown of costs.

Financial Management Services (FMS):
599,645

Strategic Acquisition Service: $5,137

Administrative Operations Service: $12,734,157
Includes costs for security, building operations, shredding, storage, graphics, property disposal, transhare, mail and payroll services.

Federal Occupational Health (FOH): **$2,194,358**
FDA agency health units and services

Information & System Management Services **($15,395,377):**

Freedom of Information (FOIA) $154,739

Unified Financial Management Systems (UFMS) $6,282,770
The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.

HCAS O&M $2,220,468
HCAS O&M services provide support for daily operations of the HCAS application.

Telecommunication Services $997,887
Telecommunications team offers expertise on technical design & support for customer systems.

HHS NET $1,007,388

Enterprise Application $4,732,125
Services include activities for HHS' civilian employees and Commissioned Corps Officers, and maintenance and operation of the systems housing current and historical pay and leave records.

JOINTLY FUNDED PROJECTS:

Human Resource Center – Rockville **$20,767,000**

$8,978,647

($7,137,227)

Unified Financial Management System Upgrade **$1,412,000**

To support the business need for UFMS to stay current—new version of the Oracle E-Business Suite and Database software.

Enterprise Information Management **$4,631,581**
FDA's contribution to the HHS Enterprise Infrastructure Fund. Funds are used for Enterprise Information Technology programs/projects outlined in the Enterprise Information Technology Strategic Plan or benefitting the corporate enterprise, such as enterprise buys/licenses.

International Health Bilateral Agreement **$1,093,646**
Agreement to provide funding in support of the bilateral-multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs

Other Jointly Funded Projects **($1,841,420):**

CFO Audit of Financial Statements $361,133
Audit services to be performed at the Food and Drug Administration (FDA) in support of the fiscal year 2010 financial statement audit of the Department of Health and Human Services (DHHS) and its components, and related services contracted and monitored by Office of the Inspector General (OIG)

Office of Public Health/Blood Safety $300,000
Agreement to provide funding for the advisory committee on Blood Safety

Regional Health Administrators $308,010
IAG with OS/Office of Public Health & Science to support ten Regional Health Administrators. Their core mission is to promote understanding of and improvements in public health and to conduct specific management and control functions within their respective regions.

President's Council on Bioethics $294,000
TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology

Fed/Strive Health and Wellness Center $2,101

Funds from the Health and Wellness Center are used to provide a portion of the on-going operational costs of a healthy facility.

Motor Vehicle Information & Management $8,000
Agreement to support the MVIMS, which generates reports on federal agency vehicle fleet expenditures

Homeland Security Presidential Directive 12 $98,822
Supports the Policy for a Common Identification Standard for Federal Employees and Contractors

Media Monitoring $122,726
Provides Agency leadership and staff with the latest analysis of what the media is reporting about Department-wide and Agency-specific priorities, initiatives, and programs

Intra-department Council on Native American Affairs $10,143
IAG with DHHS, Administration on Children and Families, for staff and administrative support for the Interdepartmental Council for Native American Affairs (ICNAA)**,** to conduct semi-annual Council meetings, Executive Committee meetings and assignments.

National Science Advisory Board for Biosecurity $325,485
Agreement with NIH to develop improved biosecurity measures for classes of legitimate biological research that could be misused to threaten public health or national security

NIH Negotiation of Indirect Cost Rates (New) $11,000
Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2011 Actual, and FY 2012 and 2013 Estimates

Activity	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
ASSESSMENTS	**1,161,109**	**1,134,966**	**1,146,316**
FEE FOR SERVICE	**30,928,674**	**26,941,978**	**27,211,398**
Program Support Center/FOH/OS	*13,338,939*	11,390,087	11,503,988
Federal Occupational Health	*2,194,358*	2,595,000	2,620,950
Information System Management Service	*15,395,377*	*12,956,891*	*13,086,460*
JOINTLY FUNDED PROJECTS	**29,745,647**	**29,752,151**	**31,594,246**
Human Resources Consolidation Costs	*20,767,000*	*22,366,000*	*24,155,280*
Unified Financial Management System Upgrade	1,412,000	1,011,000	1,011,000
Enterprise Information Management	*4,631,581*	*3,413,466*	*3,447,601*
International Health - Bilateral Agreement	*1,093,646*	*1,093,646*	*1,093,646*
Other Jointly Funded Projects	*1,841,420*	*1,868,039*	*1,886,719*
Total	**61,835,430**	**57,829,095**	**59,951,959**

Geographic Distribution of Facilities

12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
AMDL	Ammendale Building - Glassware Washing and Document Rooms	CDER/CFSAN	BELTSVILLE	MD	HEADQUARTERS	GSA Leased
BRF	Beltsville Research Facility - Laboratory	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-1	Beltsville Research Facility - Support Bldg	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-2	Beltsville Research Facility - Carpentry Shop	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-3	Beltsville Research Facility - Maintenance Building	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-4	Beltsville Research Facility - Hazmat Trailers	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BRF-5	Beltsville Research Facility - Block Building	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
BS-BLU	Border Station - Port Huron, MI	ORA	PORT HURON	MI	CENTRAL-CHICAGO	GSA Leased
BS-CAL1	Border Station - Calais, ME	ORA	CALAIS	ME	NORTHEAST-NEWYORK	GSA Owned
BS-CALEX	Border Station - Calexico, CA - Annex Building	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Leased
BS-HIGH	Border Station - Highgate Springs, VT	ORA	HIGHGATE SPRINGS	VT	NORTHEAST-NEWYORK	GSA Owned
BS-HLT2	Border Station - Houlton, ME - Truck Facility	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Owned
BS-HLT3	Border Station - Houlton, ME - LPOE	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Owned
BS-LAR3	Border Station - Laredo TX - Village Plaza	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Leased
BS-LEW	Border Station - Lewiston Bridge	ORA	LEWISTON	NY	NORTHEAST-NEWYORK	GSA Leased
BS-MEM	Resident Post - Memphis, TN	ORA	MEMPHIS	TN	SOUTHEAST-ATLANTA	GSA Leased
BS-PEA	Border Station - Peace Bridge	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
BS-SSMAR	Border Station - Sault Ste Marie, MI	ORA	SAULT STE MARIE	MI	CENTRAL-CHICAGO	GSA Owned
BS-WIL	Resident Post - Wilmington, NC	ORA	WILMINGTON	NC	SOUTHEAST-ATLANTA	GSA Leased
CC-ANCH	Daycare - Tundra Tykes	ORA	ANCHORAGE	AK	PACIFIC-OAKLAND	GSA Leased
CC-DESM	Daycare - Shared Use	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Leased
CC-SEA	Daycare - Park Place Building - Joint Use	ORA	SEATTLE	WA	PACIFIC-OAKLAND	GSA Leased
CHUR	Office Of Internal Affairs - OCI Church St	OCI	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
CORP	Corporate Building	CTP	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
CPK1	Harvey W Wiley Building	CFSAN	COLLEGE PARK	MD	HEADQUARTERS	GSA Owned
CPK2	University Station	CFSAN	RIVERDALE	MD	HEADQUARTERS	GSA Leased
CRAB	Crabb Building	OC/ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
DDA	Division of Drug Analysis - St Louis	CBER	ST LOUIS	MO	HEADQUARTERS-FIELD	GSA Leased
DDA-WULAB	CDER St. Louis Lab at Washington University	CDER	ST LOUIS	MO	HEADQUARTERS-FIELD	GSA Leased
DI-1	Dauphin Island - Seafood Laboratory	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DI-2	Dauphin Island - Generator Buildings	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DI-3	Dauphin Island - Outer Buildings	CFSAN	DAUPHIN ISLAND	AL	HEADQUARTERS-FIELD	FDA Owned
DO-ATL	District Office - Regional Office - Atlanta	ORA	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Leased
DO-BLT	District Office - Baltimore	ORA	BALTIMORE	MD	CENTRAL-PHILADELPHIA	GSA Leased
DO-CHI	District Office - Chicago	ORA	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
DO-CIN	District Office - Forensic Chemistry - Cincinnati	ORA	CINCINNATI	OH	CENTRAL-PHILADELPHIA	GSA Leased

Geographic Distribution of Facilities
Page 2
12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
DO-DAL	District Office and SW Imports - Dallas	ORA	DALLAS	TX	SOUTHWEST-DALLAS	GSA Leased
DO-DEN	District Office and Lab - Denver	ORA	LAKEWOOD	CO	SOUTHWEST-DALLAS	GSA Owned
DO-DET	District Lab - Detroit	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Leased
DO-DET1	District Office - Detroit	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Leased
DO-FLA	District Office - Florida - Maitland	ORA	MAITLAND	FL	SOUTHEAST-ATLANTA	GSA Leased
DO-KS	District Office and Lab - Kansas City	ORA	LENEXA	KS	SOUTHWEST-DALLAS	GSA Leased
DO-KS1	District Office Annex - Kansas City	ORA	LENEXA	KS	SOUTHWEST-DALLAS	GSA Leased
DO-MIN1	District Office - Minneapolis	ORA	MINNEAPOLIS	MN	CENTRAL-CHICAGO	GSA Leased
DO-NSH	District Office - Nashville	ORA	NASHVILLE	TN	SOUTHEAST-ATLANTA	GSA Leased
DO-NWE	District Office - New England	ORA	STONEHAM	MA	NORTHEAST-NEWYORK	GSA Leased
DO-NWJ	District Office - New Jersey	ORA	PARSIPPANY	NJ	CENTRAL-PHILADELPHIA	GSA Leased
DO-NYK	District Office - Regional Office and Lab - New York	ORA	JAMAICA	NY	NORTHEAST-NEWYORK	GSA Leased
DO-PHI	District Office - Regional Office and Lab - Philadelphia	ORA	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Owned
DO-SAN	District Office and Lab - San Francisco - Alameda	ORA	ALAMEDA	CA	PACIFIC-OAKLAND	GSA Leased
DO-SEA	Pacific Regional Lab NW - Seattle	ORA	BOTHELL	WA	PACIFIC-OAKLAND	GSA Owned
ELEM	Element Building	ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
FHSL	Fishers Lane 5630	CDER/OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
FO-CEROC	Central Regional Office - Chicago	OCI	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
FO-CHSO	Field Office - OCI Chicago	OCI	LISLE	IL	HEADQUARTERS-FIELD	GSA Leased
FO-GRA	Field Office - OCI Dallas	OCI	GRAPEVINE	TX	SOUTHWEST-DALLAS	GSA Leased
FO-KCSO	Field Office - OCI Kansas City	OCI	MISSION	KS	HEADQUARTERS-FIELD	GSA Leased
FO-MISO	Field Office - OCI Miami	OCI	PLANTATION	FL	HEADQUARTERS-FIELD	GSA Leased
FO-NYSO	Field Office - OCI New York	OCI	JERSEY CITY	NJ	HEADQUARTERS-FIELD	FDA Leased
FO-SDSO	Field Office - OCI Los Angeles	OCI	SAN CLEMENTE	CA	HEADQUARTERS-FIELD	FDA Leased
FO-WASO	Field Office - OCI Washington State	OCI	KIRKLAND	WA	PACIFIC-OAKLAND	GSA Leased
HHSS	Mary E Switzer Building SW	OC	WASHINGTON	DC	HEADQUARTERS	GSA Owned
HILL	Hillandale Building	CDER	SILVER SPRING	MD	HEADQUARTERS	GSA Leased
IM-BUF	Import Office - Buffalo	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
IRV-1	Los Angeles District Office/Pacific Regional Office and Lab SW - Irvine	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned
IRV-2	Irvine - Hazmat	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned
IRV-3	Irvine - Security Gate House	ORA	IRVINE	CA	PACIFIC-OAKLAND	FDA Owned
MM2	Montrose Metro 2	ORA/CDER/OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MOD1	Muirkirk MOD1 Laboratory	CFSAN	LAUREL	MD	HEADQUARTERS	FDA Owned
MOD2	Muirkirk MOD2 Laboratory - Bldg A	CVM	LAUREL	MD	HEADQUARTERS	GSA Owned
MOFF	Moffett Center	CFSAN	BEDFORD PARK	IL	HEADQUARTERS-FIELD	GSA Leased
MPN1	Metro Park North 1	CVM/CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased

Geographic Distribution of Facilities

12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
MPN2	Metro Park North 2	OC/OCI/CDER/CVM	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN4	Metro Park North 4	CVM/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN5	Metro Park North 5	CVM/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MPN7	Metro Park North 7	CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
MUIRK-B1	Muirkirk - B1 - Animal Caretakers	CFSAN	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B2	Muirkirk - B2 - Research Fac Dogs	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B3	Muirkirk - B3 - Research Fac Lamb	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-B4	Muirkirk - B4 - Research Fac-Swin	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C1	Muirkirk - C1 - Animal Caretakers	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C2	Muirkirk - 8501 G Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C3	Muirkirk - C3 - Research Fac Cows	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C4	Muirkirk - C4 - Research Fac-Sheep	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C5	Muirkirk - C5 - Research Fac-Cattle	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-C6	Muirkirk - C6 - Research Fac Cattle	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-D1	Muirkirk - D1 - 8501 L Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-D2	Muirkirk - D2 - Feed Mixing	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-E1	Muirkirk - E1 - Research Fac-Poultry	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-F1	Muirkirk - F1 - Quarantine	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-H1	Muirkirk - H - Aquaculture	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-L	Muirkirk - L - Hay Storage	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-M	Muirkirk - M - Animal Loafing	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-N	Muirkirk - N- Pump Equipment	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-PP	Muirkirk - Pasture Pads	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-W	Muirkirk - Waste Storage Area	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
NCTR-05A	NCTR - Building 5A-Lab - Animal Rooms	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05B	NCTR - Building 5B - Labs and Admin	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05B-HM	NCTR - Haz Mat Portable At 5B	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05C	NCTR - Building 5C - Admin and Computer Center - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-05D	NCTR - Building 5D - Diet Prep - Lab	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-06	NCTR - Building 6	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-07	NCTR - Building 7 - Boiler Plant	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-09	NCTR - Building 9 - Main Electrical Substation	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-10	NCTR - Building 10 - Library	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-11	NCTR - Building 11 - Water Treatment Plant	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-12	NCTR - Building 12 - Cafeteria and Conference Room	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-13	NCTR - Building 13 - Administrative	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned

Geographic Distribution of Facilities
Page 4
12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
NCTR-14A	NCTR - Building 14A - Lab and Animal Holding	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-14B	NCTR - Building 14B - Labs and Animal Holding	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-14C	NCTR - Building 14C - Lab	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-15	NCTR - Building 15 - Admin Office	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-16	NCTR - Building 16 - Paint Shop	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-17	NCTR - Building 17 - Multi-use	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-20	NCTR - Building 20 - Maintenance Building	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-21	NCTR - Building 21 - Security Building	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-26	ORA Regional Laboratory- Arkansas - NCTR - Building 26	ORA	JEFFERSON	AR	SOUTHWEST-DALLAS	FDA Owned
NCTR-28	NCTR - Building 28 - Golf Cart Charging Station	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-31	NCTR - Building 31 - Communications And Copy Center	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-32	NCTR - Building 32 - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-37	NCTR - Building 37 - Hazardous Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-44	NCTR - Building 44 - Waste Water Treatment	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-45	NCTR - Building 45 - Maintenance	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-46	NCTR - Building 46 - Incinerator	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-50	NCTR - Building 50 - Main Administration	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-51	NCTR - Building 51 - Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-52	NCTR - Building 52 - Warehouse	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53A	NCTR - Building 53A - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53B	NCTR - Building 53B - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53C	NCTR - Building 53C - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53C-HM	NCTR - Haz Mat Portable At 53C	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53D	NCTR - Building 53D - Labs and Animals	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-53E	NCTR - Building 53E - Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-54	NCTR - Building 54 - Occup Health EMCS	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-58	NCTR - Building 58 - Main Corridors - storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-58B	NCTR - Building 58B - Connecting Corridors	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-60	NCTR - Building 60 - Microbiology Labs	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-62	NCTR - Building 62 - Labs, BSL and Primates	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-70	NCTR - Building 70 - Common - Conference Room	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-71	NCTR - Building 71 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-72	NCTR - Building 72 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-73	NCTR - Building 73 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-74	NCTR - Building 74 - Residence - Dormitories	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-85A	NCTR - Building 85A - Warehouse and Laundry	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
NCTR-85B	NCTR - Building 85B - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-85C	NCTR - Building 85C - Storage	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-P01	NCTR - Guard Portable Shed Delivery	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-P19	NCTR - Guard Portable Shed Roadway	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-T05	NCTR - Building T-5 - Office Trailer	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-T45	NCTR - Building T-45 - Modular Offices - Facility Maint Contractor	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NETS-336	Quonset Hut - Building 336	N/A	NORTH KINGSTOWN	RI	HEADQUARTERS	FDA Owned
NLRC	Nicholson Lane Research Center	CBER	KENSINGTON	MD	HEADQUARTERS	GSA Leased
NLRC-D	Nicholson Lane Research Center	CBER	KENSINGTON	MD	HEADQUARTERS	FDA Leased
OAK4	Oakgrove Building - 2094 Gaither	CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
OAK8	Oakgrove Building - 2098 Gaither	CDRH	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
PIFO	Piccard Building 1350	CDRH/ORA	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
PRK-ATL	Parking - Atlanta, GA - OCI	OCI	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Owned
PRK-BUF	Parking - Buffalo Niagara Center	ORA	BUFFALO	NY	NORTHEAST-NEWYORK	GSA Leased
PRK-CHI	Parking - Union Station	ORA	CHICAGO	IL	CENTRAL-CHICAGO	GSA Leased
PRK-COL	Parking Garage - MJ Perry Jr	ORA	COLUMBIA	SC	SOUTHEAST-ATLANTA	GSA Owned
PRK-DM	Parking - Ampco System Parking	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Leased
PRK-FTM	Parking - City of Palms Garage	ORA	FORT MYERS	FL	SOUTHEAST-ATLANTA	GSA Leased
PRK-JAC	Parking Garage - JRA Facility No 3	ORA	JACKSON	MS	SOUTHEAST-ATLANTA	GSA Leased
PRK-OKL	Parking Garage - OKC Federal	ORA	OKLAHOMA CITY	OK	SOUTHWEST-DALLAS	GSA Owned
PRK-PHIL	Parking - PHIL Parking Authority Garage	ORA	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Leased
PRK-RAL1	Parking - Terry Sanford Federal Building	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Owned
PRK-RAL2	Parking Deck - Moore Square	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Leased
PRK-SUN	Parking - Sunrise, FL - OCI	OCI	PLANTATION	FL	SOUTHEAST-ATLANTA	GSA Leased
RKW2	Rockwall II Building	CBER/CDER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
RKWL	Rockwall Building	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
RL-SE	Regional Laboratory - Southeast Atlanta Annex II	ORA	ATLANTA	GA	SOUTHEAST-ATLANTA	GSA Leased
RO-BORO1	Resident Office - OCI Wakefield, MA	OCI	WAKEFIELD	MA	NORTHEAST-NEWYORK	GSA Leased
RO-DAL	Regional Office - Dallas, TX	ORA	DALLAS	TX	SOUTHWEST-DALLAS	GSA Leased
RO-GARO	Resident Office - OCI Atlanta	OCI	ATLANTA	GA	HEADQUARTERS-FIELD	GSA Owned
RO-NORO	Resident Office - OCI New Orleans	OCI	COVINGTON	LA	HEADQUARTERS-FIELD	GSA Leased
RO-P	Pacific Regional Office - Oakland	ORA	OAKLAND	CA	PACIFIC-OAKLAND	GSA Owned
RO-PH	Resident Office - OCI Phoenix	OCI	PHOENIX	AZ	HEADQUARTERS-FIELD	GSA Leased
RO-SFRO	Resident Office - OCI San Francisco	OCI	OAKLAND	CA	HEADQUARTERS-FIELD	GSA Leased
RO-SJRO	Resident Office - OCI San Juan	OCI	SAN JUAN	PR	HEADQUARTERS-FIELD	GSA Leased
RO-TXRO	Resident Office - OCI Austin	OCI	AUSTIN	TX	HEADQUARTERS-FIELD	GSA Leased

Geographic Distribution of Facilities

12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
RP-ABQ	Resident Post - Albuerque, NM	ORA	ALBUQUERQUE	NM	SOUTHWEST-DALLAS	GSA Leased
RP-ABY2	Border Station - Alexandria Bay, NY	ORA	ALEXANDRIA BAY	NY	NORTHEAST-NEWYORK	GSA Owned
RP-AGU	Resident Post - Aguada, PR	ORA	AGUADA	PR	SOUTHEAST-ATLANTA	GSA Leased
RP-ALB	Resident Post - Albany, NY	ORA	ALBANY	NY	NORTHEAST-NEWYORK	GSA Leased
RP-ANCH	Resident Post - Anchorage, AK	ORA	ANCHORAGE	AK	PACIFIC-OAKLAND	GSA Owned
RP-ARD	Resident Post - Arden, NC	ORA	ARDEN	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-AUG	Resident Post - Augusta, Me	ORA	AUGUSTA	ME	NORTHEAST-NEWYORK	GSA Leased
RP-AUS1	Resident Post - Austin, TX	ORA	AUSTIN	TX	SOUTHWEST-DALLAS	GSA Leased
RP-BCR1	Resident Post - Boca Raton, FL - Atrium Financial Center	ORA	BOCA RATON	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-BEN	Resident Post - Bensenville, IL	ORA	BENSENVILLE	IL	CENTRAL-CHICAGO	GSA Leased
RP-BIN	Resident Post - Binghamton, NY	ORA	BINGHAMTON	NY	NORTHEAST-NEWYORK	GSA Owned
RP-BIR	Resident Post - Birmingham, AL	ORA	BIRMINGHAM	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-BLA	Border Station - Blaine, WA - Breezeway	ORA	BLAINE	WA	PACIFIC-OAKLAND	GSA Owned
RP-BLA1	Border Station - Blaine, WA - Cargo	ORA	BLAINE	WA	PACIFIC-OAKLAND	GSA Owned
RP-BOI1	Resident Post - Boise, ID - Mclure Federal Bulding	ORA	BOISE	ID	PACIFIC-OAKLAND	GSA Leased
RP-BRD	Resident Post - Bridgeport, CT	ORA	BRIDGEPORT	CT	NORTHEAST-NEWYORK	GSA Owned
RP-BRN	Resident Post - Brunswick, OH	ORA	BRUNSWICK	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-BRV	Border Station - Brownsville, TX	ORA	BROWNSVILLE	TX	SOUTHWEST-DALLAS	GSA Owned
RP-BTA	Border Station - Bota, TX - Bridge of the America's	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-BTR1	Resident Post - Baton Rouge, LA - Citiplace Centre	ORA	BATON ROUGE	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-CALX	Border Station - Calexico, CA - Modular Bldg	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Owned
RP-CHG	Resident Post - Chattanooga, TN	ORA	CHATTANOOGA	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-CHP3	Resident Post - Champlain NY - Cargo Building	ORA	CHAMPLAIN	NY	NORTHEAST-NEWYORK	GSA Owned
RP-CHR	Resident Post - Charleston, SC	ORA	CHARLESTON	SC	SOUTHEAST-ATLANTA	GSA Leased
RP-CHT	Resident Post - Charlotte, NC	ORA	CHARLOTTE	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-CIN	Resident Post - Cincinnati, OH	ORA	CINCINNATI	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-CLX	Border Station - Calexico, CA - Import Bldg	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Leased
RP-CNP2	Resident Post - Los Angeles, CA	ORA	WOODLAND HILLS	CA	PACIFIC-OAKLAND	GSA Leased
RP-COB1	Resident Post - Columbia, SC	ORA	COLUMBIA	SC	SOUTHEAST-ATLANTA	GSA Owned
RP-COL1	Resident Post - Columbus, OH	ORA	COLUMBUS	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-CON	Resident Post - Concord, NH	ORA	CONCORD	NH	NORTHEAST-NEWYORK	GSA Owned
RP-COV	Resident Post - Covington, LA - Resource Bank Building	ORA	COVINGTON	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-DAV	Resident Post - Davenport, IA	ORA	DAVENPORT	IA	SOUTHWEST-DALLAS	GSA Leased
RP-DEM	Resident Post - Des Moines, IA	ORA	DES MOINES	IA	SOUTHWEST-DALLAS	GSA Owned
RP-DEN	Resident Post - Denver Airport, Denver, CO	ORA	DENVER	CO	SOUTHWEST-DALLAS	GSA Leased
RP-DET	Border Station - Detroit, MI	ORA	DETROIT	MI	CENTRAL-CHICAGO	GSA Owned

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
RP-DFW	Resident Post - DFW Airport, TX - Grapevine	ORA	DALLAS	TX	SOUTHWEST-DALLAS	GSA Leased
RP-DMT	Resident Post - Dundalk, MD - Import	ORA	BALTIMORE	MD	CENTRAL-PHILADELPHIA	GSA Leased
RP-EGL	Border Station - Eagle Pass, TX	ORA	EAGLE PASS	TX	SOUTHWEST-DALLAS	GSA Leased
RP-ELP	Resident Post - El Paso, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-ELP1	Resident Post - El Paso, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Leased
RP-ELZ	Resident Post - Elizabeth, NJ	ORA	ELIZABETH	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-ETP	Border Station - Eastport, ID	ORA	EASTPORT	ID	PACIFIC-OAKLAND	GSA Owned
RP-EVN	Resident Post - Evansville, IN	ORA	EVANSVILLE	IN	CENTRAL-CHICAGO	GSA Leased
RP-FRE	Resident Post - Fresno, CA	ORA	FRESNO	CA	PACIFIC-OAKLAND	GSA Leased
RP-FRG	Resident Post - Fargo, ND	ORA	FARGO	ND	CENTRAL-CHICAGO	GSA Owned
RP-FTM1	Resident Post - Fort Myers, FL	ORA	FORT MYERS	FL	SOUTHEAST-ATLANTA	GSA Owned
RP-FTW	Resident Post - Fort Worth, TX	ORA	FORT WORTH	TX	SOUTHWEST-DALLAS	GSA Owned
RP-FWN	Resident Post - Standard Federal Plaza, Fort Wayne, IN	ORA	FORT WAYNE	IN	CENTRAL-CHICAGO	GSA Leased
RP-GNB	Resident Post - Green Bay, WI	ORA	GREEN BAY	WI	CENTRAL-CHICAGO	GSA Leased
RP-GRN	Resident Post - Greenville, NC	ORA	GREENVILLE	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-GRO	Resident Post - Greensboro, NC	ORA	GREENSBORO	NC	SOUTHEAST-ATLANTA	GSA Leased
RP-GRP	Resident Post - Grand Rapids, MI	ORA	GRAND RAPIDS	MI	CENTRAL-CHICAGO	GSA Leased
RP-GRV	Resident Post - Greenville, SC	ORA	GREENVILLE	SC	SOUTHEAST-ATLANTA	GSA Leased
RP-GUR	Resident Post - Gurnee, IL	ORA	GURNEE	IL	CENTRAL-CHICAGO	GSA Leased
RP-HAR	Resident Post - Harrisburg, PA	ORA	HARRISBURG	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-HEL	Resident Post - Helena MT	ORA	HELENA	MT	PACIFIC-OAKLAND	GSA Leased
RP-HIN	Resident Post - Hinsdale, IL	ORA	HINSDALE	IL	CENTRAL-CHICAGO	GSA Leased
RP-HLW	Resident Post - Hollywood, FL	ORA	HOLLYWOOD	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-HON	Resident Post - Honolulu, HI	ORA	HONOLULU	HI	PACIFIC-OAKLAND	GSA Owned
RP-HOU2	Resident Post - Houston, TX	ORA	HOUSTON	TX	SOUTHWEST-DALLAS	GSA Leased
RP-HRT	Resident Post - Hartford, CT	ORA	HARTFORD	CT	NORTHEAST-NEWYORK	GSA Owned
RP-IND	Resident Post - Indianapolis, IN	ORA	INDIANAPOLIS	IN	CENTRAL-CHICAGO	GSA Leased
RP-INF	Resident Post - International Falls, MN	ORA	INTERNATIONAL FALLS	MN	CENTRAL-CHICAGO	GSA Leased
RP-JKS	Resident Post - Jackson, MS	ORA	JACKSON	MS	SOUTHEAST-ATLANTA	GSA Owned
RP-JKV	Resident Post - Jacksonville, FL	ORA	JACKSONVILLE	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-KAL	Resident Post - Kalamazoo, MI	ORA	KALAMAZOO	MI	CENTRAL-CHICAGO	GSA Owned
RP-KNX	Resident Post - Knoxville, TN	ORA	KNOXVILLE	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-LAFA	Resident Post - Lafayette, LA	ORA	LAFAYETTE	LA	SOUTHEAST-ATLANTA	GSA Owned
RP-LAR	Border Station - Laredo, TX - USBS Columbia Import Dock	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LAR1	Border Station - Laredo, TX - USBS J&L Bridge 2, Bldg 2	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LAR2	Border Station - Laredo World Trade Bridge, TX	ORA	LAREDO	TX	SOUTHWEST-DALLAS	GSA Leased

Geographic Distribution of Facilities

12/14/2011

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
RP-LAX3	Resident Post - El Segundo at North Sepulveda Blvd	ORA	EL SEGUNDO	CA	PACIFIC-OAKLAND	GSA Leased
RP-LI	Resident Post - Long Island, NY	ORA	CENTRAL ISLIP	NY	NORTHEAST-NEWYORK	GSA Owned
RP-LRK	Resident Post - Little Rock, AR	ORA	LITTLE ROCK	AR	SOUTHWEST-DALLAS	GSA Owned
RP-LSV	Resident Post - Louisville, KY	ORA	LOUISVILLE	KY	CENTRAL-PHILADELPHIA	GSA Leased
RP-LTS	Border Station - Los Tomates, TX	ORA	BROWNSVILLE	TX	SOUTHWEST-DALLAS	GSA Owned
RP-LVG	Resident Post - Las Vegas, NV	ORA	LAS VEGAS	NV	PACIFIC-OAKLAND	GSA Owned
RP-MAD	Resident Post - Madison, WI	ORA	MADISON	WI	CENTRAL-CHICAGO	GSA Leased
RP-MAS2	Border Station - Massena, NY - Port of Massena	ORA	MASSENA	NY	NORTHEAST-NEWYORK	GSA Owned
RP-MEM	Resident Post - Memphis, TN	ORA	MEMPHIS	TN	SOUTHEAST-ATLANTA	GSA Leased
RP-MET	Resident Post - Metairie Center	ORA	METAIRIE	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-MGN	Resident Post - Morgantown, WV	ORA	MORGANTOWN	WV	CENTRAL-PHILADELPHIA	GSA Leased
RP-MIA1	Resident Post - Miami, FL- Domestic	ORA	MIAMI	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-MIA3	Resident Post - Miami, FL - USPS Mail Facility	ORA	MIAMI	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-MOB	Resident Post - Mobile, AL	ORA	MOBILE	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-MTG2	Resident Post - Sterling Centre	ORA	MONTGOMERY	AL	SOUTHEAST-ATLANTA	GSA Leased
RP-MVN	Resident Post - Mount Vernon, IL	ORA	MT VERNON	IL	CENTRAL-CHICAGO	GSA Owned
RP-NBR	Resident Post - North Brunswick, NJ	ORA	NORTH BRUNSWICK	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-NOG	Border Station - Nogales, AZ - N Frank Reed	ORA	NOGALES	AZ	SOUTHWEST-DALLAS	GSA Leased
RP-NOG2	Border Station - Nogales, AZ - Truck Compound	ORA	NOGALES	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-NOVA	Resident Post - Falls Church, VA	ORA	FALLS CHURCH	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-NWW	Resident Post - New Windsor, NY	ORA	NEW WINDSOR	NY	NORTHEAST-NEWYORK	GSA Leased
RP-OGD	Border Station - Ogdensburg, NY	ORA	OGDENSBURG	NY	NORTHEAST-NEWYORK	GSA Leased
RP-OKL	Resident Post - Oklahoma City, OK	ORA	OKLAHOMA CITY	OK	SOUTHWEST-DALLAS	GSA Owned
RP-OMH1	Resident Post - Omaha, NE - Empire Court	ORA	OMAHA	NE	SOUTHWEST-DALLAS	GSA Leased
RP-ONT	Resident Post - Ontario, CA	ORA	ONTARIO	CA	PACIFIC-OAKLAND	GSA Leased
RP-OROV	Resident Post - Oroville, WA	ORA	OROVILLE	WA	PACIFIC-OAKLAND	GSA Owned
RP-OTA	Border Station - Otay Mesa, CA - Via De La Amistad	ORA	SAN DIEGO	CA	PACIFIC-OAKLAND	GSA Owned
RP-OTA1	Border Station - Otay Mesa, CA - Otay Professional Bldg	ORA	OTAY	CA	PACIFIC-OAKLAND	GSA Leased
RP-PDX	Resident Post - Portland Airport, OR	ORA	PORTLAND	OR	PACIFIC-OAKLAND	GSA Leased
RP-PEM	Border Station - Pembina, ND	ORA	PEMBINA	ND	CENTRAL-CHICAGO	GSA Leased
RP-PEO1	Resident Post - Peoria, IL	ORA	PEORIA	IL	CENTRAL-CHICAGO	GSA Leased
RP-PER	Resident Post - Perrysburg, OH	ORA	PERRYSBURG	OH	CENTRAL-PHILADELPHIA	GSA Leased
RP-PHIL	Field Office - OCI Philadelphia	OCI	PHILADELPHIA	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PHR	Border Station - Pharr, TX - Import Dock	ORA	PHARR	TX	SOUTHWEST-DALLAS	GSA Owned
RP-PHRR	Border Station - Pharr, TX - Modular Bldg	ORA	PHARR	TX	SOUTHWEST-DALLAS	GSA Owned
RP-PHX	Resident Post - Phoenix, AZ	ORA	TEMPE	AZ	SOUTHWEST-DALLAS	GSA Leased

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
RP-PIT	Resident Post - Pittsburgh, PA	ORA	PITTSBURGH	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PON	Resident Post - Ponce, PR	ORA	PONCE	PR	SOUTHEAST-ATLANTA	GSA Leased
RP-PORT	Resident Post - Portsmouth, VA - Mast One	ORA	PORTSMOUTH	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-PROV	Field Office - OCI Providence, RI	OCI	NORTH PROVIDENCE	RI	NORTHEAST-NEWYORK	GSA Leased
RP-PRV1	Resident Post - Providence, RI	ORA	EAST PROVIDENCE	RI	NORTHEAST-NEWYORK	GSA Leased
RP-PS	Resident Post - Seattle, WA	ORA	SEATTLE	WA	PACIFIC-OAKLAND	GSA Leased
RP-PTLD	Resident Post - Beaverton, OR	ORA	BEAVERTON	OR	PACIFIC-OAKLAND	GSA Leased
RP-RAL	Resident Post - Raleigh, NC	ORA	RALEIGH	NC	SOUTHEAST-ATLANTA	GSA Owned
RP-RCH	Resident Post - Richmond, VA	ORA	RICHMOND	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-REN	Resident Post - Reno, NV	ORA	RENO	NV	PACIFIC-OAKLAND	GSA Owned
RP-RGC	Border Station - Rio Grande City, TX	ORA	RIO GRANDE CITY	TX	SOUTHWEST-DALLAS	GSA Leased
RP-RNK	Resident Post - Roanoke VA	ORA	ROANOKE	VA	CENTRAL-PHILADELPHIA	GSA Leased
RP-ROC	Resident Post - Rochester, NY	ORA	ROCHESTER	NY	NORTHEAST-NEWYORK	GSA Leased
RP-SA	Resident Post - San Antonio, TX	ORA	SAN ANTONIO	TX	SOUTHWEST-DALLAS	GSA Leased
RP-SAC	Resident Post - Sacramento, CA	ORA	SACRAMENTO	CA	PACIFIC-OAKLAND	GSA Owned
RP-SAO	Resident Post - San Diego, CA	ORA	SAN DIEGO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SAV	Resident Post - Savannah, Ga	ORA	SAVANNAH	GA	SOUTHEAST-ATLANTA	GSA Owned
RP-SBD	Resident Post - South Bend, IN	ORA	SOUTH BEND	IN	CENTRAL-CHICAGO	GSA Leased
RP-SFX	Resident Post - San Francisco Airport, CA	ORA	SAN FRANCISCO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SFX2	Resident Post - San Francisco at Oyster Point	ORA	SAN FRANCISCO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SHV	Resident Post - Shreveport, LA	ORA	SHREVEPORT	LA	SOUTHEAST-ATLANTA	GSA Leased
RP-SJO	Resident Post - San Jose, CA	ORA	SAN JOSE	CA	PACIFIC-OAKLAND	GSA Leased
RP-SLB	Resident Post - St Louis, MO	ORA	MAPLEWOOD	MO	SOUTHWEST-DALLAS	GSA Leased
RP-SLC	Resident Post - Salt Lake City, UT	ORA	SALT LAKE CITY	UT	SOUTHWEST-DALLAS	GSA Leased
RP-SNL3	Commercial Inspection Building - San Luis	ORA	SAN LUIS	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-SNT2	Border Station - Santa Teresa, NM	ORA	SANTA TERESA	NM	SOUTHWEST-DALLAS	GSA Owned
RP-SPD	Resident Post - San Pedro, CA	ORA	SAN PEDRO	CA	PACIFIC-OAKLAND	GSA Leased
RP-SPG	Resident Post - Springfield, MO	ORA	SPRINGFIELD	MO	SOUTHWEST-DALLAS	GSA Leased
RP-SPO1	Resident Post - Spokane Valley, WA	ORA	SPOKANE VALLEY	WA	PACIFIC-OAKLAND	GSA Leased
RP-SPR	Resident Post - Springfield, IL	ORA	SPRINGFIELD	IL	CENTRAL-CHICAGO	GSA Leased
RP-STO1	Resident Post - Stockton, CA	ORA	STOCKTON	CA	PACIFIC-OAKLAND	GSA Leased
RP-STOM	Resident Post - St Thomas, VI	ORA	ST. THOMAS	VI	SOUTHEAST-ATLANTA	GSA Leased
RP-SWG	Border Station - Sweetgrass, Mt	ORA	SWEETGRASS	MT	PACIFIC-OAKLAND	GSA Owned
RP-SXF	Resident Post - Sioux Falls, SD	ORA	SIOUX FALLS	SD	CENTRAL-CHICAGO	GSA Leased
RP-SYR1	Resident Post - Syracuse, NY	ORA	SYRACUSE	NY	NORTHEAST-NEWYORK	GSA Leased
RP-TAC	Resident Post - Tacoma, WA	ORA	TACOMA	WA	PACIFIC-OAKLAND	GSA Leased

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
RP-TAL1	Resident Post - Tallahassee, FL	ORA	TALLAHASSEE	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-TEC	Border Station - Tecate, CA	ORA	TECATE	CA	PACIFIC-OAKLAND	GSA Owned
RP-TIF	Resident Post - Tifton, GA	ORA	TIFTON	GA	SOUTHEAST-ATLANTA	GSA Leased
RP-TMP1	Resident Post - Tampa, FL	ORA	TAMPA	FL	SOUTHEAST-ATLANTA	GSA Leased
RP-TUL2	Resident Post - Tulsa, OK	ORA	TULSA	OK	SOUTHWEST-DALLAS	GSA Leased
RP-TUS	Resident Post - Tucson, AZ	ORA	TUCSON	AZ	SOUTHWEST-DALLAS	GSA Owned
RP-VHS	Resident Post - Voorhees, NJ	ORA	VOORHEES	NJ	CENTRAL-PHILADELPHIA	GSA Leased
RP-WAU	Resident Post - Wauwatosa, WI	ORA	WAUWATOSA	WI	CENTRAL-CHICAGO	GSA Leased
RP-WBAR	Resident Post - Wilkes Barre, PA	ORA	WILKES BARRE	PA	CENTRAL-PHILADELPHIA	GSA Leased
RP-WHP	Resident Post - White Plains, NY	ORA	WHITE PLAINS	NY	NORTHEAST-NEWYORK	GSA Leased
RP-WIC	Resident Post - Wichita, KS	ORA	WICHITA	KS	SOUTHWEST-DALLAS	GSA Leased
RP-WIL	Resident Post - Wilmington, DE	ORA	WILMINGTON	DE	CENTRAL-PHILADELPHIA	GSA Leased
RP-WOR1	Resident Post - Worcester, MA	ORA	WORCESTER	MA	NORTHEAST-NEWYORK	GSA Leased
RP-YSL	Border Station - Ysletta, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
SJN-DO	San Juan - FDA Laboratory Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO1	San Juan - New Administration Building - TORO Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO2	San Juan - Administration Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO3	San Juan - Conference Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO4	San Juan - Maintenance Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO5	San Juan - Generator Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO6	San Juan - Boat House Building	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SJN-DO7	San Juan - Guard Booth	ORA	SAN JUAN	PR	SOUTHEAST-ATLANTA	FDA Owned
SPS	OCI Task Force Beltsville, MD - Special Prosecution Staff	OCI	BELTSVILLE	MD	HEADQUARTERS	GSA Leased
TECH	Technology Center	CDRH/OC	GAITHERSBURG	MD	HEADQUARTERS	GSA Leased
WARE	FDA Warehouse - Parklawn Drive	OC/CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
WEAC	WEAC Engineering And Analytical Center	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-1	WEAC- Storage Warehouse 7	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-2	WEAC- Old Mouse House	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-3	WEAC - Storage Warehouse 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-4	WEAC- Fire Extinguisher Shed	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-5	WEAC - Hazmat Trailer 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-6	WEAC - Hazmat Trailer 2	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-7	WEAC - Hazmat Building	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-8	WEAC - Freezer 1	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC-9	WEAC - Freezer 2	ORA	WINCHESTER	MA	NORTHEAST-NEWYORK	FDA Owned
WLKN	FDA Warehouse - Wilkins Ave	OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased

*Real Property ID	Building Name	FDA Center	City	State	FDA Region Code	Ownership (HHS-11)
WO-CDER 1	White Oak CDER Office Building 1	OC/CDER/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO-LSB	White Oak Life Sciences Building	CDER/CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO1	White Oak Building 1	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO130	White Oak Building 130	CDRH	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO2	White Oak Building 2	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO31	White Oak Building 31	CDER/OC/ORA	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO32	White Oak Building 32	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO51	White Oak Building 51	CDER	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO62	White Oak Building 62	CDRH/OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO66	White Oak Building 66	CDRH/OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WOC1	Woodmont Office Center	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
WOC2	Woodmont Place	CBER	ROCKVILLE	MD	HEADQUARTERS	GSA Leased

BLANK PAGE

Food and Drug Administration
FY 2013 Congressional Budget Request
Table of Contents

Food and Drug Administration
House and Senate FY 2013
Significant Items

House Significant Items
Contained in House Report 112-101
June 3, 2011

Item 1 – Spending Plans – Within 30 days from the enactment of this Act, the Commissioner shall notify the Committees on Appropriations of both Houses of Congress, on the allocation of the funds provided herein by account, and within each account by program, project and activity. (p.51) (DBEC)

FDA Action
On January 5, 2012, FDA provided the 30-day report that the Committee requested.

Item 2 – Food Safety Research – The Committee urges FDA to collaborate on its research needs where possible to reduce redundancy regarding food safety research in produce and to find efficiencies where possible when constructing new research facilities**.** (p.51)

FDA Action
FDA has developed three, cascading strategic plans to organize and coordinate food safety research: the FDA-wide Advancing Regulatory Science (ARS) Strategic Plan, released August 2011, the Foods Program draft Food and Veterinary Medicine (FVM) Strategic Plan, released for public comment in September 2011, and the Strategic Plan for CFSAN Science and Research (CSR), released November 2010. For example, the CSR plan directly supports the achievement of ARS plan Goal 6, "Implement a New Prevention-Focused Food Safety System to Protect Public Health," and FVM Strategic Plan Program Goal 3, "Strengthen scientific leadership, capacity, and partnership to support public health and animal health decision making."

FDA uses its strategic plans to target and coordinate regulatory science resources for food safety across the Agency on mission-driven priority areas, such as produce safety. The CSR plan identifies seven areas of high priority research needed to support the proposed produce safety rule. CFSAN uses the plan as a basis for prioritizing and coordinating research projects among its research and program offices, as well as with CVM and ORA. All projects are assigned leads and evaluated against specific timelines under the auspices of the CFSAN Senior Science Advisor and the Office of Foods.

Produce safety research is also conducted by extramural research partners, such as the Western Center for Food Safety (WCFS), which was established in 2008 by an FDA cooperative agreement with the Western Institute for Food Safety and Security (WIFSS) of the University of California, Davis. By engaging external Centers of Excellence on high-priority research projects, such as produce safety, FDA is able to achieve significant efficiencies in conducting research by reducing redundancy and the cost of research facilities.

Item 3 – Trade Facilitation & Interagency Cooperation –The current fiscal environment requires that efforts to enhance safety must be directed towards the most serious compliance infractions. The Committee strongly encourages FDA to establish a pilot project to expedite imports for highly compliant importers. Such project could be modeled on the Customs and Border Protection (CBP) Customs- Trade Partnership Against Terrorism and Importer Self-Assessment programs. The goal would be new trade facilitation methods for low-risk, shippers and cargo that could be incorporated into the import inspection process, thereby enabling FDA to better target Federal resources. FDA is strongly encouraged to provide clear guidelines for those shippers who are low-risk and to collaborate with CBP and other relevant agencies on this work. FDA is directed to provide a report to the Committee on its efforts in this regard by December 1, 2011. (p.52) (ORA)

FDA Action
FDA will provide the report that the Committee requested.

Item 4 – Independent Post-Market Surveillance – Concerns have been raised that those at FDA who approve drugs also have a large role in determining how they are regulated for safety in post-marketing surveillance. The Committee directs FDA to issue a report by March 31, 2012, that would outline the process necessary to create an independent office within the agency that is focused on postmarket evaluation with the controls and separation of duties necessary to make unbiased decisions on safety and advocacy. This process should also ensure that the post-market surveillance and pre-market functions can work collaboratively so that science-based, post-market assessments can formally feed back to officials involved with making pre-market drug approvals. (p.52)

FDA Action
FDA will provide the report that the Committee requested.

Item 5 – Pediatric Devices – The Committee supports FDA's efforts in addressing the need for improved pediatric medical devices. Since the inception of Demonstration Grants for Improving Pediatric Device Availability, four

consortia funded by the Office of Orphan Products Development have assisted in the development of more than 80 potential pediatric devices. While the Committee does not have additional resources to provide an increase, the Committee directs that FDA maintain level funding for this program. (p.52)

FDA Action
Subject to any changes to the FDA appropriation after the enactment of P.L. 112-55, FDA will maintain level funding for this program as requested by the committee.

Item 6 – Influenza Vaccines – The Committee is aware FDA has not yet exercised its authority under the Accelerated Approval of Biological Products regulation to approve licenses for adjuvanted seasonal influenza vaccines that have a proven safety record. While discussions about licensing such a vaccine have been ongoing at FDA, no pathway for approval has been established. The Committee believes FDA has the authority to approve these vaccines and encourages FDA to exercise that authority. The Committee is also aware that clinical studies are needed to further the development of new treatments for emerging public health requirements and for pandemic preparedness. The Committee urges FDA to work with interagency partners to ensure funding is available to conduct these needed clinical studies. (p.52)

FDA Action
The approval pathways for adjuvanted seasonal vaccines do not differ from those for unadjuvanted seasonal influenza vaccines.

Under the traditional approval pathway, an adjuvanted seasonal influenza vaccine can be licensed provided that the applicant has demonstrated safety and effectiveness through adequate and well controlled clinical trials in the proposed target population and has submitted a biologics license application. Under the accelerated approval process, licensure is based on a demonstration of an immune response, which is a surrogate endpoint reasonably likely to predict clinical benefit. This approval is contingent upon the applicant studying the vaccine further to verify and describe its actual clinical benefit. The accelerated approval process is available for adjuvanted influenza vaccines.

In 2007, FDA issued guidance documents on seasonal and pandemic influenza vaccines that also address adjuvants. Copies of these guidance documents can be found on FDA's website at:

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074794.htm and

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074786.htm

For the 2009 H1N1 pandemic vaccine, clinical data from studies supported by the Department of Health and Human Services (DHHS) and manufacturers showed that currently approved standard doses of non-adjuvanted licensed vaccines induced an excellent immune response against the 2009 H1N1 virus and an adjuvanted influenza vaccine was not necessary. In the United States the ability to use licensed influenza vaccines, which have an extensive record of safe and effective use, contributed to public confidence in and use of the 2009 H1N1 vaccines. However, to prepare for a greater public health emergency in response to the H1N1 pandemic, the DHHS stockpiled adjuvant and the DHHS and FDA were prepared to allow the use of unlicensed adjuvanted vaccines under emergency-use authorization. The scientific leadership of HHS agencies met periodically to consider this and repeatedly determined that the use of non-adjuvanted licensed vaccines was appropriate for the public health response to the H1N1 pandemic.

Studies are currently underway to determine whether the addition of adjuvants to trivalent inactivated seasonal influenza vaccines enhances their effectiveness. Some of these studies have received support from DHHS. Because seasonal vaccines are administered to over 100 million people every year, including young children and pregnant women, it is important to ensure that adjuvanted seasonal influenza vaccines will have an excellent safety profile, similar to currently licensed seasonal influenza vaccines.

The FDA has met with and provided advice and guidance to manufacturers that have submitted investigational new drug applications for adjuvanted seasonal influenza vaccines to ensure the availability of the needed safety and efficacy data.

Item 7 – Pediatric Cancer – The Committee notes cancer remains the leading cause of disease-related death in children. The incidence of childhood cancer is increasing and more effective and less toxic treatments are needed. The Committee recognizes that only one drug has been approved for pediatric cancer in the last twenty years. The Committee encourages FDA to collaborate with industry and the pediatric cancer community to promote the development of new therapies. (p.52)

FDA Action

FDA continues to prioritize interactions with sponsors (pharmaceutical companies), the National Institutes of Health, the European Medicines Agency and other academic partners on new treatment options for pediatric cancer patients.

FDA issued a specific guidance for sponsors on how to participate in the Best Pharmaceuticals for Children Act (BPCA) incentive program for the development of products directed to treat pediatric cancers.

BPCA encourages development of products for treating pediatric cancer patients through granting product exclusivity based on limited clinical development.

To date, FDA has granted exclusivity and expanded labeling under BPCA for the following drugs used for treatment of pediatric patients with cancer: Afinitor (10/2010), Gleevec (9/2006), Arranon (10/2005), Zofran (3/2005), Busulfex (1/2003), Clolar (12/2004) and Elitek (7/2002). Additionally, outside of BPCA the following drugs have FDA approval for use in pediatric cancer treatment: Elspar (3/2007), Oncaspar (7/2006) and Erwinaze (11/2011).

Informative labeling changes to assure safe and effective use of the following nine drugs for pediatric cancer have been made since 2000: Vinorelbine, Temozolomide, Topotecan, Fludarabine, Irinotecan, Gemcitabine, Oxaliplatin, Docetaxel, and Fludarabine.

Also, FDA's Center for Drug Evaluation and Research's Office of Hematology and Oncology Products initiated biennial meetings of the FDA's pediatric subcommittee of the Oncologic Drugs Advisory Committee to facilitate review and discussion of potential development plans for select new drugs in the pediatric population.

Item 8 – Sunscreen – In August 2007, FDA published a proposed rule for over-the-counter sunscreens that would require UVB and UVA testing and labeling. Given the importance of this rule to protecting Americans against skin cancer, the Committee is concerned that FDA has not issued a final rule. The Committee instructs FDA to issue a final rule before December 31, 2011. (p.53)

FDA Action
On June 17, 2011, FDA published the new sunscreen Final Rule to address UVB and UVA efficacy testing and labeling for sunscreen products as well as skin cancer labeling statements that are dependent on the degree of sun protection provided by the product.

Item 9 – Gluten-free Rulemaking – Public Law 108–282 required a final rule to define and permit the use of the term ''gluten-free'' on food labels not later than August 2008. Given the importance of this rule to protecting consumers, the Committee is concerned that FDA has not issued a final rule. The Committee instructs FDA to issue a final rule before December 31, 2011. (p.53)

FDA Action
FDA recognizes the importance of issuing a final rule on gluten-free food labeling as quickly as possible, and fully intends to achieve this goal. To develop an effective, science-based standard, FDA recently reopened the comment period

on the proposed rule to release the Agency's safety assessment on gluten exposure in persons with celiac disease and solicit comments on it. The comment period closed on October 3, 2011 and FDA received more than 1,300 comments. It was not possible for FDA to review all of these comments, complete the rulemaking process, and publish a final rule by December 31, 2011. However, FDA intends to publish by the end of FY 2012 a final rule that will establish a regulatory definition of the food labeling term "gluten-free."

Item 10 – OTC Cold Medicines for Children –The Committee is concerned that FDA has not issued a proposed rule revising the monograph regulating the labeling of over-the-counter cough and cold products for children. The Committee directs the agency to publish a proposed rule by December 31, 2011, based on scientific evidence for safety and efficacy in pediatric populations and consistent with the October 19, 2007, joint recommendations of its Pediatric Advisory Committee and Nonprescription Drugs Advisory Committee. (p.53)

FDA Action

FDA acknowledges the importance of issuing a proposed rule addressing potential changes to the labeling of over-the-counter cold and cough products for use in children. Although the changes being considered are very complex and require appropriate justifications, the FDA is working expeditiously to issue this proposed rule.

Item 11 – Medical Devices Advisory Committee –The Committee commends FDA for convening the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee in March 2010 to review the medical device classification of tanning beds. The Committee encourages the agency to act in a timely fashion to finalize its review and make formal recommendations regarding this classification. (p.53)

FDA Action

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee convened in March, 2011 to receive testimony from more than 50 professional societies, industry representatives, melanoma survivors or family members of melanoma victims, and other interested parties on the public health issues surrounding tanning lamps. The expert panel reached a consensus that tanning beds/lamps should be up-classified from their current Class I medical device status to provide greater scrutiny of the safety and effectiveness of these devices. A majority of the panel also favored restricting tanning lamps to adult use and disclosing more information on the risks of tanning to consumers.

FDA is reviewing the Advisory Committee's recommendations to reclassify tanning lamps and determine who should and should not use the devices. The

Agency is also evaluating additional controls based on the Advisory Committee's recommendations.

FDA is developing a regulation to amend current performance standards for tanning lamps to assure their safety and safe use.

Item 12 – Seafood Advisory –The Committee is concerned about differing messages from Federal agencies to pregnant women regarding the nutritional value of seafood consumption during pregnancy. The Committee directs FDA to initiate formal reconsideration of the 2004 advisory in consideration of the 2010 Dietary Guidelines. FDA shall report to the Committee within 90 days of enactment of this Act on progress made and a timeline for final action on a new FDA advisory. (p.53)

FDA Action

FDA is discussing with the Environmental Protection Agency (EPA) an update of the 2004 advisory regarding the nutritional value of seafood consumption during pregnancy, in light of, among other things, a net benefits assessment conducted by FDA and the 2010 Dietary Guidelines. The agencies intend to issue a draft of an updated advisory early this year and then engage the public on this topic through public meetings and comments this year. This may include a consultation with the FDA Advisory Committee on Risk Communication.

Item 13 – Nutrition Labeling –The Committee is concerned with the proposed rule that FDA issued on April 6, 2011, on nutrition labeling of standard menu items in restaurants and similar retail food establishments. The proposed rule would include establishments that are not primarily in the business of selling food for immediate consumption or selling food that is prepared or processed on the premises. These establishments are not similar to restaurants and the Committee believes that FDA should define the term ''restaurant'' to mean only restaurants doing business marketed under the same name or retail establishments where the primary business is the selling of food for immediate consumption. The Committee urges FDA to use the proposed alternative definition in the rule that would encompass only establishments where the primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises. (p.53)

FDA Action

FDA is aware of the Committee's concerns about FDA's definition of "restaurant and similar retail food establishment" and the Committee's support for FDA's alternate definition in the proposed rule that would encompass only establishments where the primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises. FDA received many comments on the proposed definition of "restaurant and

similar retail food establishment," ranging from comments similar to the Committee's, comments supporting FDA's proposed definition, and comments supporting a definition to include all facilities that serve restaurant and restaurant-type foods. FDA is proceeding in a deliberative manner to ensure that all comments are fully evaluated and their views considered before a final regulation is issued.

Item 14 – FDA Spending – The Committee is deeply troubled about the expenditure of scarce appropriated funds investigating alleged use of performance enhancing drugs. The Committee can discern no prudent interest for the FDA to investigate allegations that unapproved drugs may have been used outside the United States, where there is no allegation that they were sought to be imported into the U.S. and no risks to public health in the U.S. It exemplifies the problems identified by the GAO in 2010, which found that the FDA has failed to exercise appropriate oversight of the Office of Criminal Investigation or to ensure that its activities are consistent with the FDA's mission and priorities. The Committee takes no position on the merits of any pending allegations, but holds concerns about the use of taxpayer funds for investigations falling outside the agency's core missions. (p.53)

FDA Action

The illegal distribution of misbranded and unapproved drugs, which are often foreign sourced, diverted, and/or counterfeit, are prohibited criminal violations under the Food, Drug and Cosmetic Act. These violations are serious crimes with dangerous public health consequences. Performance enhancing drugs, which are typically foreign sourced, remain a concern at FDA as they are a distinct public health issue, particularly to a very vulnerable element of our society, our nation's youth. FDA does not investigate allegations involving unapproved drugs used outside the United States, where there is no allegation of an attempt to introduce the drugs into U.S. commerce.

FDA Commissioner Hamburg addressed the concerns raised by the 2010 GAO report in her March 11, 2011 appearance before Congressman Jack Kingston, Chairman Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and related agencies. FDA has a series of procedures, adopted in 2010, to ensure that the priorities of OCI and the rest of FDA are aligned. These procedures, which are set forth in FDA Staff Manual Guides and its Regulatory Procedures Manual, provide for regular coordination of Agency priorities between OCI and each of the Agency's Centers.

Senate Significant Items
Contained in Senate Report
Number 112-73
Date September 7, 2011

Item 15 – FSMA –The Committee recommendation includes an increase of $40,000,000 for FDA to begin implementation of the Food Safety Modernization Act FSMA]. This legislation will establish a prevention- focused food safety system and leverage the work of FDA's State and local food safety partners. Due to budgetary constraints, the Committee was unable to provide the full funding request for implementation of FSMA, and directs FDA to apply these increased funds to the highest priority food safety activities. These activities could include publication of new preventative controls for food processing facilities, additional import oversight and inspections of both foreign and domestic facilities, and improved scientific capabilities. The Committee directs FDA to provide a report within 30 days of enactment of this act on how it intends to allocate these funds.

FDA Action
On January 5, 2012, FDA provided the 30-day report that the Committee requested.

Item 16 – MCM – The Committee also provides an increase of $19,038,000 for activities relating to advancing medical countermeasures. This initiative was begun in August 2010 in order to increase the U.S. readiness against public health threats, and will allow FDA to work with other Government agencies to facilitate the development of safe and effective medical countermeasures to protect the Nation from chemical, biological, radiological, nuclear, and emerging infectious disease threats. Again, due to budgetary constraints, the Committee was unable to provide the full funding request for these activities, and directs FDA to provide funding to the highest priority activities relating to these initiatives. The Committee directs FDA to provide a report within 30 days of enactment of this act on how it intends to allocate these funds.

FDA Action
On **January 3, 2012,** FDA provided the 30-day report that the Committee requested.

Item 17 – The Committee expects FDA to continue all projects, activities, laboratories, and programs as included in the fiscal year 2012 budget request, unless otherwise specified.

FDA Action
Subject to any changes to the FDA appropriation after the enactment of P.L. 112-55, FDA will continue all projects, activities, laboratories, and programs as included in the fiscal year 2012 budget request at the funding level recommended by the Committee.

Item 18 – **Adjuvanted Influenza Vaccines –** The Committee recognizes the importance of FDA exercising its authority under the Accelerated Approval of Biological Products regulation to approve licenses for adjuvanted seasonal influenza vaccines, which are currently being used in seasonal influenza campaigns in Europe. The Committee believes that FDA has sufficient authority under existing regulations to approve adjuvanted vaccines. The Committee is also aware that adjuvanted seasonal influenza clinical studies are needed to further encourage the development of new treatments for emerging public health requirements and for pandemic preparedness. The Committee urges the FDA to work collaboratively with industry and other Federal agencies to facilitate the design and conduct the necessary studies. (p.80)

FDA Action
The approval pathways for adjuvanted seasonal vaccines do not differ from those for unadjuvanted seasonal influenza vaccines.

Under the traditional approval pathway, an adjuvanted seasonal influenza vaccine can be licensed provided that the applicant has demonstrated safety and effectiveness through adequate and well controlled clinical trials in the proposed target population and has submitted a biologics license application. Under the accelerated approval process, licensure is based on a demonstration of an immune response, which is a surrogate endpoint reasonably likely to predict clinical benefit. This approval is contingent upon the applicant studying the vaccine further to verify and describe its actual clinical benefit. The accelerated approval process is available for adjuvanted influenza vaccines.

In 2007, FDA issued guidance documents on seasonal and pandemic influenza vaccines that also address adjuvants. Copies of these guidance documents can be found on FDA's website at:

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074794.htm and

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074786.htm

For the 2009 H1N1 pandemic vaccine, clinical data from studies supported by the Department of Health and Human Services (DHHS) and manufacturers showed that currently approved standard doses of non-adjuvanted licensed vaccines induced an excellent immune response against the 2009 H1N1 virus and an adjuvanted influenza vaccine was not necessary. In the United States

the ability to use licensed influenza vaccines, which have an extensive record of safe and effective use, contributed to public confidence in and use of the 2009 H1N1 vaccines. However, to prepare for a greater public health emergency in response to the H1N1 pandemic, the DHHS stockpiled adjuvant and the DHHS and FDA were prepared to allow the use of unlicensed adjuvanted vaccines under emergency-use authorization. The scientific leadership of HHS agencies met periodically to consider this and repeatedly determined that the use of non-adjuvanted licensed vaccines was appropriate for the public health response to the H1N1 pandemic.

Studies are currently underway to determine whether the addition of adjuvants to trivalent inactivated seasonal influenza vaccines enhances their effectiveness. Some of these studies have received support from DHHS. Because seasonal vaccines are administered to over 100 million people every year, including young children and pregnant women, it is important to ensure that adjuvanted seasonal influenza vaccines will have an excellent safety profile, similar to currently licensed seasonal influenza vaccines.

The FDA has met with and provided advice and guidance to manufacturers that have submitted investigational new drug applications for adjuvanted seasonal influenza vaccines to ensure the availability of the needed safety and efficacy data.

Item 19 – **Agency Collaboration** – The Committee is aware of the MOU between FDA and the Centers for Medicare and Medicaid Services [CMS] to promote collaboration, and strongly supports this effort. The Committee encourages FDA to share information with CMS describing the clinical trials used to support a new drug indication, and to specifically note whether the new drug was compared to a placebo or to an active control. The Committee recommends that FDA make CMS aware of whether a newly approved drug was approved based on an application supported by clinical trials using a non-inferiority or a superiority design. (p.80)

FDA Action

FDA and CMS are currently sharing information under this MOU. FDA will take these recommendations into consideration as we continue to collaborate with CMS.

Item 20 – **Antimicrobial Resistance** – The Committee commends the FDA for publishing Draft Guidance for Industry No. 209 and for conducting a comprehensive review of the scientific evidence related to antimicrobial use in food animal production and antibiotic-resistant infections in humans. However, over a year has passed since this draft guidance was released and the FDA has not yet identified a timeframe for finalizing and implementing this guidance or for taking other proposed steps to address antimicrobial resistance. Therefore,

the Committee directs the FDA to set a timeline for when Guidance No. 209 and any implementing guidance will be finalized, when the FDA intends to release any changes to the Veterinary Feed Directive, and when it plans to issue an order regarding extra label uses of Cephalosporin drugs in food-producing animals. The Committee also recommends that FDA examine medically important antimicrobial drugs currently approved for use in food-producing animals and take steps to assure that such products are aligned with current safety standards. (p.80)

FDA Action

FDA recognizes the important public health implications of this issue and has been actively taking steps to address this safety concern.

FDA has completed a review of the public comments received on draft Guidance for Industry #209 and is developing a strategy for implementing the recommendations outlined in the draft guidance. This includes seeking input from its stakeholders, including the animal pharmaceutical industry, on approaches for voluntarily modifying medically important antimicrobial drugs currently approved for use in food-producing animals to limit their use to therapeutic purposes under veterinary oversight.

Furthermore, as comments on the guidance are being reviewed, FDA is working with a number of individual pharmaceutical companies that have approached the agency on a case-by-case basis to examine their particular products and discuss possible changes to their products to address antimicrobial resistance concerns. FDA is encouraged by the engagement of the animal pharmaceutical industry and their commitment to work cooperatively with the agency to address this issue.

Finalizing the various elements of FDA's strategy for addressing antimicrobial resistance continues to be a high priority for the Agency. FDA expects to move forward with elements of the plan in early 2012.

Item 21 – Artificial Pancreas –To foster the development of artificial pancreas technology, the Committee expects FDA to provide researchers and industry stakeholders with clear, prompt, and reasonable guidance for approval of safe and effective artificial pancreas systems for patients with type I diabetes. The FDA has taken an important first step with the issuance of guidance for an early version of an artificial pancreas system, known as a Low Glucose Suspend system. The Committee strongly encourages FDA to continue to make the advancement of more autonomous artificial pancreas technologies a priority by collaboration with stakeholders and investment of time and resources. Artificial pancreas technologies could be an important tool for patients with type 1 diabetes to achieve better glycemic control, increasing their quality of life and overall health. (p.80)

FDA Action
On December 1, FDA issued draft guidance designed to help investigators and manufacturers develop and seek approval for artificial pancreas device systems to treat type 1 diabetes. The draft guidance provides flexible recommendations for design and testing that meet statutory requirements for safety and effectiveness.

An artificial pancreas could reduce dangerous high and low blood sugars, providing a better quality of life for millions of Americans with diabetes and lower the risk for future diabetes-related complications.

The guidance recommends a three-phase clinical study progression so that studies may move to an outpatient setting as quickly as possible. To further streamline clinical studies, the guidance suggests ways sponsors may leverage existing safety and effectiveness data for components that may make up an artificial pancreas system, as well as data gathered from clinical studies conducted outside of the U.S.

FDA looks forward to reviewing comments from industry and other interested parties on the draft guidance to facilitate evaluation and review of the safety and effectiveness of this promising technology. The agency is committed to ensuring that the devices that become available that utilize this technology provide a favorable benefit to risk profile for the patients that use them.

Item 22 – **Breast Imaging Quality Standards** – The Committee is aware that FDA is currently considering the implementation of several recommendations included in the Institute of Medicine Report entitled ''Breast Imaging Quality Standards'', which was released on May 23, 2005. The Committee directs FDA to provide a report to the House and Senate Committees on Appropriations within 120 days of enactment of this act specifying which specific recommendations will be implemented, the timeline for doing so, and specific details on how the recommendations will be implemented. (p.81)

FDA Action
FDA will provide the report that the Committee requested.

Item 23 – Budget Justification – The Committee directs FDA to submit the fiscal year 2013 budget request in a format that follows the same account structure as the fiscal year 2012 budget request unless otherwise approved by the Committee. (p.81)

FDA Action
FDA will submit the fiscal year 2013 budget request in a format that follows the same account structure as the fiscal year 2012 budget request unless otherwise approved by the Committee

Item 24 – **Dietary Supplements** – The Committee is aware that U.S. consumers widely use plant-derived dietary supplements, and that FDA inspects manufacturers and distributors that are responsible for ensuring that such products are not adulterated or contaminated, and do not cause harm to the consumer. The Committee believes that methods and standards are needed to verify source plants and ingredients and to detect toxic contaminants. The Committee encourages FDA to develop guidance for industry on such methods and standards, which would enhance FDA's ability to inspect and assess industry practices for manufacturing botanical dietary supplements. (p.81)

FDA Action
FDA currently partners with academic and industry stakeholders to support development of methods and standards for manufacturing botanical dietary supplements. These agreements allow FDA to establish broad-based initiatives that enhance FDA's ability to protect overall public health by ensuring that dietary supplements are safe and their labeling is truthful and not misleading.

One example is the FDA agreement with the National Center for Natural Products Research (NCNPR) at the University of Mississippi. This collaboration creates a partnership that allows for more efficient use of botanical dietary supplements research resources in investigating potentially toxic botanical ingredients and constituents. Additionally, publications and meetings with academic and industry partners regarding best practices, including those for analysis of specific components of botanical dietary supplements, effectively provide scientific guidance for FDA and industry alike in setting and assessing industry practices for manufacturing botanical dietary supplements.

Item 25 – **Food Safety Information Sharing** – The Committee urges the Secretary of Agriculture and the Secretary of Health and Human Services to enter into a memorandum of understanding between the relevant agencies within the Department of Health and Human Services, including the Food and Drug Administration and the Centers for Disease Control and Prevention, and the relevant agencies within the Department of Agriculture, including the Food Safety and Inspection Service, the Agricultural Research Service, and the Animal and Plant Health Inspection Service, to ensure the timely and efficient sharing of all information collected by such agencies related to foodborne pathogens, contaminants and illnesses. (p.81)

FDA Action
FDA has entered into a large number of cooperative agreements with several other departments within the Executive Branch, including the Department of Agriculture, the Department of Defense, and the Department of Homeland Security, as well as agencies such as the Environmental Protection Agency (EPA). FDA is ever-vigilant for new means of cooperation between agencies and is diligent about ensuring that agreements are updated as necessary. For example, FDA entered into an MOU (225-72-2009) last year with USDA's Agriculture Marketing Service (AMS), which is designed to ensure maximum coordination and cooperation between AMS and FDA with respect to information-sharing on food safety, including produce and egg safety. Additionally, FDA has entered in an MOU with USDA's Research, Education, and Economics (REE) to establish a cooperative program with the National Institute for Food and Agriculture (NIFA) to provide training as mandated by the Food Safety Modernization Act. FDA is also currently finalizing revisions to an existing MOU between FDA, USDA, and EPA relative to the sharing of information on residues and chemical contaminants in foods. A full listing of such agreements, including additional examples of FDA food safety data-sharing, can be found at: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm.

Item 26 – Generic Drugs – The Committee recommendation includes no less than $97,218,000 for the generic drugs program at FDA, of which no less than $52,947,000 is for the Office of Generic Drugs. (p.81)

FDA Action
Subject to any changes to the FDA appropriation after the enactment of P.L. 112-55, during FY 2012, FDA will support this activity at the funding level recommended by the Committee.

Item 27 – Medical Device Safety – The Committee strongly encourages the Center for Devices and Radiological Health [CDRH] to complete its implementation of the Safe Medical Devices Act of 1990. The Government Accountability Office [GAO] identified the unfinished implementation of this act as one of the main causes of including CDRH on GAO's ''high-risk'' list of Government agencies. The Committee directs CDRH to report on its progress of the implementation of the Safe Medical Devices Act within 120 days of the enactment of this act. (p.81)

FDA Action
FDA will provide the report that the Committee requested.

Item 28 – **GAO Recommendations** – The Committee also encourages CDRH to implement the GAO recommendation for CDRH to strengthen its post-market surveillance of medical devices. The Committee supports CDRH's use of Section 522 authority to study high-risk medical devices that were cleared through the 510(k) process, such as metal-on-metal hip implants. The Committee commends CDRH on meeting with medical experts and leaders of medical device registries that currently exist and recommends that CDRH continue to work with stakeholders to develop a more robust post-market surveillance program for medical devices. (p.81)

FDA Action

FDA has stepped up its postmarket device surveillance efforts and engaged with a wide spectrum of stakeholders to identify safety signals as early as possible and take appropriate action. These efforts include combining and leveraging advances in epidemiology, statistics, and biomedical research to assess medical device safety and effectiveness through the Medical Device Epidemiology Network (MDEpiNet). As part of the MDEpiNet Initiative, FDA held a general public meeting and three targeted workshops with diagnostics, orthopedics, and surgical device stakeholders. In addition, a Science/Infrastructure Center and Methodology Center were established at two of our partner academic institutions to facilitate more informed decision-making about medical devices.

Access to already established data sources through device registries is an essential complement to monitor device performance in a timely and cost effective manner. FDA has played an important role in the development of the infrastructure needed for appropriate postmarket surveillance of medical devices through device registries. In 2011, FDA facilitated development of the American College of Cardiology/Society of Transthoracic Surgeons (ACC/STS) Transcatheter Valve Therapy Registry and engaged in further infrastructure building for the International Consortium of Orthopedic Registries (ICOR), the ICD and Leads registries (held by ACC/STS), and the Kaiser family of registries. We will continue to engage in collaborations with US and international professional organizations, academia, and the medical device industry to develop better systems for postmarket surveillance. MDEpiNet provides the platform for such collaborations.

Postmarket surveillance under section 522 of the Federal Food, Drug, and Cosmetic Act is an integral component of our postmarket surveillance toolkit. Study plans are submitted by sponsors and must be approved by FDA prior to study initiation. In 2011, FDA issued 149 "522 orders" for three device areas up from 13 orders for two device areas issued in the prior year.

Item 29 – Nanotechnology – The Committee recognizes that FDA is developing the facilities and expertise to study nanotechnology within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research, and its consolidated headquarters at White Oak, Maryland. The Committee supports FDA in its mission to expand upon current research in nanotechnology and supports the development of a Nanotechnology Core Center to meet this mission. The Committee believes a Nanotechnology Core Center should be designed to support nanotechnology toxicity studies, develop analytical tools to quantify nanomaterials in complex matrices, and develop procedures for characterizing nanomaterials in FDA-regulated products. (p.82)

FDA Action

With Congressional support, FDA has strengthened its regulatory capability for the Agency's Nanotechnology Regulatory Science Research Program by using a three-prong FDA-wide effort: (1) Development of a core infrastructure with equipment and expertise to provide FDA regulatory scientists with experience and knowledge in nanotechnology. This is demonstrated at FDA's Jefferson's Laboratories, nanotechnology facility which is fully operational and has been supporting FDA research and toxicology projects since 2010 and the co-development of a White Oak Campus nanotechnology facility supporting FDA characterization and manufacturing projects. (2) A training program provided by FDA review scientists and experts with laboratory experience with nanomaterials. This program was established in 2011. (3) Collaboration on regulatory science research projects addressing FDA's regulatory needs. The FDA CORES program was established in 2011 and includes other US government agencies within the National Nanotechnology Initiative (NNI) and academic institutions. Investments to date have provided a sound base for FDA.

With continued investments, FDA will build upon the base that has been established for the Agency's Nanotechnology Regulatory Science Research Program. The continued support will enable the agency to address questions related to the safety, effectiveness, product quality, and/or regulatory status of products that contain nanomaterials or otherwise involve the use of nanotechnology; develop models for safety and efficacy assessment; and study the behavior of nanomaterials in biological systems and their effects on human health.

Item 30 – **Obesity Therapeutics** – The Committee is concerned with the absence of novel medicines to treat obesity, the second leading cause of preventable deaths in the United States and a disease linked to cancer, high blood pressure, heart disease, diabetes, and stroke. With only diet, exercise, and gastric surgery as options, the lack of obesity medications is a significant unmet medical need. The Committee directs FDA to report by March 30, 2012 on the steps it will take to support the development of new treatments for obesity, including the use of its Risk Evaluation and Mitigation Strategy and other post-

marketing authorities, to mitigate risk and ensure rigorous post-market scrutiny while increasing access to novel medications. (p.82)

FDA Action
FDA will provide the report that the Committee requested.

Item 31 – **Office of Cosmetics and Colors [OCAC]—**The Committee provides not less than $11,700,000 for cosmetics activities, including not less than $7,200,000 for the Office of Colors and Cosmetics. Funding provided for OCAC is for direct support of the operation, staffing, compliance, research and international activities performed by this office. (p.82)

FDA Action
FDA will support this activity at the funding level provided by the Committee in FY 2012, subject to any changes to the FDA appropriation after the enactment of P.L. 112-55.

Item 32 – Packaged Ice – The Committee believes it is important that FDA provide guidance to manufacturers of packaged ice to ensure a safe product is sold to consumers. The Committee understands that a Citizens Petition was recently submitted to FDA regarding packaged ice, and encourages FDA to respond to this petition promptly. (p.82)

FDA Action
FDA received a petition on December 17, 2010 from the Packaged Ice Association that, among other things, asked FDA to establish a standard of identity (SOI) for packaged ice mirrored after the bottled water SOI. In the Statement of Grounds, the petitioner states concerns with the lack of inspection and no specific reference in FDA's regulations that identifies packaged ice as a food or establishes good manufacturing practices for packaged ice as the primary grounds for requesting an SOI.

FDA issued an interim response to the petitioner on June 17, 2011 indicating that we had not reached a decision on the petition in the first 180 days. We are still in the review/evaluation stage of the petition and have not yet reached a final decision. However, as noted in the petition, FDA did issue a food facts sheet clarifying that we do regulate packaged ice as a food. The full article is available at: http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm197586.htm.

As resources permit, FDA plans to reach a final decision on this petition later this year.

Item 33 – Seafood Advisory – The Committee is concerned about differing messages from Federal agencies to pregnant women regarding the nutritional value of seafood consumption during pregnancy. The Committee directs FDA to initiate formal reconsideration of the 2004 advisory in consideration of the 2010 Dietary Guidelines. FDA shall report to the Committee within 120 days of enactment of this act on progress made and a timeline for final action on a new FDA advisory. (p.82)

FDA Action

FDA is discussing with the Environmental Protection Agency (EPA) an update of the 2004 advisory regarding the nutritional value of seafood consumption during pregnancy, in light of, among other things, a net benefits assessment conducted by FDA and the 2010 Dietary Guidelines. The agencies intend to issue a draft of an updated advisory early this year and then engage the public on this topic through public meetings and comments this year. This may include a consultation with the FDA Advisory Committee on Risk Communication. A report to Congress on reconsideration of the 2004 advisory was completed by CFSAN in September 2011 and submitted by HHS on December 29, 2011.

Item 34 – Seafood Economic Integrity – The Committee recognizes the importance of seafood to a healthy diet, but is concerned that FDA does not focus sufficient attention on economic integrity issues, particularly with respect to mislabeling of species, weights, country of origin, and treatment. The Committee encourages FDA to work with States and the Department of Commerce to more aggressively combat fraud in parts of the seafood industry. (p. 82)

FDA Action

For over 30 years, the Food and Drug Administration has been implementing systems and protocols with our State, territorial, tribal, and local regulatory partners to rapidly identify contaminated food via inspectional and sample analysis collaboration, determine the cause, and remove contaminated products from the marketplace. Within the Food Inspection State Contract Program, FDA currently collaborates with 24 states to perform 1131 Seafood HACCP inspections in which results and outcomes are shared with the respective FDA district offices. In the last 2 years, FDA has delivered 18 joint (FDA & State) Seafood Training courses. Along with HACCP food safety principles and label reviews, the joint training sessions include a dedicated section to economic fraud. The FDA also works closely with the National Fisheries Institute and NOAAs National Marine Fisheries Service to address economic fraud issues.

Item 35 – Seafood Safety –The Committee is aware that FDA currently inspects less than 2 percent of imported seafood. Further, many of these imports may contain substances that are banned in the United States. Therefore, the Committee directs FDA to develop a comprehensive program for imported

seafood, in accordance with the Food Safety Modernization Act, to ensure the safety of seafood. (p.83)

FDA Action
Since 1997, FDA has required all foreign seafood processors to implement seafood HACCP (Hazard Analysis Critical Control Point) programs for product intended for consumption in the United States. Foreign processors must address all food safety issues, implement safety controls, and maintain records of their activities as part of their HACCP program. FDA audits these programs during foreign facility inspections and as part of their importer verification procedures. Non-compliant processors or importers are banned from shipping product into the U.S. until corrections have been made.

In addition to the mandated HACCP programs, FDA has recently developed and utilized an electronic system (PREDICT) that prioritizes entries of imported seafood for sampling based on product risk. This allows FDA to focus available resources more effectively on products and processors that are more likely to submit adulterated foods for entry. Products that are unlikely or less likely to be adulterated receive a lower priority for sampling. The controls mandated by FSMA will further enhance the control of foreign sources of seafood and are currently under development, including third party accreditation of importers.

Item – 36 – **Trade Facilitation and Interagency Cooperation** – The current fiscal environment requires that efforts to enhance safety must be directed toward the most serious compliance infractions. The Committee strongly encourages FDA to establish a pilot project to expedite imports for highly compliant importers. The goal would be new trade facilitation methods for low-risk, shippers and cargo that could be incorporated into the import inspection process, thereby enabling FDA to better target Federal resources. FDA is strongly encouraged to provide clear guidelines for those shippers who are low-risk and to collaborate with industry, Customs and Border Protection and other relevant agencies on how such a program could be implemented. FDA is directed to provide a report to the Committee on its efforts in this regard within 120 days of enactment of this act. (p.83)

FDA Action
FDA will provide the report that the Committee requested.

Conference Report Significant Items
Contained in Conference Report 112-284
To accompany H.R. 2112
Date November 14, 2011

Item 37 – Administrative Savings – The conference agreement includes the following increases: $39,000,000 to begin implementation of the Food Safety Modernization Act; $20,038,000 for advancing medical countermeasures…the conferees direct FDA to provide a report within 30 days of enactment of this Act on how it intends to allocate these increases. (p.185)

FDA Action
On January 5, 2012 and January 3, 2012, FDA provided the reports that the Committee requested.

Item 38 – Pre-Market Approval Times - The conferees direct that, within 90 days of the date of enactment of this Act, FDA report on the average number of calendar days that elapsed from the date that drug applications (including any supplements) were submitted to the agency under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) until the date that the drugs were approved; the average number of calendar days that elapsed from the date that applications for device clearance (including any supplements) under section 510(k) of the FD&C Act or for premarket approval (including any supplements) under section 515 of the FD&C Act were submitted to the agency until the date that the devices were cleared; and the average number of calendar days that elapsed from the date that biological license applications (including any supplements) were submitted to the agency under section 351 of the Public Health Service Act until the date that the biological products were licensed. (p. 186) (Office of Planning)

FDA Action
FDA will provide the report that the Committee requested.

Item 39 – OTC Cold Medicines for Children - The conferees are concerned that FDA has not issued a proposed rule revising the monograph regulating the labeling of over-the-counter cough and cold products for children. The conferees direct the FDA to publish a proposed rule by December 31, 2011, based on the latest scientific evidence for safety and efficacy in pediatric populations. (p.186) (

FDA Action
FDA acknowledges the importance of issuing a proposed rule addressing potential changes to the labeling of over-the-counter cold and cough products for use in children. Although the changes being considered are very complex and

require appropriate justifications, the FDA is working expeditiously to issue this proposed rule.

Item 40 – **Nanotechnology -** The conferees recognize that FDA is developing facilities and expertise to study nanotechnology within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research, and its consolidated headquarters at White Oak, Maryland. The conferees support FDA in its mission to expand upon current research in nanotechnology and support the eventual development of a Nanotechnology Core Center to meet its mission**.** (p. 186) (OCS [lead], in consultation with NCTR)

FDA Action

FDA investments will continue to enable the agency to address questions related to the safety, effectiveness, product quality, and/or regulatory status of products that contain nanomaterials or otherwise involve the use of nanotechnology; develop models for safety and efficacy assessment; and study the behavior of nanomaterials in biological systems and their effects on human health. FDA will continue activities that meet the following FDA-wide priorities: (1) scientific staff development and professional training, (2) laboratory and product testing capacity, and (3) collaborative and interdisciplinary research to address product characterization and safety.

Item 41 – **Imported Seafood -** The conferees are aware that FDA currently inspects less than 2 percent of imported seafood. Further, many of these imports may contain substances that are banned in the United States. Therefore, the conferees direct FDA to develop a comprehensive program for imported seafood. (p.186)

FDA Action

Since 1997, FDA has required all foreign seafood processors to implement seafood HACCP (Hazard Analysis Critical Control Point) programs for product intended for consumption in the United States. Foreign processors must address all food safety issues, implement safety controls, and maintain records of their activities as part of their HACCP program. FDA audits these programs during foreign facility inspections and as part of their importer verification procedures. Non-compliant processors or importers are banned from shipping product into the U.S. until corrections have been made.

In addition to the mandated HACCP programs, FDA has recently developed and utilized an electronic system (PREDICT) that prioritizes entries of imported seafood for sampling based on product risk. This allows FDA to focus available resources more effectively on products and processors that are more likely to submit adulterated foods for entry. Products that are unlikely or less likely to be

adulterated receive a lower priority for sampling. The controls mandated by FSMA will further enhance the control of foreign sources of seafood and are currently under development, including third party accreditation of importers.

Item 42 – **Approval Process transparency -** The conferees emphasize the importance of predictability and transparency in the FDA approval process, and urge FDA to remain focused on its core mission of ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, fostering the development of medical products to support the counterterrorism effort, and helping to speed innovation of safe and effective products that improve the lives of patients and consumers. The conferees urge FDA to be responsive, timely, and transparent throughout the approval process for all human and veterinary drugs, biological products, medical devices, and medical countermeasures.

FDA Action

The Centers for Drugs, Biologics, and Devices and Radiologic are committed to predictability, consistency, and transparency of of their respective review processes, including training of reviewers, interaction with sponsors, and implementation and tracking of policies to ensure the highest quality and timeliness of regulatory science.

Item 43 – **Food Safety** – The conferees note that the most recent CDC estimates are that only 20 percent of foodborne illnesses are from 31 known pathogens such as norovirus, salmonella and clostridium. Since 80 percent of illnesses are caused by unknown sources, FDA is encouraged to work with the public and private sectors to gain a better understanding of the causes of illness. FDA's broader understanding of unknown sources should contribute towards the development of new strategies, policies, and foodborne illness prevention methods. While simultaneously seeking answers to unknown sources and plans to address these hazards, FDA has to do a better job of identifying more effective food safety activities that will reduce illnesses, hospitalizations, and deaths associated with the other 20 percent of foodborne illness. Within the funding level for food safety, FDA is directed to develop a clear strategy on how the agency can prioritize intervention methods along the farm to fork continuum to reduce illness once they have discovered the sources for a much greater proportion of unknown agents and to tie the funding levels for food safety to increased levels of activities to both the known and the unknown sources of illness. The conferees direct FDA to include this information in the fiscal year 2013 budget justifications to Congress. (p.186)

FDA Action

FDA has included information on its food safety strategy in the fiscal year 2013 budget justifications to Congress.

BLANK PAGE

Food and Drug Administration
Fact Sheet – Alabama

FDA Presence

- 9 employees in Alabama
- Resident Posts in Birmingham, Mobile, and Montgomery
- Employees report to New Orleans District – in Nashville, TN
- Nashville, TN reports to Southeast Region in Atlanta, Georgia.

Industry Presence in State - 1,860 FDA-regulated establishments[1]

- Food establishments – includes cosmetics – 37 percent
- Medical Device and radiological establishments – 26 percent
- Human Drug establishments – 18 percent
- Animal drug and feed establishments – 13 percent
- Biological establishments – includes blood banks – 6 percent.

Industry Highlights

- 3 ports of entry – Mobile, Huntsville, Birmingham
- Mobile – exportation of grain products and importation of food and seafood products
- Seafood – primary food industry includes Gulf shrimp, crab, oysters from the coast and farm–raised catfish
- Agriculture – poultry, timber, cattle, cotton, soybeans, and peanuts
- Medical device presence
- Clinical research activity – medical university settings
- Biologics presence – regional blood testing facilities
- The Gulf Coast area – still recovering from Hurricanes Katrina & Rita in 2005
- Deepwater Horizon Oil Spill in 2010 severely affected the seafood industry.

Contracts, Partnerships & Special Programs

State Contracts

- Alabama Department of Public Health – food manufacturer sanitation inspections
- Alabama Department of Agriculture and Industries – BSE inspections.

State Partnerships

None

Special Programs

- Active Food Safety Task Force – AL Department of Public Health, AL Department of Agriculture, Auburn Cooperative Extension Service, AL

[1] Some firms are in more than one category.

Restaurant Association, AL Grocers' Association and AL Retail Foods Association.

Food and Drug Administration
Fact Sheet – Alaska

FDA Presence

- 4 FDA employees in Alaska
- Resident Post – Anchorage
- Anchorage reports to: Seattle District in Bothell, WA
- Bothell, WA reports to Pacific Region in Oakland, CA

Industry Presence in State – 555 FDA–regulated establishments[2]

- Food establishments – includes cosmetics – 79 percent
- Medical device and Radiological establishments – 13 percent
- Human drug establishments – 3 percent
- Biologic establishments, includes blood banks – 2 percent
- Animal drug and feed establishments – 3 percent

Industry Highlights

- Alaska supplies most of America's salmon, crab, halibut, and herring
- Alaska is the number one producer of wild salmon in the world and has the only salmon industry certified as "sustainable "
- Alaska ranks as one of the top ten seafood producers worldwide. More than 6 million pounds of seafood are harvested off Alaska each year – 60% of all U.S. production
- The total value of Alaska seafood production has topped $2.5 billion annually for several years.
- Dutch Harbor and Kodiak consistently rank as two of the top three ports in the U.S. for tonnage of seafood brought in
- Alaska has over 33,000 miles of shoreline – more than the rest of the U. S. combined.

Contracts, Partnerships & Local Activities

State contracts

Alaska Department Environment and Conservation

- Conduct food safety inspections, conduct seafood HACCP inspections.

Alaska Department of Health

- Conduct inspections of mammography facilities.

[2] Some firms are in more than one category.

State Partnerships

Alaska Department of Environmental Conservation

- Conduct inspections of the fish and fishery products processing industry for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations
- Conduct mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms in the State of Alaska.

Food and Drug Administration
Fact Sheet – American Samoa

FDA Presence

- 9 FDA employees in Hawaii
- Resident Post – Honolulu
- Employees report to San Francisco District, Alameda, CA
- Alameda, CA reports to Pacific Region, Oakland, California

Industry Presence in State – 4 FDA–regulated establishments[3]

- Food establishments – includes cosmetics – 33 percent
- Animal drug and feed establishments – 33 percent
- Human drug establishments – 17 percent
- Biologic establishments – includes blood banks – 0 percent
- Animal drug and feed establishments – 17 percent.

Industry Highlights

- Tuna fishing and tuna processing plants are the backbone of the private sector, with canned tuna the primary export
- This is a traditional Polynesian economy – more than 90 percent of the land is communally owned

Food and Drug Administration
Fact Sheet – Arkansas

FDA Presence

- 373 FDA employees and 318 contractors in Arkansas
    - Dallas District Resident Post in Little Rock, Arkansas – Three investigators report to Dallas District Office
    - Arkansas Regional Laboratory, Jefferson – Ninety-one employees report to Southwest Region, Dallas, Texas
    - National Center for Toxicological Research (NCTR), Jefferson – 245 FTE+ 318 contractors
    - 34 FDA headquarters employees that work onsite at NCTR

[3] Some firms are in more than one category.

- Import entries are handled out of the Dallas Southwest Import District Office and through the Dallas District Staff located in Arkansas.

Industry Presence in State – 1,380 FDA–regulated establishments [4]

- Food establishments – includes cosmetics – 54 percent
- Animal drug and feed establishments –16 percent
- Medical device and Radiological establishments – 14 percent
- Human drug establishments – 12 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights

- Retail/Warehousing – Wal-Mart World headquarters in Bentonville, AR
- Eggs – Arkansas is a major egg production state
- Poultry – Arkansas is the home of several Tyson poultry production facilities
- Canning – Arkansas is the home of Allen Canning, Gerber and Bush food manufacturers
- Grains – Arkansas includes significant rice, wheat, corn, and soybean production
- Farming – Arkansas includes productive animal feed production and catfish farming
- Drug/Medical Devices – Baxter is located in Mountain Home, AR
- Southwest Import District – Approximately 647 line entries were received in Fiscal Year 2007. Primary products imported are alcoholic beverages, cosmetics, and animal drugs.

Contracts, Partnerships & Local Activities

State Contracts

- Arkansas Department of Health – conducts food sanitation inspections and inspections of mammography facilities
- Arkansas State Plant Board – conducts feed mill inspections; determines compliance with BSE Rule.

State Partnerships

- Arkansas Department of Health – shares oversight and authority of regulated dairy manufacturing facilities; agreement with the Jefferson Labs (NCTR) for emergency space; shares in an informal reciprocal agreement with ARL for FERN
- Local Activities, FERN – NCTR, an FDA research center, employs 225 government scientists and 318 contract support personnel who develop, modify or validate FDA regulatory standards
- Current work includes:

[4] Some firms are in more than one category.

    - studies applying new technologies to provide data more easily extrapolated in humans
    - investigating the possibility of interspecies transfer of antimicrobial resistance mechanisms to humans
    - developing knowledge and techniques that will lead to the development of more effective drugs and more personalized medicine
    - defining methods of identifying subpopulations that are susceptible to particular chemical carcinogens and likely to experience adverse drug reactions or decreased drug efficacy
    - studying the interaction of light with cosmetic ingredients and tattoo pigments.
- Arkansas Department of Health Public Laboratory is a FERN Chemistry laboratory
- Dallas District Public Affairs Specialists – Respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including a growing number of Hispanic workers employed by the poultry industry
- Southwest Import District Public Affairs Specialist – Focuses on Import issues, conducts education and outreach to the Import industry, State and other government officials, and supports border health issues

Food and Drug Administration
Fact Sheet – Arizona

FDA Presence

- 34 employees in Arizona (LOS-DO has 14 employees in Arizona)
- Resident Posts: Phoenix , Tucson
- Employees report to Los Angeles District, Irvine, CA
- Irvine, CA reports to Pacific Region, Oakland, CA
- Southwest Import District Resident Post – Nogales – 16 employees; San Luis, AZ – 3 employees who report to the Southwest Import District, Dallas, TX.

Industry Presence in State: 2,570 FDA–regulated establishments

- Food establishments – includes cosmetics – 39 percent
- Medical Device and Radiological establishments – 32 percent
- Human Drug establishments – 16 percent
- Biological establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 8 percent.

Industry Highlights

- 5 firms in Arizona that produce human biological products including 6 plasmaphoeresis centers and 4 American Red Cross facilities

- More than 10 manufacturers of vitamin and mineral Over-the-Counter products
- Southwest Import District received 532,568 line entries for fiscal year 2009. The primary products are: Fresh Produce, Frozen Shrimp, and Medical Devices.

Contracts and Partnerships:

State Contracts

- Arizona Radiation Regulatory Agency – inspections of mammography facilities
- Arizona Department of Agriculture – inspections of feed mills for medicated feeds and BSE.

State Partnerships

- Arizona Department of Agriculture – agree to establish working arrangements on mutual planning and share reports of inspection, investigations, and analytical findings on raw agricultural products
- Arizona Department of Health Services – coordinate retail food protection, including Hazard Analysis and Critical Control Points principles to control food safety hazards
- Southwest Import District Public Affairs Specialist – focuses on import issues, conducts education and outreach to the import industry, state and other government officials and supports border health issues.

Food and Drug Administration
Fact Sheet – California

FDA Presence

- 507 FDA employees in California –includes SWID & PRL–SW. 247 employees are in Southern California with the remaining in Northern California
- SAN–DO Resident Posts are in – Fresno, Sacramento, San Jose, and Stockton. South San Francisco Resident Post slated to open in 2011
- LOS–DO Resident Posts are in San Diego, San Pedro, Long Beach (CES) and Torrance (International Mail Facility), LAX, Ontario and Canoga Park
- Employees report to San Francisco District, Alameda, and Los Angeles District in Irvine which reports to the Pacific Region Office, Oakland
- Resident Posts – San Diego, San Pedro, LAX, Ontario and Canoga Park report to Los Angeles District, Irvine, which reports to Pacific Region, Oakland
- Pacific Region Laboratory Southwest, Irvine reports to Pacific Region, Oakland

- Southwest Import District Resident Posts – 40 employees – Otay Mesa, Calexico, San Diego Seaport/Airport, and Tecate report to Southwest Import District, Dallas, Texas which report to the Southwest Region, Dallas, Texas
- San Francisco District Laboratory, reports to San Francisco District, in turn reports to Pacific Region Office.

Industry Presence in State – 20,419 FDA–regulated establishments

- Food establishments – includes cosmetics – 44 percent
- Medical device and Radiological establishments – 36 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 7 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights

- California has the greatest number of medical device and biotechnology firms of any area in the US. They are concentrated in the San Francisco Bay Area, Orange County and San Diego areas
- California is a major producer of tree nuts and the only state that produces almonds
- California continues to lead the nation in the fresh vegetable market, accounting for 44 percent of the U.S. harvested area, 49 percent of the national production, and 50 percent of the total value, for the 24 selected crops estimated
- California receives an estimated 25 – 30 percent of all FDA regulated commodities imported into the US, and contains the largest harbor complex in the country. 1,100 ocean shipping containers, containing foodstuffs arrive each day in the Port of Los Angeles/Long Beach, increasing at approximately 20 percent annually. The district serves as the “Gateway to the Orient” for imports and exports and with the import operations along the U.S. and Mexico border, a significant “Gateway to Mexico ” A total of 70 percent of all incoming cargo is believed to stay within the state boundaries
- Ports of entry along the California/Mexico border as well as the San Diego airport and seaport accounted for 2,036,846 line entries in Fiscal Year 2009
- Ports of entry along the California/Mexico border as well as the San Diego airport and seaport accounted for 3,162,823 line entries in Fiscal Year 2010.

Contracts & Partnerships

State Contracts

- California Department of Food & Agriculture (CDFA) – Conduct follow up investigations of reported tissue residues of food animals detected at the time of slaughter and conduct inspections of feed mills and BSE
- California Department of Public Health (CDPH) – Conduct inspections of food manufacturing facilities, mammography facilities and x–ray testing

State Partnerships

California Department of Food & Agriculture (CDFA)

- Coordinate efforts to prevent unsafe imported dairy products from entering commerce
- Coordinate inspections of medicated feed mills and residue investigations
- Coordinate regulatory activities involving pesticide residues on raw agricultural commodities.

California Department of Public Health (CDPH)

- Conduct inspections of seafood processing facilities
- Coordinate retail food protection efforts to promote HACCP principles for food safety
- Conduct inspections of all Acidified & Low Acid Canned Food processors
- Continue partnership with the laboratory in Los Angeles to co–locating employees and sharing equipment
- Establish partnership to co–locate employees in Sacramento
- Conduct inspections of new x–ray assemblies or re–assemblies
- Share inspectional and other information to ensure unified food safety programs
- Coordinate cooperative agreement to support the California Egg Quality Assurance Plan.

California Department of Pesticides Regulations

- Information exchange of positive Pesticides findings and firm follow up. California Department of Pesticides Enforcement Branch conducts sample collections and trace backs. Notifies FDA of violative samples for import targeting.

Other Partnerships in California

- Coordinate with American Council for Food Safety & Quality to maintain sanitation and compliance with regulations for dried fruit and tree nut products
- Information sharing with the University of California, Irvine, through an electronic communication system that transmits current health information regarding toxic substances throughout the California County Health Departments
- Southwest Import District Public Affairs Specialist – The primary focus is on Import issues. The SWID PAS conducts education and outreach to the

Import industry, U.S. Customs Broker Associations, state and other government officials and supports border health issues.
- Collaborate with the Western Institute for Food Safety and Security (WIFSS) for outreach and education to food manufacturers, growers and distributors
- RRT State/Adopted Manufacturing Food Program Standards

Food and Drug Administration
Fact Sheet – Colorado

FDA Presence

- 138 FDA employees in Colorado in the Denver District Office which reports to the Southwest Region, Dallas, Texas
- Denver port of entry with one employee reports to Southwest Import District in Dallas, Texas
    - Southwest Import District Reports to the Southwest Regional Office in Dallas Texas

Industry Presence in State – 2,736 FDA–regulated establishments

- Food establishments – includes cosmetics – 43 percent
- Medical device and Radiological establishments – 23 percent
- Human drug establishments – 16 percent
- Animal drug and feed establishments – 15 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights

- Colorado is a major cattle producer and also raises large numbers of hogs and sheep. Weld, Morgan, Larimer, and Boulder counties are the national center for the production of cattle fattened in feedlots rather than on the open range
- Colorado ranks high among the U.S. states in the amount of land under irrigation. Corn –maize, wheat, and hay are the major crops
- Colorado has a major food and food product industry
- The industrial and service sectors in Colorado have expanded greatly. The state's economy is diversified and is notable for its concentration of scientific research and high–technology industries
- Other Colorado industries include food processing, transportation equipment, machinery, chemical products, minerals, and tourism, particularly ski destinations such as Aspen and Vail
- Colorado also produces the largest amount of beer of any state
- Imports into Colorado – The Southwest Import District (SWID in Dallas) received 26,608 line entries for fiscal year 2010 through Colorado ports of entry. Primary products are medical devices, alcoholic beverages, cosmetics, and medical devices.

Contracts & Partnerships:

State Contracts

- Colorado Department of Public Health & Environment – conduct food sanitation inspections (231 total food inspections), and inspections of mammography facilities
- Colorado Department of Agriculture – Conduct inspections of feed mills for medicated feed and BSE Rule Compliance (85 total inspections)

State Partnerships

- Colorado Department of Public Health & Environment – Conduct inspections of artificial tanning facilities and conduct federal compliance testing of new assemblies or re–assemblies of x–ray equipment

Food and Drug Administration
Fact Sheet – Connecticut

FDA Presence

- 15 FDA employees in Connecticut (12 District, 1 Regional in Hartford, 1 Foreign Cadre in Hartford, and 1 Foreign Cadre in Bridgeport)
- Resident Posts: Hartford – 11 employees, and Bridgeport –4 employees; Report to New England District, Stoneham, Massachusetts, which reports to Northeast Region, Jamaica, New York.

Industry Presence in State **– 1,689 FDA–regulated establishments**

- Food establishments – includes cosmetics – 33 percent
- Medical Device and Radiological establishments – 43 percent
- Human drug establishments – 18 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments –includes blood banks – 3 percent

Industry Highlights

- Connecticut has 20 percent of the District's Official Establishment Inventory of regulated firms with an emphasis on food and medical devices
- Several major pharmaceutical manufacturers are located in the state
- Connecticut continues to hold dairy, poultry, tobacco, vegetables and fruit as its most important agricultural assets
- Several food and pharmaceutical companies comprise Connecticut’s top 100 industries, , including United Natural Foods, Bozzuto’s, Purdue Pharma, LP, and IMS Health, Inc.
- Included in Connecticut’s top 25 imported products are cane,,beet sugar and coffee.

Contracts, Partnerships & Local Activities:

State Contracts

- Connecticut Department of Consumer Protection – conduct food sanitation inspections, conduct seafood and juice Hazard Analysis and Critical Control Point (HACCP) inspections, and participate in FDA's Manufactured Food Regulatory Program Standards
- Connecticut Department of Environmental Protection –Conduct inspections of mammography facilities.

Local Activities

- Connecticut has a Food Safety Task Force in which FDA is a participant.

Food and Drug Administration
Fact Sheet – Delaware

FDA Presence:

- 12 FDA employees in Delaware
- Resident Post: Wilmington
  Reports to: Philadelphia District, Philadelphia, Pennsylvania
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 223 FDA-regulated establishments[5]

- Food establishments – includes cosmetics – 37 percent
- Medical device and radiological establishments – 33 percent
- Human drug establishments – 19 percent
- Animal drug and feed establishments – 5 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Active seafood industry

Contracts, Partnerships & Local Activities:

State contracts

- Delaware Department of Health – Conducts inspections of mammography facilities
- Conducts inspections of mammography facilities

State Partnerships

Delaware Food Safety Council (DFSC)

- A partnership with the state and local governments, academia, industry, and USDA to address food safety issues.

Memorandum of Understanding

Delaware Department of Agriculture – Tissue Residue

[5] Some firms are in more than one category.

Food and Drug Administration
Fact Sheet – District of Columbia

FDA Presence:

- 13 FDA employees in District of Columbia
- Resident Post: Falls Church Resident Post services Washington D.C
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 331 FDA–regulated establishments

- Food establishments – includes cosmetics – 54 percent
- Medical device and Radiological establishments – 24 percent
- Human drug establishments – 11 percent
- Biologic establishments – includes blood banks – 9 percent
- Animal drug and feed establishments – 1 percent

Contracts & Partnerships:

State Partnerships

District of Columbia Department of Health, Health Care Regulation and Licensing Administration

- support DC Department of Health Food Safety Program in developing and coordinating resources
- provide training to augment the Retail Food Safety Program
- coordinate other activities, including inspection of food manufacturers and processors, food warehouses, and seafood facilities.

Food and Drug Administration
Fact Sheet – Florida

FDA Presence:

- 163 FDA employees in Florida (includes 6 student)
- Resident Posts: Boca Raton, Ft. Myers, Jacksonville, Miami (Domestic), Tallahassee, Tampa, Miami (Imports), Port Everglades (co–located with USCBP), Miami International Mail Facility
- Major Import Ports: Miami, Jacksonville, and Tampa
- Report to Florida District Office, Maitland, FL
- Maitland, FL reports to Southeast Region, Atlanta, GA

Industry Presence in Florida – 8,440 FDA–regulated establishments

- Food establishments – includes cosmetics – 39 percent
- Medical devices and Radiological establishments – 39 percent
- Human drug establishments – 16 percent
- Animal drug and feed establishments – 3 percent

- Biologics establishments – 4 percent

Industry Highlights:

- Miami – largest port in U.S. for importation of fresh seafood
- Miami – fifth largest port in U.S. for importation of FDA regulated commodities
- 359 class II & III medical device firms

Contracts, Partnerships & Local Activities:

State Contracts

- Florida Department of Agriculture & Consumer Services (FDACS), Division of Food Safety contracted to perform food safety and seafood HACCP inspections
- FDACS, Division of Agricultural Environmental Services contracted to perform BSE inspections
- Florida Department of Health contracted to conduct mammography and x–ray inspections.

Cooperative Agreement

- FDACS, Division of Agricultural Environmental Services – cooperative agreement with FDA for BSE surveillance activities.

Partnership

- FDACS, Bureau of Chemical Residue Laboratories shares volatile pesticide residue results from imported and domestic produce with FLA–DO.

Collaborative Activities

- FLA-DO works with FDACS, Divisions of Food Safety, and Agricultural Environmental Services, and Office of Agricultural Emergency Preparedness, Florida Department of Health and Florida Department of Business & Professional Regulation to develop a rapid response team.

Food and Drug Administration
Fact Sheet – Georgia

FDA Presence:

- 247 FDA employees in Georgia
- Resident Posts in Georgia: Middle Georgia, Savannah, and Tifton
  Report to: Atlanta District, Atlanta, who
  Reports to: Southeast Region, Atlanta
- Southeast Regional Laboratory, Atlanta
  Reports to: Southeast Region, Atlanta
- HQ employees in GA: Facilities – 2, Financial Mgmt. Br.– 3, OAGS – 2, OC – 1, LMR – 1, DHRD –1, CFSAN – 1, DFS – 1, DFI – 1, OSITS – 5.

Industry Presence in State – 3,180 FDA-regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical Device and Radiological establishments – 28 percent
- Human Drug establishments – 12 percent
- Animal Drug and Feed establishments – 10 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- American Red Cross Regional Blood Bank
- Life Share Corp. HQ (formerly Serologicals) – major plasmapheresis center
- Cryolife – largest/major tissue bank processor
- Atlanta Hartsfield-Jackson International Airport land port – 85,510 import entries per annum – condoms, gloves, seafood, produce, medical devices
- Savannah seaport –118,046 import entries per annum – canned foods, medical devices, bulk grains, agricultural products, and juices
- Brunswick seaport – less than 80 entries per annum – 90% seafood.

Contracts, Partnerships & Local Activities:

State Contracts

Georgia Department of Agriculture

- inspects for food sanitation, feed mills, and BSE
- Inspects egg facilities.

Georgia Department of Natural Resources

- inspects mammography facilities.

Other Partnerships

- training activities to promote health and scientific education with Morris Brown College
- educational activities to promote health and dispense information on disease prevention with Spellman College
- development of problem solving models associated with complex scientific and public health challenges in minority communities with Morehouse School of Medicine.

Local Activities

- Assist state laboratories with analytical issues
- FDA ACNA Lab (National nutrition analysis/labeling service lab)
- Microbiology and Chemistry labs for foods, drugs, and cosmetics
- Georgia Food Safety & Defense Task Force
- Interagency Pest Risk Committee

Food and Drug Administration
Fact Sheet – Guam

FDA Presence:

- 9 FDA employees in Hawaii
- Resident Post: Honolulu
- Honolulu reports to: San Francisco District, Alameda, CA
- San Francisco reports to Pacific Region, Oakland, CA

Industry Presence in State – 36 FDA–regulated establishments

- Food establishments – includes cosmetics – 64 percent
- Medical device and radiological establishments – 22 percent
- Human drug establishments – 8 percent
- Biologic establishments – includes blood banks – 6 percent

Industry Highlights:

- More than half of the few FDA-regulated firms in Guam are related to the food industry, with the remaining spread fairly evenly among biologics, drugs, and device industries
- Guam exports copra, fish, and handmade goods
- Maize, cassava, bananas, and coconuts are grown for domestic consumption
- The island is also an important re-export center for distribution of goods throughout the Pacific, particularly to Micronesia.

Food and Drug Administration
Fact Sheet – Hawaii

FDA Presence:

- 9 FDA employees in Hawaii
- Resident Post: Honolulu
  Reports to: San Francisco District, Alameda, California, who
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 616 FDA–regulated establishments

- Food establishments – includes cosmetics – 58 percent
- Medical device and radiological establishments – 29 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 4 percent
- Animal drug and feed establishments – 2 percent

Industry Highlights:

- Staff an International Mail Facility in conjunction with DHS/CBP (Customs and Border Protection) to detain counter drugs via international mail
- Seafood, domestic and imports, is the largest industry on the Islands
- Importation of goods to and through Hawaii to the mainland accounts for 1/3 of FDA resources covering the review, inspection and sampling of products primarily from Asia.

Contracts, Partnerships & Local Activities:

State Contracts

Hawaii Department of Health

- Conduct inspections of mammography facilities
- Conduct diagnostic x-ray field tests.

State Partnerships

Hawaii Department of Health

- Conduct inspections of new x-ray assemblies or re-assemblies
- Support for a Food Safety Task Force for food safety.

Hawaii Department of Agriculture & Department of Health

- Support the Egg Quality Assurance Plan, an integrated voluntary food safety program designed to ensure quality and safety of eggs (with USDA, University of Hawaii and industry).

Local Activities

Ongoing public affairs cooperation with the

- Hawaii Food Manufacturers Association,
- University of Hawaii,
- Hawaii Cooperative Extension Service,
- Hawaii Dietetic Association,
- Hawaii Section/Institute of Food Technologists, and
- Hawaii Department of Health.

Food and Drug Administration
Fact Sheet – Idaho

FDA Presence:

- 8 FDA employees in Idaho
- Resident Post: Boise, Eastport
  Report to: Seattle District, Bothell, Washington
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 995 FDA–regulated establishments

- Food establishments – includes cosmetics – 61 percent
- Animal drug and feed establishments – 12 percent
- Medical device and radiological establishments – 14 percent
- Human drug establishments – 11 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Idaho is number one in the nation in the production of potatoes, trout and winter peas. Idaho produces 30% of U.S. potatoes, 50% of processed

potatoes and 76 % of food size trout. The state ranks in the top 10 in 22 other agricultural products.

- Out of 144 commodities, Idaho is in the top 10 in more than 30
- Food processing is the second largest industry, next to high tech. Idaho's high–tech industry is one of the state's largest employers
- The dairy industry is the largest single agricultural industry

Contracts, Partnerships & Local Activities

State Contracts

- Conducts food sanitation inspections

State Partnerships

- Idaho Department of Health and Welfare
- Establish working arrangements for food safety and sanitation inspections of food firms
- Inspect new x-ray assemblies or re-assemblies

Idaho Department of Agriculture

- Participation with the Idaho Bureau of Homeland Security Agro-Terrorism Group
- Regular interaction with Idaho Tech help to provide training to regional food processing companies

Food and Drug Administration
Fact Sheet – Illinois

FDA Presence:

- 124 FDA employees
- ORA Central Region Headquarters – 24 FDA employees
- Chicago District Office – 100 FDA employees
  Resident Posts: Mt. Vernon, Gurnee, Peoria, Hinsdale, Springfield, and O'Hare
  Report to: Chicago District, Chicago, Illinois
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,391 FDA-regulated establishments

- Food establishments – includes cosmetics – 41 percent
- Medical device and Radiological establishments – 38 percent
- Human drug establishments – 11 percent
- Animal drug and feed establishments – 6 percent
- Biologic establishments – includes blood banks – 4 percent

Imports:

- Imports – 500,000 lines processed per year
- Primary imports are alcoholic beverages (finished), bakery products, vegetables and fruit
- Receives product from 129 countries

Industry Highlights:

- Food processing is the state's number one manufacturing activity. State is the number one pumpkin and horseradish producer in the U.S. as well as one of the top soybean and corn producing states
- Number of high risk food firms is 462
- Number of class I device firms is 390 and the number of class II device firms is 281
- Archer Daniels Midland headquarters– $70B in revenue. ADM is the world's largest corn processor and the biggest processor of oil seeds – soybeans, cottonseed, sunflower seeds, and flaxseed in the U.S.
- World's largest wet corn mill owned by ADM
- Kraft Foods headquarters – $48B in revenue – Second largest food company in the world. Has 11 brands with revenues exceeding $1 billion, including: Kraft, Jacobs, LU, Maxwell House, Cadbury, Trident, Milk, Nabisco and its Oreo brand, Philadelphia, and Oscar Mayer
- Abbott Laboratories – $30B in pharmaceutical revenue
- Baxter International and Medline Industries, Inc. – both are Fortune 250, $10B medical device firms
- World class medical research universities include the University of Illinois, Northwestern University, University of Chicago, and Rush University Medical School, National Center for Food Safety and Technology
- Headquarters of PepsiCo Americas, Sara Lee, Walgreens McDonalds
- Largest U.S. source of pumpkins and pumpkin canning
- Major distribution hub for country – 300 of Fortune 500 companies operate major regional or national distribution centers in Illinois. There are 3,000 public warehousing facilities and 6,000 trucking companies.

Contracts, Partnerships, and Local Activities:

State Contracts

Illinois Department of Agriculture

- Feed mill inspections: 100 Bovine Spongiform Encephalopathy (BSE) and 13 Good Manufacturing Practices (GMP)

Illinois Department of Public Health

- Food safety inspections: 390 food inspections per year, 20 seafood inspections, and 5 Low acid canned food (LACF) inspections

Illinois Department of Revenue, Liquor Control Commission

- Tobacco Compliance and Enforcement: Conduct inspections of retail establishments to enforce the Youth Access and Advertising Regulations that took effect on June 22, 2010

State Cooperative Agreements (Grants)

Illinois Department of Agriculture

- Bovine Spongiform Encephalopathy (BSE): $1.2 million dollar cooperative agreement over five years – In previous two years over 1,000 cattle feed samples were analyzed

Illinois Dept. of Public Health Laboratory, for Microbiology

- Microbiology Program: Food Emergency Response Network (FERN) laboratory to provide additional capacity for analyzing food samples in the event of food borne disease outbreaks or other large scale food emergency events

Partnerships

Illinois Public Health Association

- Support annual Illinois Food Safety Symposium, HIV/STD Conference, Emergency Meeting and more

Great Lakes Regulatory Science and cGMP Conference

- This is a co-sponsorship agreement to promote understanding between FDA, industry, and academia on pharmaceutical manufacturing issues

Institute for Food Safety and Health

- This national partnership exists between the Illinois Institute of Technology, FDA, and the food industry to strengthen understanding of food safety science

Food and Drug Administration
Fact Sheet – Indiana

FDA Presence:

- 23 FDA employees in Indiana
- Resident Post: Indianapolis, Evansville, and South Bend
  Reports to: Detroit District Office, Detroit, Michigan
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 2,738 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 26 percent
- Animal drug and feed establishments – 12 percent
- Human Drug establishments (includes Medical Gas) – 12 percent
- Biological establishments – includes blood banks – 5 percent
- Bioresearch Monitoring establishments – 4 percent

Industry Highlights:

- Major drug manufacturers include Eli Lilly, Bristol Myers Squibb, Pfizer, Baxter, Cook, and Schwarz.

- Home to three of the world's largest orthopedic implant makers (Zimmer, Biomet, and DePuy), and major diagnostics manufacturer, Roche Diagnostics. Other large device firms such as Cook Inc., and Hill-Rom.
- Very active Medical Device Industry Association known as the Indiana Medical Device Manufacturers Council (IMDMC). Played a major role in implementation of FDA Modernization Act (FDAMA) and medical device inspection initiatives
- Infant formula manufacturer, Mead Johnson Nutrition
- Federal Express Hub in Indianapolis

Contracts & Partnerships:

State Contracts

Indiana Board of Health:

- Conduct inspections of mammography facilities
- Egg Rule Contract (New FY11)

Purdue University (Indiana Office of State Chemists)

- Conduct medicated feed mill and BSE inspections.

State Partnerships

Indiana Department of Health:

- Coordinate inspection plan to increase consumer safety by coordinating inspectional information of non-retail food establishments.

Indiana State Board of Animal Health:

- Share information on tissue residues in food producing animals

Food and Drug Administration
Fact Sheet – Iowa

FDA Presence:

- Ten FDA employees in Iowa
- Resident Posts: Davenport (2), and Des Moines (8)
  Report to: Kansas City District, Lenexa, Kansas
  Reports to: Southwest Region, Dallas, Texas

Industry Presence in State – 2,239 FDA-regulated establishments

- Food establishments – includes cosmetics – 50 percent
- Animal drug and feed establishments – 29 percent
- Medical device and radiological establishments – 13 percent
- Human drug establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

The Southwest Import District is responsible for imported products into Iowa. The primary imported products are alcoholic beverages, medical devices, and drugs**.**

Industry Highlights:

- Diverse, with all major FDA program areas represented
- Iowa ranks number one in the nation in revenue from the production and marketing of corn, soybeans and hogs
- Food processing remains Iowa's leading manufacturing industry
- Iowa has a heavy concentration of In-vitro diagnostic establishments:
- In-vitro diagnostic establishments: Iowa has a heavy concentration of these
- Bioresearch: One of the few bioequivalency testing facilities in the country
- State reports 1800 biotech firms and rank 1st in number of acres producing biotech corn and soybeans

Contracts, Partnerships & Local Activities:

State Contracts

Iowa Department of Agriculture and Land Stewardship

- Conduct inspections of medicated feed mills to ensure safety and BSE control
- Conduct targeted egg inspections in response to major recall in 2011

Iowa Department of Inspections and Appeals

- Conduct food safety inspections

State Partnerships

Iowa Department of Agriculture and Land Stewardship

- Coordinate oversight of regulated dairy manufacturing facilities
- Awarded partnership to upgrade automation hardware to support cooperation with FDA at national and District levels

Local Activities

- Iowa Food Safety Task Force – Established under FDA-funded grant
- Iowa is one of 8 states awarded FDA funding under a cooperative agreement to enhance their animal safety and BSE prevention programs
- KAN-DO coordinated with the State of Iowa in response to major flooding along the Missouri river in 2011. Disaster continues to have major impact on crops and agricultural land in Iowa and Missouri
- Kansas City District houses FDA's Total Diet Research and Pesticide Center Laboratory

Food and Drug Administration
Fact Sheet – Kansas

FDA Presence:

- 133 FDA employees in Kansas

- Resident Posts: Wichita (5)
  Reports to: Kansas City District, Lenexa, Kansas, who
  Report to: Southwest Region, Dallas, Texas
- Regional Staff: Lenexa (3)
- Headquarters Staff: DFO/OITSS Staff: Lenexa (4); & DFI Staff: Lenexa (1); DFSR Staff: Manhattan (1); OSS (1)

Industry Presence in State – 1,935 FDA-regulated establishments

- Food establishments – includes cosmetics – 51 percent
- Animal drug and feed establishments – 23 percent
- Medical device and radiological establishments – 15 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Agriculture-based economy
- Top producer of wheat, sorghum, corn, and sunflowers
- Produced 6.6 million head of cattle in the year 2000
- Significant animal feed industry
- The largest concentration of animal health industry in the world between Manhattan (KS) and Columbia (MO)
- The Southwest Import District is responsible for imported products in Kansas. The primary products imported are grain, seafood, animal drugs/devices, fresh vegetables, and cosmetics.

Contracts and Partnerships:

State contracts

Kansas Department of Agriculture (KDA)

- Conduct inspections of medicated animal feed mills to ensure safety and BSE control
- Conduct food safety inspections

Kansas Department of Health and the Environment

- Conduct mammography facility inspections

State Partnerships

Kansas Department of Agriculture

- Share responsibility for regulating dairy manufacturing facilities.

Local Activities

- KAN-DO is cooperating with state and local regulatory officials in Kansas to develop a statewide “food and agriculture emergency plan”
- Kansas is one of 8 states awarded FDA funding under a cooperative agreement to enhance their animal safety and BSE prevention programs
- Kansas City District houses FDA’s Total Diet Research and Pesticide Center Laboratory

Food and Drug Administration
Fact Sheet – Kentucky

FDA Presence:

- 13 FDA employees in Kentucky
- Resident Post: Louisville
  Reports to: Cincinnati District, Cincinnati, Ohio
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,911 FDA-regulated establishments

- Food establishments – includes cosmetics – 54 percent
- Medical device and Radiological establishments – 22 percent
- Human drug establishments – 12 percent
- Biologic establishments – includes blood banks – 3 percent
- Animal drug and feed establishments – 9 percent

Industry Highlights:

- Agriculture – Kentucky is the home of a significant agricultural base including dairy and food processing plants
- Medical device – Kentucky includes medical device and in–vitro diagnostic manufacturers
- Biologic – Kentucky is the home of blood and plasma firms, clinical research and bioresearch facilities
- Drugs – Kentucky has a growing pharmaceutical industry.

Contracts, Partnerships & Local Activities:

State Contracts

Kentucky Department of Public Health

- Conduct inspections of mammography facilities
- Conduct food safety inspections including Seafood HACCP
- Biannual meetings with Food Safety Branch

University of Kentucky

- Conduct inspections of medicated feed mills and BSE
- Yearly meeting with UK Regulatory Services – CVM/Feed issues.

State Partnerships

Kentucky Cabinet for Health Services of Commonwealth of Kentucky

- Coordinate testing of new and reassembled x-ray equipment
- Coordinate testing of new and reassembled x-ray equipment
- FDA provided funding so KY employees could attend FDA training courses
- CIN-DO developed a Tissue Residue Outreach Program to discuss illegal drug residues with farmers throughout the state

- Participated in Food Inspections including environmental sampling.

Local Activities

- CIN-DO attends Kentucky Food Safety Task Force meetings composed of State, Federal, Academic, and Industry Representatives with an interest in food safety and security
- CIN-DO holds an annual partnership meeting with KY Feed and KY Food Safety.

Food and Drug Administration
Fact Sheet – Louisiana

FDA Presence:

- 18 FDA employees in Louisiana
- Resident Posts in Louisiana: Baton Rouge, Covington, Lafayette, Mandeville, Metairie, and Shreveport
  Report to: New Orleans District (currently located in Nashville, TN), who Reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State – 2,583 FDA-regulated establishments

- Food establishments – includes cosmetics – 60 percent
- Medical device and Radiological establishments – 18 percent
- Human drug establishments – 12 percent
- Biologic establishments – includes blood banks – 4 percent
- Animal drug and feed establishments – 5 percent

Industry Highlights:

- Seafood –a primary industry supplying large volumes of shrimp, crawfish, crabs, oysters and fish. Fish include native wild and farm-raised, marine and fresh water species
- Imports – New Orleans is a major port, with green coffee the leading commodity
- Agriculture – major portions of Louisiana are supplying agricultural products, such as rice, soybeans, corn, sugar cane, poultry and cattle. Timber is the largest and most valuable agricultural product in Louisiana.
- Exports – Using the Mississippi River for transportation, the mid-continent of the United States markets its grain products to the world through port facilities located along the river in the vicinity of New Orleans.
- The Gulf Coast Area was affected by Hurricanes Katrina & Rita in 2005 and Hurricane Gustave in 2008. The industry is still recovering and will continue to be for a number of years.
- The Deepwater Horizon oil spill in 2010 has significantly affected the Gulf Coast seafood industry.
- A 2010 oil leak in an Assumption Parish sugarcane field caused substantial damage to crops in that area.

Contracts & Partnerships:

State contracts

Department of Health and Hospitals

- Conduct inspections of food for sanitation and seafood for Hazard Analysis and Critical Control Points (HACCP) requirements.

Department of Agriculture and Forestry

- Conduct follow-up investigations of violative tissue residues in food animals at the time of slaughter.

State Partnerships

Department of Health and Hospitals

- Coordinate public health emergencies in mutual areas of responsibility
- Share oversight and authority of regulated dairy manufacturing facilities

Department of Agriculture & Forestry

- Maintain a program for monitoring pesticide residues in raw agricultural commodities.

Special Programs

- LA Food Safety Network, established in 2007, which consists of: LA Department of Health & Hospitals; LA Department of Agriculture & Forestry; U.S. Department of Agriculture; LSU Extension Service; LA Restaurant Association and LA Grocers' Association

Food and Drug Administration
Fact Sheet – Maine

FDA Presence:

- 18 FDA employees in Maine, including one Foreign Cadre (Augusta)
- Resident Post: Augusta (10 employees) and
- Border Stations: Houlton (4 employees) and Calais (4 employees)
  Report to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 988 FDA-regulated establishments

- Food establishments – includes cosmetics – 69 percent
- Medical Device and Radiological establishments – 16 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 3 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Maine's inventory of firms makes up 11% of the District's Official Establishment Inventory of FDA-regulated firms, with the majority of those firms involved in the production and distribution of foods, and more than half of those firms involving seafood/shellfish products.
- Maine's agricultural outputs are seafood (notably lobsters), poultry and eggs, dairy products, cattle, blueberries, apples, and maple sugar. Aroostook County is known for its potato crops. Western Maine aquifers and springs are a major source of bottled water (Poland Spring water is the Northeast's preferred brand).
- Included in the State of Maine's top 25 imported products are food items, such as potatoes and salmon which arrive at various ports of entry. Most imported goods enter the State from Canada.

State Contracts & Partnerships:

State Contracts

Maine Department of Agriculture

- Conduct food sanitation inspections
- Conduct seafood and juice HACCP (Hazard Analysis and Critical Control Point) inspections

Maine Department of Human Services

- Conduct inspections of mammography facilities
- Participates in FDA's Manufactured Food Regulatory Program Standards.

Local Activities

- Maine has the Food Safety Group that meets to discuss food safety issues and allows us to foster contacts in the event of a food emergency. The group is made up of ME CDC, Agriculture, Health Inspection Program, Education, U Maine Cooperative extension, Marine Resources and FDA.
- Maine is also represented on the Board of Directors of the Northeast Food and Drug Officials Association (NEFDOA) by Hal Prince at the Maine Dept. of Agriculture, Food & Rural Resources and Lisa Brown at the DHHS Health Inspection Program. An annual training conference in Mystic Connecticut was held in May 2011.
- Hal Prince also attended the AFDO Annual Education Conference in Plano TX in June 2011.
- Maine Department of Agriculture and the DHHS Health Inspection Program are jointly hosting the FDA Northeast Region Annual Food Protection Seminar in Portland Maine in August 2011.

Food and Drug Administration
Fact Sheet – Maryland

FDA Presence:

- 66 FDA employees in Maryland
- Resident Posts: Dundalk Marine Terminal (imports)
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 2,861 FDA-regulated establishments

- Food establishments – includes cosmetics – 48 percent
- Medical device and Radiological establishments – 29 percent
- Human drug establishments – 11 percent
- Biologic establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 7 percent

Industry Highlights:

The industry in the state is very diverse and representative of the FDA national inventory, including large, medium and small firms active in all FDA regulated industries:

- Federal Food Service facilities
- Seafood
- Spices
- Bioresearch monitoring facilities (clinical investigators)
- Biotech facilities
- Imported products through the Port of Baltimore and BWI Airport

Contracts & Partnerships:

State Contracts

Maryland Department of Health and Mental Health

- Food/Seafood: Contract includes 180 inspections of food/seafood manufacturers, repackers, distributors, and warehouses; and collection of 21 samples.

Maryland Department of Agriculture

- Tissue Residue: Contract includes 5 inspections in follow-up to USDA findings of drug residues in excess of established tolerances in animals sold for human consumption.
- Bovine Spongiform Encephalopathy (BSE**)**: Contract includes 50 inspections of feed manufacturers, retail operations, haulers and collection of 150 feed samples.

Food and Drug Administration
Fact Sheet – Massachusetts

FDA Presence:

- 173 FDA employees in Massachusetts including the Regional Food & Drug Director, District Director, Compliance Branch, Investigations

Branch, Management Program and Support Branch, State Programs Branch, Winchester Engineering and Analytical Center (WEAC), Regional Emergency Response Coordinator, QMS, and Public Affairs

- Resident Post: Worcester (5 employees) and
- Border Station: Boston (12 employees)
  Report to: New England District, Stoneham, MA, District employees (92)
  Reports to: Northeast Region, Jamaica, NY
- Regional Food & Drug Director, WEAC (50 employees), State Programs Branch (5), Regional Quality System Manager, and the Regional Emergency Response Coordinator who
  Report to: Northeast Region, Jamaica, NY
- HQ employees: DCIQA (1), DIO (2), DFSR (1), OAGS (1), QMS (1) (District)

Industry Presence in State – 4,080 FDA-regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical Device and Radiological establishments – 34 percent
- Human drug establishments – 13 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Houses almost one–half of the regulated industry in New England with special emphases in biotechnology, medical devices, and foods. Serves as corporate headquarters for many of these firms
- In addition, as a coastal state, Massachusetts has a large inventory of seafood establishments. Massachusetts is one of the leading commercial fishing states. New Bedford accounts for about half the scallops produced in the nation. This industry delivers a broad range of product including cod, flounder, haddock, lobster, ocean perch, whiting, clams, crabs, hake, herring, pollock, squid, swordfish and tuna.
- Massachusetts' top five agricultural products are greenhouse and nursery products, cranberries, dairy products, sweet corn, and apples.
- The state is one of the world's important medical research centers and private universities and colleges are major employers.
- Included in the Commonwealth of Massachusetts' top 25 imported products are medical devices, food products and seafood.
- The WEAC laboratories provide specialized analytical services in engineering, medical device and radionuclide analysis. In this regard, the WEAC facility is FDA's only major field laboratory installation to provide service in these areas. WEAC is the primary field laboratory upon which CDRH relies for its analytical services. All engineering analysis for the GWQAP analytical program is performed at WEAC. In addition to the specialized analytical procedures for radionuclides in foods and radiopharmaceuticals, WEAC performs chemical and microbiological testing.

State Contracts and Partnerships:

State Contracts

Massachusetts Department of Public Health

- Conduct inspections of mammography facilities
- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections
- Participate in FDA's Manufactured Food Regulatory Program Standards

Local Activities

- FDA is a participant in Massachusetts Partnership for Food Safety and the Massachusetts Coalition for Food Safety and Defense activities.
- Massachusetts has applied to participate in the Food Protection Task Force Conference.
- The Massachusetts Bureau of Environmental Health (BEH) accepted an FDA Food Protection Rapid Response Team (RRT) and Program Improvement Prototype Project Grant**.** Through the cooperative agreement the Bureau (BEH) will enhance the capacity of its Food Protection Program (FPP) through continuous program assessment and staff development and training. MDPH proposes to work closely with FDA over the course of three years to enhance food emergency response capacity by improving existing regulatory programs for manufacturing facilities. The FDA Food Protection Plan will be incorporated into the FPP enhancements in order to implement food safety prevention, intervention and response into all steps of the food supply chain.
- Commonwealth of Massachusetts, in conjunction with FDA's New England District Office, hosted the National Center for Biomedical Research and Training (NCBRT) course: *A Coordinated Response to Food Emergencies: Practice and Execution.* This was held on January 24-25, 2011.

Food and Drug Administration
Fact Sheet – Michigan

FDA Presence:

- 113 FDA employees in Michigan
- Resident Posts: Grand Rapids, Kalamazoo, Detroit Ambassador Bridge, Port Huron and Sault Saint Marie
  Report to: Detroit District Office, Detroit, MI
  Reports to: Central Region Office, Chicago, IL

Industry Presence in State – 3,561 FDA–regulated establishments

- Food establishments – includes cosmetics – 44 percent

- Medical Device and Radiological establishments – 30 percent
- Animal drug and feed establishments – 12 percent
- Human Drug establishments (includes Medical Gas) – 11 percent
- Biological establishments – includes blood banks – 4 percent
- Bioresearch Monitoring Establishments – 5 percent

Industry Highlights:

Major firms:

- Drugs:JHP Pharmaceuticals, Pharmacia and Upjohn Co. Div. of Pfizer, Dow Chemical, Perrigo, Albemarle Corporation, Vertellus Health and Specialty Products, Caraco Pharmaceutical.
- Foods: Mead Johnson Nutritionals, Ross Laboratories, Gerber Products, Kellogg Co., Post Cereals.
- Devices: Dow Corning, Stryker Instruments, Terumo Cardiovascular Systems Corp., Atek Medical Manufacturing, Amigo Mobility, Tri–State Hospital Supply.
- Biologics: Emergent BioDefense Operations Lansing (formerly Bioport, sole source of Anthrax vaccine), American Red Cross National Testing Laboratory.
- Imports: Detroit District ports of entry include airports, seaports, and border crossings along the Canadian border. FDA–regulated commodities entering through these ports include food, drugs, medical devices and radiological products, biologics and cosmetics.

Contracts & Partnerships:

State Contracts

Michigan Department of Agriculture and Rural Development

- Conduct medicated feed mill and BSE rule inspections
- Conduct follow up investigations of violative drug tissue residues of food animals detected at the time of slaughter.
- Conduct food safety inspections (410 Inspections in FY10).
- Egg Rule Contract (New FY–11)

Michigan Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Michigan Department of Agriculture

- Implement an inspection plan to assure quality of non–Interstate Milk Shippers dairy products, other foods & drinks produced at dairy plants.
- Collect animal feed samples for FDA pesticide residue analysis.

Michigan Department of Public Health

- Educate consumers about the risks and dangers of health fraud.

State Cooperative Agreements

- BSE
- Rapid Response Team

Food and Drug Administration
Fact Sheet – Minnesota

FDA Presence:

- 98 FDA employees in Minnesota
- Resident Post: International Falls
  Reports to: Minneapolis District: Minneapolis
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,385 FDA-regulated establishments:

- Food establishments – includes cosmetics – 40 percent
- Medical device and Radiological establishments – 19 percent
- Animal drug and feed establishments – 34 percent
- Human drug establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- There are 10 ports of entry in the State of Minnesota.
- FDA regulated import entries are predominantly human food whole grain and milled products and non–medicated feed on the Northern border. Entries made through the Minneapolis ports are predominately Medical Devices and human food with fewer human drugs, radiological products and ceramic ware.
- Minnesota FDA regulated import entries are predominantly handled out of the Minneapolis District Office and one Resident Post on the Canadian border – International Falls. Assistance may also be given by our Madison Resident Post as needed.

Industry Highlights:

- Leads the nation in production of sugar beets, green peas and sweet corn for processing, and turkeys
- Second in the nation in production of spring wheat, oats, dry edible beans, and canola. Other key crops/products include canola, corn, dry edible beans, sunflowers, soybeans, barley, potatoes, flaxseed, total cheese, American cheese, cheddar, milk, honey, milk cows, and hogs.
- Minnesota ranks sixth nationally in agricultural exports
- Minnesota is home to such major firms as Medtronic, General Mills, 3M, Pillsbury, Land 0'Lakes, Boston Scientific, and St. Jude Medical
- The University of Minnesota and the Mayo Clinic are very active in medical bio–research

Contracts & Partnerships:

State Contracts

Minnesota Department of Agriculture

- Conduct GMP inspections of licensed medicated feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food safety inspections, seafood HACCP, juice HACCP, LACF, and elevator inspections.
- Conduct follow–up investigations of first time violators of tissue residues in food animals.

Minnesota Department of Health

- Conduct MQSA audits of mammography facilities.

State Cooperative Agreements (Grants)

Minnesota Department of Agriculture

- BSE cooperative agreement to develop and improve the infrastructure of the state feed safety and BSE prevention programs.
- Food Safety Task Force to coordinate and address food safety and defense issues among regulated industry and regulators within the state.
- Food Protection Rapid Response Team Cooperative Agreement is to develop and sustain an all Food Hazards Rapid Response Team, encompassing both food and feed protection programs, through a process to further enhance and build the infrastructure of State food protection programs.

Food and Drug Administration
Fact Sheet – Mississippi

FDA Presence:

- 7 FDA employees in Mississippi
- Resident Post: Jackson
  Reports to: New Orleans District (currently located in Nashville, TN), who
  Reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State – 1006 FDA-regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical device and Radiological establishments – 25 percent
- Human drug establishments – 12 percent
- Animal drug and feed establishments – 13 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Two major ports of entry – Gulfport, Pascagoula. Most bananas imported into the U.S. are entered through the Port of Gulfport.
- Seafood – Mississippi's primary food industry includes Gulf shrimp and oysters from the coast and farm–raised catfish in the Delta.

- Agriculture – Poultry, timber, cattle, cotton, and soybeans are major agricultural crops.
- Ship building is a sizeable industry located in the city of Pascagoula.
- Human Drugs and Devices – Baxter operates a large LVP and device manufacturing facility in Cleveland.
- The Gulf Coast area was affected by Hurricanes Katrina & Rita in 2005. The industry is still recovering and will continue to be for a number of years.
- The Deepwater Horizon oil spill in 2010 significantly affected the Gulf Coast seafood industry.

Contracts & Partnerships:

State Contracts

Mississippi Department of Health

- Conduct food sanitation inspections.

State Partnerships

Mississippi Department of Health

- Share oversight and authority of regulated Interstate Milk Shippers, Milk Processing Plants, and IMS listed Single Service Container Manufacturing Plants in Mississippi.
- Cooperate in the evaluation of Mississippi's efforts to control contributing factors linked to food borne illness outbreaks.

Mississippi Departments of Marine Resources, Agriculture, and Health

- Establish a cooperative emergency response plan for natural disasters.

Special Programs

- Food Safety Task Force, which includes: MS Department of Health; MS Department of Agriculture and Commerce; MS Department of Marine Resources; MS State University Extension Service; MS Chemical Laboratory; MS Restaurant Association, and MS Farm Bureau.

Food and Drug Administration
Fact Sheet – Missouri

FDA Presence:

- 68 FDA employees in Missouri.
- Resident Posts: St. Louis (26), Springfield (4)
  Report to: Kansas City District, Lenexa, Kansas, who
  Reports to: Southwest Region, Dallas, Texas
- CDER National Division of Pharmaceutical Analysis *(St. Louis – 38)*

Industry Presence in State – 2,745 FDA-regulated establishments

- Food establishments – includes cosmetics – 41 percent
- Medical device and Radiological establishments – 25 percent
- Animal drug and feed establishments – 15 percent

- Human drug establishments – 14 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Key Agricultural Products:

– Major crops include soybeans, corn and wheat
– During CY 2000, the state produced 4.4 M head of cattle and 263 M chickens

- Bio–technology– Missouri ranks 11th among the top 25 biotechnology industry states in U.S.
- Major Veterinary Pharmaceutical Industry
- Southwest Import District handles imports for Missouri. The majority of products are medical devices and foods.
- The largest concentration of animal health industry in the world situated between Columbia (MO) and Manhattan (KS) aka "America's Animal Health Corridor"

Contracts, Partnerships & Local Activities:

State contracts

Missouri Department of Health and Senior Services

- Conduct inspections of mammography facilities.
- Conduct food safety inspections

State Partnerships

Missouri Department of Agriculture

- Conduct inspections and information sharing related to BSE.

Missouri Department of Health and Senior Services

- Coordinate the oversight of dairy manufacturing facilities
- Awarded to accomplish staphylococcus aureus survivability study

Local Activities

- Pharmaceutical Technical Exchange Association meets semi-annually and organized by FDA's Kansas City District to facilitate information exchange among the 200 member firms.
- KAN-DO cooperated with Missouri in response to major flooding along the Missouri river in 2011. The disaster continues to have major impact on crops and the agricultural industry in Iowa, Nebraska and Missouri.
- After 7th most deadly tornado in U.S. history struck Joplin, MO, cadres of KAN-DO investigators were dispatched to inspect FDA–regulated firms, including blood banks and food storage facilities.

Food and Drug Administration
Fact Sheet – Montana

FDA Presence:

- 6 FDA employees in Montana

- Resident Posts: Helena and Sweet grass
  Report to: Seattle District: Bothell, Washington,
  Reports to: Pacific Region: Oakland, California

Industry Presence in State – 1,178 FDA-regulated establishments

- Food establishments – includes cosmetics – 65 percent
- Medical device and Radiological establishments – 11 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 14 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

- Production and processing of high protein grains and cereals is the leading agricultural activity, followed by beef.
- The largest General Mills facility is located in Billings, Montana.
- Over 270 grain elevators are subject to FDA inspectional jurisdiction.

Contracts & Partnerships

State contracts

Montana Department of Agriculture

- Conduct BSE inspections.

Montana Department of Public Health and Human Services

- Conducts inspections of mammography facilities and food facilities.
- Conducts food sanitation inspections.

State Partnerships

Montana Department of Agriculture

- The cooperative program encourages work sharing, data sharing, and educational exchange with respect to safety of animal feed.

Montana Department of Public Health and Human Services

- Establish working arrangements concerning mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms operating in Montana.

Food and Drug Administration
Fact Sheet – Nebraska

FDA Presence:

- 5 FDA employees in Nebraska
- Resident Post: Omaha (4)
- Reports to: Kansas City District, Lenexa, Kansas
- Reports to: Southwest Region, Dallas, Texas
- Reports to HQ: OA/OIM/DIO (1)

Industry Presence in State – 1,345 FDA-regulated establishments

- Food establishments – includes cosmetics – 44 percent
- Animal drug and feed establishments – 30 percent
- Medical device and radiological establishments –14 percent
- Human drug establishments –10 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

Key Agricultural State

- Major products include cattle, corn, hogs, soybeans, wheat, sorghum
- Major Industry involves food processing of state's farm output
- In 2004, produced 6.7 M cattle; 3 M hogs, 15 M chickens/broilers

Imports in Nebraska:

- Import entries are handled by the Southwest Import District. The primary products are fresh fruits and vegetables, candies, cosmetics and devices.

Contracts, Partnerships & Local Activities:

State Contracts

Nebraska Department of Agriculture

- Conduct inspections of the animal feed industry for compliance of GMP & BSE regulations.
- Conduct food safety inspections.

State Partnerships

Nebraska Department of Agriculture

- Share oversight of dairy manufacturing facilities.

Local Activities

- Nebraska is 1 of 8 states awarded funding under a cooperative agreement designed to enhance animal feed safety and BSE prevention programs.
- Nebraska Department of Agriculture has enrolled in FDA's nationally recognized Retail Food Standards Program.
- Nebraska Food Safety Task Force – Established under FDA-funded grant.

Food and Drug Administration
Fact Sheet – Nevada

FDA Presence:

- 3 FDA employees in Nevada
- Resident Posts: Reno, Las Vegas
  Reports to: San Francisco District, Alameda, California, who
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 831 FDA-regulated establishments

- Medical device and radiological establishments – 43 percent
- Food establishments – includes cosmetics – 25 percent
- Animal drug and feed establishments – 12 percent
- Human drug establishments – 14 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Growth of tourism and entertainment industry — more than 7,000 food service establishments in Clark County (including Las Vegas) alone and expansion of food–related industries in the state.

Contracts & Local Activities:

State Contracts

Nevada Department of Health and Human Services

- Conduct inspections of food manufacturing facilities
- Conduct inspections of mammography facilities.
- Adopted the Manufacturing Food Program Standards in 2011

Local Activities

- Ongoing public affairs cooperation with Nevada Cooperative Extension Service, Nevada Dietetic Association, University of Nevada-Las Vegas and University of Nevada-Reno.
- FDA has worked closely with the Nevada State Health Division, Bureau of Health Protection Services, in oversight and training in areas of acidified foods and fluid milk, to provide for better coverage and more uniform application of laws and regulations.
- Nevada Food Protection Task Force – Established under FDA-funded grant.

Food and Drug Administration
Fact Sheet – New Hampshire

FDA Presence:

- 3 FDA employees
- Resident Post: Concord
  Reports to: New England District, Stoneham, Massachusetts who Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 623 FDA-regulated establishments:

- Food establishments – includes cosmetics – 44 percent
- Medical Device and Radiological establishments – 37 percent
- Human drug establishments – 14 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- New Hampshire's inventory makes up approximately 7% of the New England District Official Establishment Inventory of regulated firms, with an emphasis on foods and medical devices.
- Dairy farming and dairy products contribute about 31% of the state's total agricultural receipts.
- Sweet corn and potatoes are the leading vegetable crops while apples are the leading fruit crop.
- Included in New Hampshire's top 25 imported products are food items, such as frozen fish fillets, and medical device instruments.

State Contracts, Partnerships & Local Activities

None

Food and Drug Administration
Fact Sheet – New Jersey

FDA Presence:

- 103 employees in New Jersey
- Resident Posts: Voorhees, North Brunswick
  Report to: New Jersey District, Parsippany, New Jersey
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,207 FDA-regulated establishments

- Food establishments – includes cosmetics – 47 percent
- Medical Device and Radiological establishments – 32 percent
- Human Drug establishments – 16 percent
- Biological establishments – includes blood banks – 3 percent
- Animal drug and feed establishments – 2 percent

Industry Highlights:

- New Jersey is recognized as the global epicenter of the pharmaceutical industry, with 15 of the world's 25 largest pharmaceutical companies having major facilities there. Also home to more pharmaceutical companies than any other state in the country, or any other country in the world.
- Throughout the 1990's, NJ-based pharmaceutical companies discovered and developed more than 1/3 of new drugs approved by FDA and are responsible for over 40% of the prescription medicine sales in the U.S.
- The medical device industry produces approximately 8% of U.S. medical technology sales.
- NJ also has a large and thriving seafood industry and is home to numerous major food-processing companies.

Contracts & Partnerships:

State Contracts

New Jersey Department of Health and Senior Services

- Conducts over 400 food safety inspections, including seafood and juice HAACP inspections.

New Jersey Department of Environmental Protection

- Conducts inspections of mammography facilities

New Jersey Department of Agriculture

- Conducts follow up investigations of violative tissue residues in food animals found at the time of slaughter.
- Conduct inspections of feed mills and feed generators for compliance with medicated feed and BSE–related requirements.

State Partnerships

New Jersey Department of Health and Senior Services

- Training and equipment to enhance capabilities to conduct food safety inspections.
- Public health and food safety educational projects to increase awareness and protect consumers from unsafe food handling practices

New Jersey Department of Agriculture

- Educational project to enhance farmers dairy cattle medication record keeping and prevention of pathogen related illness from dairy herds

New Jersey Department of Environmental Protection

- Equipment and supplies to enhance collection and analysis of agricultural food commodities for pesticide levels.

Food and Drug Administration
Fact Sheet – New Mexico

FDA Presence:

- 3 FDA employees in New Mexico.
- Albuquerque Resident Post with2 employees reports to: Denver District Office in Denver, Colorado
  Denver District Office Reports to SW Regional Office in Dallas Texas
- Santa Teresa Resident Post with 1 employee and Columbus Resident Post with 0 employees report to Southwest Import District in Dallas, Texas
  Southwest Import District Reports to the Southwest Regional Office in Dallas Texas

Industry Presence in State – 805 FDA-regulated establishments

- Food establishments – includes cosmetics – 44 percent
- Human drug establishments – 20 percent
- Medical device and Radiological establishments – 19 percent
- Animal drug and feed establishments – 11 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Cattle and dairy products are major animal products of New Mexico.
- Limited, scientifically controlled dry land farming prospers alongside cattle ranching. Major crops include hay, nursery stock, pecans, and Chile peppers. Hay and sorghum top the list of major dry land crops. Farmers also produce onions, potatoes, and dairy products. New Mexico specialty crops include pinon nuts, pinto beans, and chilies.
- Industrial output, centered around Albuquerque, includes electric equipment, petroleum and coal products, food processing, printing and publishing, and stone, glass, and clay products. Defense–related industries include ordnance. Important high–technology industries include lasers, data processing, and solar energy.
- Imports in New Mexico: The Southwest Import District (SWID in Dallas) received 93,605 line entries during FY 2010 through New Mexico ports of entry. The primary imported products are alcoholic beverages and seafood.

Contracts and Partnerships:

State Contracts

New Mexico Department of Agriculture and Environmental Services

- Conduct inspections of medicated feed mills for safety and BSE control.

New Mexico State University

- Conduct scientific review of rapid test methods for validity and potential use in FDA Laboratories for regulatory screening

State Partnerships

New Mexico Department of Agriculture

- Conduct federal compliance testing of new assemblies or re–assemblies of x–ray equipment.

New Mexico Departments of Health, Agriculture, Environment, Livestock; Albuquerque City Health Department, Bernalillo County Environmental Health Department; NM Food Producers/Processors Association; NM University Cooperative Extension Service; and other industry and consumer groups Formalize ongoing cooperative program to educate regulators, industry & consumers on HACCP, food safety principles, & develop/implement statewide HACCP training plan.

Food and Drug Administration
Fact Sheet – New York

FDA Presence:

- 407 FDA employees in New York State
- Resident Posts: Albany, Alexandria Bay, Binghamton, Champlain, Central Islip, Massena, New Windsor, Ogdensburg, Rochester, Syracuse, Port

Elizabeth, NJ and White Plains, and Buffalo. 2 permanent offices at the Port of Buffalo (Peace Bridge and Lewiston Bridge)
Report to: New York District, Jamaica NY (238 District employees) who Reports to: Northeast Region, Jamaica, NY
Regional Office (12 employees), Northeast Regional Laboratory (130 employees), NY who reports to: Northeast Region
HQ Employees: OIM (14), OFS (4), DFFI (8), DCMO (1)

Industry Presence in State – 10,039 regulated establishments

- Food establishments – includes cosmetics – 42 percent
- Medical Device and Radiological establishments – 34 percent
- Human drug establishments – 12 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Imports – New York District ports of entry include airports, a seaport (located in Port Elizabeth, NJ), and numerous border crossings along the Canadian border. About 20% of the FDA regulated commodities enter the country through New York. Cheese, cosmetics, and active pharmaceutical ingredients are the top three high volume commodities. An international postal facility at JFK Airport requires New York District surveillance activity to regulate a significant volume of pharmaceutical entries. Another facility is located in Secaucus, NJ where mail from ocean borne carriers is handled. Along the Canadian Border we are successful in improving our effectiveness in import coverage by leveraging with the NY State Department of Agriculture and Markets, the Canadian Food Inspection Agency, Health Canada and with other government agencies including, Customs and Border Protection, USDA, Fish and Wildlife Service and the US Postal Service.
- Generic drugs – New York supports a significant generic drug industry.
- Bioresearch – A significant number of clinical investigators and Institutional Review Boards affiliated with NYC metropolitan hospitals.
- Dairy – New York is one of the lead dairy states in the country.
- Livestock – New York receives a significant number of reports on violative residues in food animals detected at the time of slaughter from the USDA.
- Food – New York is the home of a highly visible food interstate conveyance sanitation program at the airports, rail and bus transportation locations. Food processors would include smoked fish, seafood, vegetables and cheese.
- There were 3,793,248 line entries of FDA–regulated products that were imported through the New York ports of entry through August 15, 2011; 4,545,760 line entries of FDA regulated products are projected to come through New York ports by the end of FY 2011.

Contracts & Partnerships:

State contracts

New York Department of Agriculture and Markets

- Conducts sanitation, seafood HACCP, juice HACCP, LACF/AF, BSE, medicated feed and tissue residue inspections.
- NYSDAM is in phase III of the food audit process and is responsible for conducting audits of its own inspectors.

New York State Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

New York Department of Agriculture and Markets

- Coordinate the food protection efforts to reduce consumer risk, eliminate duplication, define regulatory roles, and improve communication.
- Provides information on State initiated recalls.
- Collects food samples for pesticide analysis.

Other

- Conduct inspections of mammography facilities by NY City inspectors.
- Enhanced collaborative efforts with Customs and Border Protection resulting in the detection of entries previously circumventing entry review process.
- NYSDAM and FDA work together to halt the entry and distribution of adulterated foods of import origin. This effort includes the sampling of imported foods encountered by NYSDAM in the domestic marketplace for ultimate submission to FDA for analysis. When a violation is confirmed, NYSDAM will initiate the appropriate regulatory action on the market while FDA will initiate an Import Alert to prevent future entries of the violative product.
- Collaborate with the Office of the Canadian Consulate General to conduct periodic new exporter seminars, using education as a means to achieve compliance. The Consulate coordinates logistics regarding meeting sites, reproduction of handouts, and solicitation of attendees. FDA provides an instructor and materials.
- Leveraging with the Canadian Food Inspection Agency and Health Canada to share information when high risk violations are encountered in products crossing the border. This offers enhanced consumer protection to both US and Canadian Consumers.

Food and Drug Administration
Fact Sheet – North Carolina

FDA Presence:

- 18 FDA employees in North Carolina
- Resident Posts: Asheville, Charlotte, Greensboro, Greenville, Raleigh, and Wilmington
  Report to: Atlanta District, Atlanta, Georgia, who
  Reports to: Southeast Region, Atlanta, Georgia
- HQ employee: ORO–1

Industry Presence in State – 2,644 FDA–regulated establishments

- Food establishments – includes cosmetics – 37 percent
- Medical Device and Radiological establishments – 29 percent
- Human Drug establishments – 18 percent
- Animal Drug and Feed establishments –11 percent
- Biological establishments – includes blood banks – 5 percent

Industry Highlights:

- Major international drug firms located in Research Triangle Park area
- Significant medical device industries
- Land ports in Charlotte (15,000 entries per annum), Raleigh–Durham (27,455 entries per annum), and Greensboro (4,000 entries per annum)—major products include foods, drugs, and medical devices. Sea ports in Wilmington (3,600+ entries per annum)—major products include animal feeds and commodities such as grapes, and Morehead City–Beaufort (less than 25 entries per annum)—major products include dry bulk animal feed and human food.

Contracts, Partnerships & Local Activities:

State Contracts

North Carolina Department of Agriculture

- Conduct inspections of feed mills for medicated feed and BSE
- Conduct food sanitation inspections
- Conduct Egg Facility Inspections

North Carolina Department of Environment & Natural Resources

- Conduct inspections of mammography facilities.
- Conduct inspection of fish & fisheries products processors for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations.

State Partnerships

North Carolina Department of Agriculture and Consumer Services

- Conduct joint statutory inspectional coverage of the medical gas Manufacturing and repacking industries.
- Joint NCDA&CS–FDA Rapid Response Team for food emergencies

Local Activities

North Carolina Food Safety and Defense Task Force

Fact Sheet – North Dakota

FDA Presence:

- 8 FDA employees in North Dakota
- Resident Posts: Dunseith, Fargo, Pembina and Portal
  Report to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,425 FDA-regulated establishments

- Food establishments – includes cosmetics – 53 percent
- Animal drug and feed establishments – 40 percent
- Medical Device and Radiological establishments –5 percent
- Human drug establishments – 2 percent
- Biologic establishments – includes blood banks – 1 percent

Imports:

- There are 22 active ports of entry in North Dakota.
- FDA regulated import entries are predominantly human food whole grain and milled products and non–medicated animal feed.
- Regulated import entries are predominantly handled out of the 2 ND Northern border ports in Pembina and Portal.

Industry Highlights:

- Agriculture – North Dakota is the overall leader of wheat production and the top producer of durum wheat and spring wheat. The State also leads the nation in the production of honey, barley, lentils, sunflowers, dry edible beans, dry edible peas, flaxseed, and canola. Other key crops include oats, potatoes, and sugar beets.
- Raising elk, deer and buffalo for meat is a part of the agri-industry.

Contracts & Partnerships:

State Contracts

North Dakota Department of Agriculture

- Conduct GMP inspections of licensed feed mills, and BSE inspections of licensed and unlicensed feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

North Dakota Department of Health

- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Ohio

FDA Presence:

- 162 FDA employees in Ohio

- Resident Posts: Cincinnati South, Brunswick (Cleveland area), Columbus, and Toledo
  Report to: Cincinnati District, Cincinnati, Ohio
  Reports to: Central Region, Chicago, Illinois
- Forensic Chemistry Center: Cincinnati, Ohio
- The Cincinnati District Office and the Forensic Chemistry Center are separate organizations, each report to the Central Region in Chicago, IL.

Industry Presence in State – 5,037 FDA-regulated establishments

- Food establishments – includes cosmetics – 45 percent
- Medical Device and Radiological establishments – 31 percent
- Human drug establishments – 13 percent
- Animal drug and feed establishments – 7 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

- Foods- Ohio is headquarters to many national and international food and flavor firms. The State is a leader in many areas including: frozen specialty foods, pet food, ketchup and is the nation's largest producer of Swiss cheese and second in egg production. The world's largest pizza, soup and yogurt plants call Ohio home.
- Agriculture- Ohio includes a significant agricultural base including "mega–farms".
- Drugs- Ohio is the home of numerous pharmaceutical facilities.
- Devices: Ohio is home to firms which are worldwide supplies of x–ray equipment, wheelchairs and "sterilizers."

Contracts, Partnerships & Local Activities:

State Contracts

Department of Agriculture

- Conduct inspections of feed mills for medicated feed and BSE.
- Conduct human food sanitation inspections including Seafood & Juice HACCP.
- Conduct follow up investigations of violative drug residues in food animals at the time of slaughter.
- Conduct inspections for compliance with the Egg Rule

Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Ohio Department of Agriculture (ODA)

- Establish training for state employees in analytical procedures and joint inspections.
- Joint training of the livestock industry on producing and marketing livestock without drug residues.
- Participated in FDA eSAF training.

- Participated in Better Process Control School.
- Partnered to provide Seafood and Juice HACCP training for industry.
- Participated in Food Inspections including environmental sampling.

Ohio Department of Health (ODH)

- Conduct federal compliance testing of new or re–assemblies of x–ray equipment.

Local Activities

- CIN–DO holds an annual partnership meeting with ODA Food Division, ODA Laboratories and ODH.
- CIN–DO attends quarterly FORC–G Meetings with State and local officials on food safety issues.

Food and Drug Administration
Fact Sheet – Oklahoma

FDA Presence:

- 4 FDA employees in Oklahoma
- Resident Posts: Oklahoma City and Tulsa
  Report to: Dallas District, Dallas, Texas who
  Reports to: Southwest Region, Dallas, Texas
- Import entries are handled from the Southwest Import District office in Dallas, Texas and with the assistance of the staff located at the Dallas District Oklahoma Resident Posts.

Industry Presence in State – 2,028 FDA-regulated establishments

- Food establishments – includes cosmetics – 55 percent
- Animal drug and feed establishments – 19 percent
- Medical device and Radiological establishments – 13 percent
- Human drug establishments – 10 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Food - Oklahoma is a major egg production state and has several Tyson poultry production facilities. Also the home of Bama® pies.
- Grains – Oklahoma produces a significant amount of winter wheat, peanuts, soybeans, and seeds for sprouts.
- Farming – Oklahoma is a major producer of feeder cattle, milk and catfish.
- Medical devices – Oklahoma has major device manufacturers including Smith & Nephew Endoscopy, dental implants and kidney dialysis supplies.
- Dietary Supplements – Oklahoma houses Shaklee manufacturing.
- Bioresearch – the University of Oklahoma, School of Medicine generates work in the bioresearch program area.
- Southwest Import District- The entries received through Oklahoma are reviewed by SWID Investigators. The primary imported products are devices and processed foods.

Contracts, Partnerships and Local Activities:

State Contracts

Oklahoma Department of Health

- Conduct inspections of mammography facilities.
- Conduct inspections of food manufacturing and storage facilities

Oklahoma Department of Agriculture

- Conduct inspections of feed mills to determine compliance with BSE Rule.

State Partnerships

Oklahoma Department of Agriculture

- Share oversight and authority of regulated dairy manufacturing facilities

Dallas District Public Affairs Specialists respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including Native American tribes.

Southwest Import District Public Affairs Specialist focuses on Import issues. Conducts education and outreach to the Import industry, State and other government officials and supports border health issues.

Food and Drug Administration
Fact Sheet – Oregon

FDA Presence:

- 26 FDA employees in Oregon
- Resident Posts: Portland and Beaverton who
  Report to: Seattle District, Bothell, Washington who
  Reports to: Pacific Region, Oakland, California

Industry Presence in State – 3,009 FDA-regulated establishments

- Food establishments – includes cosmetics – 67 percent
- Medical device and Radiological establishments – 18 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

- Oregon agriculture, fisheries, and food processing activities exceed $5.25 Billion in commerce.
- Biotechnology, medical device, and medical research activities are growing industries

Contracts, Partnerships & Local Activities

State Contracts

Oregon Department of Agriculture

- Conduct food sanitation inspections.

- Conduct follow–up investigations of violative tissue residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Oregon State Department of Human Resources
- Conduct inspections of mammography facilities

State Partnerships
Oregon State Department of Agriculture
- Share information and training to enhance consumer protection in food safety.

Local Activities
FDA representatives participate in:
- Interagency Food Safety Team
- Oregon Alliance Working for Antibiotic Resistance Education
- Collaborative activity with the Northwest Food Processor Association to promote food defense awareness

Food and Drug Administration
Fact Sheet – Pennsylvania

FDA Presence:
- 113 employees in Pennsylvania
- Resident Posts: Harrisburg, Pittsburgh, Wilkes Barre
  Report to: Philadelphia District, Philadelphia
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 5,063 FDA–regulated establishments
- Food Establishments – includes cosmetics – 43 percent
- Medical Device and Radiological establishments – 29 percent
- Human Drug establishments – 18 percent
- Animal drug and feed establishments – 5 percent
- Biological establishments – includes blood banks – 5 percent

Industry Highlights:
- Pennsylvania has a large pharmaceutical industry.
- Pennsylvania is one of the Nation's largest producers of dairy products, mushrooms, poultry and eggs.

Contracts, Partnerships & Local Activities:
State Contracts:
PA Department of Agriculture (PDA)
- Conducts inspections of medicated feed mills, including coverage of BSE.
- Conducts inspections of mammography facilities

- Conducts inspections of 100–150 food manufacturers in PA annually.

State Partnerships:
PA Food Safety Council (PFSC), a partnership with the state and local governments, academia, industry and USDA to address food safety issues.
PA Department of Agriculture:
- Coordinates regulatory activities enforcing the Nutrition Labeling & Education Act.
- Coordinates work planning and inspectional activities to assure all non–medicated feed mills in PA are inspected yearly, for compliance with regulations designed to prevent the introduction of BSE

PA Department of Agriculture and the PA Department of Health:
- Assure consumers that eggs from Pennsylvania are of minimal risk of food–borne disease from *Salmonella enteriditis.*

Memorandum of Understanding (MOU):
- PA Dept. of Agriculture, PA Dept. of Health and a number of egg producers for egg inspections under the PA Egg Quality Assurance Program.
- PA Department of Agriculture – Tissue Residue

Food and Drug Administration
Fact Sheet – Puerto Rico

- 80 FDA Full Time employees in Puerto Rico
  3 Part–Time Students
  2 Science Advisors
- Resident Posts: Aguada, Ponce and US Virgin Islands
- National Drug Specialty Laboratory– Accredited in May 2006 under ISO 17025.
  Reports to: San Juan District Office,
  Reports to: Southeast Region, Atlanta, GA
- Office of Criminal Investigations (OCI): 6 FT employees– reports to OCI FLA–FO

Industry Presence in State – 1,485 FDA–regulated establishments
- Food establishments – includes cosmetics – 51 percent
- Medical device and radiological establishments – 25 percent
- Human drug establishments – 16 percent
- Animal drug and feed establishments – 5 percent
- Biologics establishments – includes blood banks – 3 percent

Industry Highlights:
- Puerto Rico has the 3rd largest bio–manufacturing capacity in the world with 53% of PhRMA affiliates
- In 2001, P.R. ranked 1st in percent share of pharmaceutical global exports

and 5th in percent share of pharmaceutical global production. In 2004, pharmaceutical exports reached $35.2 billion or 64% of all island exports.

- In 2008, 13 of the top 20 ethical prescription drug products sold in USA as well 13 of the top 20 Rx products sold globally were manufactured in PR
- Major manufacturers include: Astra Zeneca/IPR, Pfizer, Eli Lilly, Abbott, Bristol Myers Squibb, Merck Sharp & Dhome, Biovail, Amgen, Procter & Gamble, Schering–Plough, J&J Pharmaceutical Partners (Janssen, McNeil, Ortho), Legacy, Roche Pharma, and Warner–Chilcott.
- Other companies are moving part of their process development and research to PR including Bristol Myers Squibb, Abbott and Becton Dickinson.
- PR has a sizable presence of internationally recognized medical device manufacturing companies which has increased to about 80 in the last few years-approximately 50% of all pacemakers and defibrillators sold in the US mainland are manufactured here.
- San Juan is a significant trans–shipment point for cargo – fresh produce, non–perishable goods, active pharmaceutical ingredients and device parts
- Puerto Rico has the largest, noncontiguous Foreign Trade Zone (FTZ) system in the United States.
- There is one International Mail Facility located in Carolina, PR.
- In 2006, biologics produced in PR sold over $16 billion in the US alone. This, along with over $4 billion invested in biotechnology plants over the past 5 years, makes PR one of the fastest growing life sciences center in the world. 25% of the world's biological manufacturing capacity is located in Puerto Rico.

International Work:

- SJN– District operational staff is fully bilingual. 50% of our chemists and experienced investigators are active in the foreign inspection cadre. Our staff also plans and supports educational activities on QSR and GMP for representatives of regulatory agencies throughout Latin America and the Caribbean, through organizations such as ISPE, PDA, Pharmaceutical Industry Assoc. of PR, PAHO, foreign government organizations and Academia. Our employees travel to South and Central America, Mexico, Europe, Asia, and Canada, among others.

Contracts, MOUs & Partnerships:

- P.R. Department of Health– Environmental Health Division:
  - Contract to conduct inspections of food manufacturers for sanitation
  - Pilot to share violative food inspections cases to leverage enforcement.
  - MOU: Confers embargo and seizure powers to SJN–DO for inspection of regulated goods in response to natural disasters.
  - Publication of the Federal Food Code Handbook in Spanish for Health Department to train their inspectors. 200 graduated in December 2006.
  - Published a summary of the Food Code, both in Spanish and English, to train Puerto Rico and USVI food establishments' staff.

- P.R. Department of Health– Radiological Health Division:
  - Contract to conduct inspections of mammography facilities.
- P.R. Department of Agriculture:
  - MOU on emergency relocation, complying with COOP requirements.
  - Agrological Lab accepted into FERN.
- P.R. Department of Consumer Affairs
  - Pilot to share information on violative dietary supplements and unapproved drugs, particularly in the area of ED and sexual enhancement drugs.

Food and Drug Administration
Fact Sheet – Rhode Island

FDA Presence:

- 6 FDA employees in Rhode Island
- Resident Post: Riverside
  Reports to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 616 FDA–regulated establishments

- Food establishments – includes cosmetics – 46 percent
- Medical Device and Radiological establishments – 34 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments – 2 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- Rhode Island is responsible for 7% of the District's Official Establishment Inventory of FDA–regulated firms with an emphasis on foods and medical devices.
- Milk is the third–ranking agricultural product of the state. Dairy products account for about 5% of the total agricultural receipts
- Beef cattle, hogs, and chickens are raised in the state. Chicken eggs produce important revenue.
- Sweet corn is generates about 6% of the state's total agricultural receipts.
- The fishing industry includes a variety of fish, mollusks and shellfish. Lobster is the most valuable of these. Other important catches are anglerfish, clams, cod, flounder, scup, squid, whiting and yellowfish.

State Contracts and Partnerships

State Contracts

Rhode Island Department of Health

- Conduct food sanitation inspections and seafood HACCP (Hazard Analysis and Critical Control Point) inspections.
- Conduct inspections of mammography facilities.

- Participate in FDA's Manufactured Food Regulatory Program Standards.
- Rhode Island has a Food Safety Task Force in which FDA is a participant. They also hold meetings and training sessions sponsored by the Food Safety Task Force in which FDA participates.
- RI is also putting together a strategic plan to meet Healthy People 2020 Health Objectives for food safety. Once the draft plan is complete, the State will obtain input from the task force on how best to reduce illness in each of the target areas.

Food and Drug Administration
Fact Sheet – South Carolina

FDA Presence:

- 12 FDA employees in South Carolina
- Resident Posts: Charleston, Columbia, and Greenville
  Report to: Atlanta District, Atlanta, Georgia, who
  Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 1,291 FDA–regulated establishments

- Food establishments – includes cosmetics – 49 percent
- Medical Device and Radiological establishments – 27 percent
- Human Drug establishments – 12 percent
- Biological establishments – includes blood banks – 4 percent
- Animal Drug and feed establishments – 7 percent

Industry Highlights:

- Major egg industry
- Major food supplement manufacturer
- Charleston ranks 4th in the nation among the largest container seaports- 84,500+ entries annually
- major commodities include human foods and medical devices

Contracts, Partnerships & Local Activities:

State Contracts

South Carolina Department of Agriculture

- Conducts inspections of food manufacturers for sanitation.

South Carolina Department of Health & Environmental Controls

- Conduct inspections of mammography and soft drink/bottled water facilities.

Local Activities

- South Carolina Interagency Food Safety and Defense Council

Food and Drug Administration

Fact Sheet – South Dakota

FDA Presence:

- 2 FDA employees in South Dakota
- Resident Post: Sioux Falls
  Reports to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 1,127 FDA–regulated establishments

- Animal drug and feed establishments – 45 percent
- Food establishments – includes cosmetics – 42 percent
- Medical device and Radiological establishments – 8 percent
- Human Drug establishments – 4 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- 1 active port of entry
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The South Dakota FDA regulated import entries are handled out of the Minneapolis District FDA office with assistance from the Madison Resident Post as needed.

Industry Highlights:

- Agriculture- Ranks 2nd in the production of alfalfa hay, sunflowers, and flaxseed and honey.
- Other key crops include wheat, durum wheat, spring wheat, winter wheat, wheat, corn, hay, sorghum, soybeans, oats, and proso millet.
- Cattle and sheep ranching are also a significant.

Contracts:

State Contracts

South Dakota Department of Agriculture

- Conduct GMP inspections of licensed feed mills and BSE inspections of feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

South Dakota Department of Environment and Health

- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Tennessee

FDA Presence:

- 81 FDA employees in Tennessee

- Office/Resident Posts: Nashville, Chattanooga, Knoxville and Memphis, Report to: New Orleans District (currently located in Nashville, TN), who Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 3,169 FDA–regulated establishments

- Medical device and radiological establishments – 30 percent
- Food establishments – includes cosmetics – 40 percent
- Human drug establishments – 15 percent
- Biologic establishments – includes blood banks – 5 percent
- Animal drug and feed establishments – 11 percent

Industry Highlights:

- Memphis import operation reviews entries of regulated products for Fed–Ex, the nation's largest overnight courier service.
- Major medical research centers at universities and hospitals in Memphis and Nashville and a national biologics testing laboratory and several regional blood banking operations
- Major oral antibiotic manufacturer and 2 major implantable device manufacturers
- Rapidly expanding freshwater prawn/shrimp industry and 10 Paddlefish roe (domestic caviar) processors
- Industry in the Nashville area was affected by massive flooding in May 2010, and is still recovering.

Contracts & Partnerships:

State contracts

Tennessee Department of Agriculture

- Conduct sanitation inspections of food manufacturers
- Conduct BSE/ feed mill inspections

Special Programs

Tennessee Food Safety Task Force, since 2002. The TN Departments of Agriculture, Inspection & Veterinary Services; TN Department of Health Epidemiologist; TN Department of Education; Univ. of TN Agricultural Extension Service and several industry representatives meet quarterly for program planning and information sharing.

Food and Drug Administration
Fact Sheet – Texas

FDA Presence:

- 224 FDA employees in Texas
    - Dallas District (100),
    - Southwest Import District (SWID) (86),
        - Report to: Southwest Region (22),
- FDA has Import and Domestic Resident Posts in Texas:

    - Import Resident Posts: Dallas–Fort Worth International Airport, Houston Seaport/Airport, Yselta/El Paso, Laredo/Columbia/Lincoln–Juarez, Eagle Pass/ Del Rio, Rio Grande City, Pharr, Brownsville, San Antonio
    - Domestic Resident Posts: Austin, El Paso, Houston, Ft. Worth, San Antonio
- Office of Regulatory Affairs HQ (4) and Office of Shared Services/Office of Information Management (12)

Industry Presence in State – 9,382 FDA–regulated establishments

- Food establishments – includes cosmetics – 47 percent
- Medical devices and Radiological establishments – 20 percent
- Human drug establishments –13 percent
- Animal drug and feed establishments – 17 percent
- Biologics establishments – includes blood banks – 4 percent

Industry Highlights:

- Seafood – Texas Gulf Coast is the home of numerous seafood firms.
- Imports into Texas – Primary products are fresh produce, seafood, processed foods, and medical devices.
- Human Drugs and Medical Devices – Texas is the home of Alcon, Allergan, Abbott, Hoechst–Celanese, Mentor, Hospira and Cyberonics.
- The Texas Panhandle has a large number of feedlots, slaughter facilities, and rendering operations.

Contracts, Partnerships & Local Activities:

State Contracts (all with the Texas Department of State Health Services)

- Conduct inspections for food sanitation
- Conduct inspections for milk safety
- Conduct inspections for reported violative residue in food animals at slaughter
- Conduct inspections of mammography facilities
- Conduct medical device inspections

State Partnerships and Cooperative Agreements

Texas Department of Health

- Examine, sample and test imported foods, cosmetics, drugs & medical devices and take appropriate action
- Conduct inspections of medical gas and OTC drug manufacturers and repackers
- Examine, sample and test imported foods, cosmetics, drugs & medical devices and take appropriate action
- Conduct inspections of new x–ray assemblies and re–assemblies
- Coordinate inspections of dairy manufacturing facilities

- Texas received a Rapid Response Team grant

Office of the Texas State Chemist – Feed and Fertilizer Control Service

- Coordinate inspections of animal feed production and compliance with BSE rule consumer education outreach to diverse constituents.

Southwest Import District Public Affairs Specialist primary focus is on import issues. SWID PAS conducts education and outreach to the import industry, state, and other government officials and supports border health programs. Dallas District Public Affairs Specialists respond to consumers and media inquiries and conduct consumer education outreach to diverse constituents, including a large number of Hispanics.

Food and Drug Administration
Fact Sheet – U.S. Virgin Islands

FDA Presence:

- 1 Full Time FDA employee (Resident in Charge) in US Virgin Islands
- Resident Post: St. Thomas
  Reports to: San Juan District Office
  Reports to: Southeast Region, Atlanta, GA

Industry Presence in State – 75 FDA–regulated establishments

- 100 FDA–regulated establishments in US Virgin Islands
  (Some firms are in more than one category)
- Food establishments – includes cosmetics – 73 percent
- Medical device and radiological establishments – 8 percent
- Human drug establishments – 14 percent
- Biologic establishments – includes blood banks – 2 percent
- Animal drug and feed establishments – 1 percent
- Interstate Travel Program – 4 percent
- Import Operations:
  - International Mail Facility (1), located on St. Thomas;
  - Sea Container Ports (2); St. Thomas (1) and St. Croix (1)
  - Air Cargo (2): St. Thomas (1) and St. Croix (1)
  - Passenger Terminals (5): St. Thomas (2); St. Croix (2) and St. John (1)

Industry Highlights:

- 2 dairy farms.
- Charlotte Amalie is a major port for cruise ship stops.
- 1 International Mail Facility located in St. Thomas.
- Customs Service in the USVI is considered outside the Customs Territory of US, which it operates under the Danish Public Law 64. Import merchandise is carried out manually posing challenges in screening and targeting of import goods.

- Close working relations have been formed with the Federal and local government agencies including Customs and Border Protection, U.S. Postal Service, Drug Enforcement Agency, USVI Department of Health, USVI Department of Environmental Protection and Natural Resources; and the USVI Department of Consumer and Licensing.
- In Domestic Operations, the coordination of Recall Audit checks with the local USVI Health Department is crucial in that suspected adulterated products can be removed from the market on all 3 islands by virtue of joint collaboration and the use of local government embargo authority.

Contracts and Partnerships:

State Partnerships

- FDA's work, through our partnership with USVI Health Department, resulted in the adoption of two food safety laws in 2004: the Pasteurized Milk Ordinance and a modern Food Code. PMO is in abeyance.
- San Juan District has promoted use of experts within Puerto Rico to assist in the adoption of new laws and establishing a milk certification laboratory.
- The Commonwealth has provided training to USVI technologists on milk sampling and analyses, and agreed to analyze samples until USVI's milk certification lab is operational.
- Partners with the Departments of Health and Licensing and Consumers' Affairs to provide training on inspection techniques for inspectors.
- Negotiating establishment of MOU with the USVI Department of Health for granting of embargo power to FDA in case of emergencies.

Local Activities

The District's Public Affairs Office has developed and/or conducted:

- Food Defense/ALERT Outreach for Food Retailers and State Inspectors
- A brochure on Food Safety during emergencies
- Training on food safety and FSMA for government officials, academia, and industry
- Conference on diabetes and women
- Campaign on generic drugs

Food and Drug Administration
Fact Sheet – Utah

FDA Presence:

- 11 FDA employees in Utah
- Salt Lake City Resident Post reports to Denver District Office in Denver, Colorado
- Denver District Office reports to Southwest Regional Office in Dallas, Texas

Industry Presence in State – 1,304 FDA–regulated establishments

- Food establishments – includes cosmetics – 39 percent
- Medical device and radiological establishments – 27 percent
- Human drug establishments –19 percent
- Animal drug and feed establishments – 10 percent
- Biologic establishments – includes blood banks – 5 percent

Industry Highlights:

- Agriculture is dependent on irrigation, and more than —3/4 of farm income is from livestock and livestock products. Hay is the most important crop, followed by wheat, barley, and corn (maize).
- Following the national trend, farm employment and the number of farms in Utah have declined since 1960, but productivity has increased. Almost —3/4 of Utah's farm income comes from livestock products, the remainder from field crops, fruit, and canning crops.
- Utah has a thriving biotechnology and medical device manufacturing industry and is home to several of the nation's largest disposable device manufacturers.
- Imports – The Southwest Import District (SWID located in Dallas) received 6,390 entry lines for fiscal year 2010. Primary products are cosmetics and medical devices. Imports assignments issued by SWID are handled by Denver district staff.

Contracts, Partnerships & Local Activities:

State contracts

Utah Department of Health

- Conduct inspections of mammography facilities.

Utah Department of Agriculture and Foods, Regulatory Services

- Conduct inspections of feed mills for medicated feed and BSE
- Conduct 75 inspections of food firms

State Partnerships

Utah Department of Agriculture & Food, Utah Department of Health and Industry

- Support the Utah Egg Quality Assurance Plan to ensure quality and safety of shell eggs.
- Conduct feedlot inspections (15 total) for compliance with the ruminant feeding rule.

Utah Department of Environmental Quality

- Conduct inspections of new x–ray assemblies or re–assemblies.

Food and Drug Administration
Fact Sheet – Vermont

FDA Presence:

- 6 FDA employees in Vermont

- Border Station: High gate Springs
  Reports to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 616 FDA–regulated establishments

- Food establishments – includes cosmetics – 72 percent
- Medical Device and Radiological establishments – 13 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 6 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights:

- Vermont has 6% of the District's Official Establishment Inventory of FDA–regulated firms with a concentration in the food area.
- About 3/4 of Vermont's agricultural income is generated by the sale of dairy products.
- Other important livestock products are beef cattle and calves, chicken eggs, turkeys, and hogs.
- Leading vegetables grown in the state are sweet corn and potatoes. Apples are the largest fruit crop.
- Vermont is a leading maple–syrup producing state and also produces many specialty food products such as cheese, ice cream and sauces.
- Included in the State of Vermont’s top 25 imported products include food items, such as chocolate prep, maple sugar, corn, and animal feed.

State Contracts and Partnerships:

State Contracts

Vermont Department of Agriculture

- Conduct follow–up inspections/investigations of violative drug tissue residues in food animals at the time of slaughter. All inspections covered BSE.

Vermont Department of Health

- Conduct inspections of mammography facilities.
- Conduct food sanitation inspections and juice Hazard Analysis and Critical Control Point (HACCP) inspections.
- Participate in FDA’s Manufactured Food Regulatory Program Standards

Local Activities

- The State of Vermont participates in the Food Protection Task Force Conference**.**
- Representatives from the State also participated in:
  1. NEFDOA meeting in Mystic, CT in May 2011

2. AFDO Seafood Hazards Guide Training in Providence, RI in June 2011.
3. FDA Northeast Region Food Protection Seminar in Portland, ME in August 2011

- The State of Vermont also participates in the FDA New England District Tissue Residue Reduction Task Force. This task force is a collaborative initiative between the District and the VT Agency of Agriculture focused on the prevention of Illegal drug residues in meat and edible tissues of animals produced in VT for human consumption. The Task Force areas of emphasis are centered on Industry Outreach and Education, Improving FDA and VT State Investigational Effectiveness, and Promoting Compliance Outcomes.

Food and Drug Administration
Fact Sheet – Virginia

FDA Presence:

- 37 FDA employees in Virginia
- Resident Posts: Falls Church, Portsmouth, Richmond, and Roanoke
  Report to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 3,203 FDA–regulated establishments

- Food establishments – includes cosmetics – 53 percent
- Medical device and Radiological establishments – 26 percent
- Human drug establishments – 9 percent
- Animal drug and feed establishments – 8 percent
- Biologic establishments – includes blood banks – 4 percent

Industry Highlights:

The industry in the state is very diverse and representative of the FDA national inventory including large, medium and small firms active in all FDA regulated product lines.

- Seafood
- Federal Food Service facilities
- Biotechnology firms
- Headquarters of the largest blood supplier in the United States.
- Imported products via the ports of Norfolk/Newport News and Dulles International Airport

Contracts & Partnerships:

State Contracts

Virginia Department of Agriculture and Consumer Services

- Conduct 3 inspections of feed mills
- Bovine Spongiform Encephalopathy (BSE)- Contract includes 41 inspections of feed manufacturers, retail operations, haulers

- Food/Seafood- Contract includes 470 inspections of food/seafood manufacturers, repackers, distributors, and warehouses

Virginia Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Virginia Department of Agriculture and Consumer Services

- Collect and analyze food commodities grown for pesticides and industrial chemicals.

Virginia Department of Health Professions

- Conduct testing of new and re–assembled x–ray equipment.

Food and Drug Administration
Fact Sheet – Washington

FDA Presence:

- 167 FDA employees in Washington
- Resident Posts: Blaine, Seattle, Spokane, Yakima, Oroville, and Tacoma
  Report to: Seattle District: Bothell, WA who
  Reports to: Pacific Region: Oakland, California
- Pacific Northwest Regional Laboratory: Bothell, who reports to Pacific Region

Industry Presence in State – 5,163 FDA–regulated establishments

- Food establishments – includes cosmetics – 66 percent
- Medical device and Radiological establishments – 17 percent
- Human drug establishments – 6 percent
- Animal drug and feed establishments – 9 percent
- Biologic establishments – includes blood banks – 2 percent

Industry Highlights

Washington leading industries include dairy, fruit, biotechnology, and medical devices. Washington ranks in the top 5 nationwide in production of 29 different agricultural products. Washington is one of the largest and most diversified food and agricultural exporters.

Contracts, Partnerships & Local Activities

State Contracts: Washington Department of Agriculture

- Conduct inspections for food sanitation.
- Conduct investigations of reported violative residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Washington Department of Health

- Conduct inspections of mammography facilities. Conduct inspections of new X–ray assemblies or re–assemblies.

State Partnerships

Washington Department of Agriculture

- Coordinate the regulation for food safety by work sharing, data sharing and educational exchange, including all current and future inspectional and sampling contracts
- Coordinate the regulation of the fish and fishery products processing industry
- Participate in a cooperative program, which encourages work sharing, data sharing, and educational exchange concerning animal feed safety.

Local Activities

- Member of the Food Safety Review Council. The group works in partnership with the Department of Health in developing advisory technical interpretations of the state food service regulations and other matters.
- Member of the Washington State Subcommittee on Agricultural and Food Safety. The group works to reduce the vulnerability to a terrorist attack on agricultural industry and to improve coordination and collaboration among key partners.

Food and Drug Administration
Fact Sheet – West Virginia

FDA Presence:

- 3 FDA employees in West Virginia
- Resident Posts: Charleston and Morgantown
  Reports to: Baltimore District, Baltimore, Maryland
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 810 FDA–regulated establishments

- Food establishments – includes cosmetics – 53 percent
- Medical device and Radiological establishments – 22 percent
- Animal drug and feed establishments – 12 percent
- Human drug establishments – 10 percent
- Biologic establishments – includes blood banks – 3 percent

Industry Highlights:

- One of the largest producers of generic drug tablets in the country.
- Aquaculture (seafood)
- Many small acidified food producers (cottage industries)

Contracts & Partnerships:

State Contracts

West Virginia Bureau of Public Health

- Conduct 80 inspections for food safety.

- Conduct inspections of mammography facilities.

West Virginia Department of Agriculture

- Conduct 45 inspections of warehouses and seafood processors for food safety.
- Monitor and perform inspections of 30 feed mills, renderers and others to assure compliance with BSE regulations.

State Partnerships

West Virginia Department of Agriculture

- Conduct inspections of fish farms and processors, collect samples and analyze for pesticide and industrial chemical residues

West Virginia Radiological Health Program

- Conduct inspections new and reassembled x–ray equipment

Food and Drug Administration
Fact Sheet – Wisconsin

FDA Presence:

- 40 Full Time employees in Wisconsin
- Resident Posts: Milwaukee, Madison, Green Bay, La Crosse and Stevens Point
  Report to: Minneapolis District, Minneapolis, Minnesota
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 4,600 FDA–regulated establishments

- Food establishments – includes cosmetics – 56 percent
- Animal drug and feed establishments – 19 percent
- Medical device and Radiological establishments – 15 percent
- Human drug establishments – 7 percent
- Biologic establishments – includes blood banks – 2 percent

Imports:

- There are 3 ports of entry in the State of Wisconsin.
- FDA regulated import entries are primarily food, food additives, and medical devices.
- The Wisconsin FDA regulated import entries are handled out of the Minneapolis FDA office with assistance from the Madison Resident Post as needed.

Industry Highlights:

- Milk & Dairy – Leads the nation in total cheese, American cheese, Muenster cheese, Italian cheese, dry whey, and milk goat production; second in dairy cows, milk, butter, and mozzarella cheese.
- Cranberries – Ranks first in cranberry production.

- Low Acid Canned Foods – Ranks first in snap beans. Significant processing includes carrots, sweet corn, green peas, cucumbers/pickles, cabbage (kraut), and beets.
- Seafood – Home of more than 90 firms that process or handle seafood.
- Agriculture – Ranks first in corn for silage and oats production. Significant production occurs for: strawberries, maple syrup, mint for oil, potatoes, tart cherries, and ginseng.
- Medical Devices – Wisconsin is the home of 3 major medical device manufacturers: GE Medical Systems; General Electric Medical Systems Information Technology; & GE Imaging.

Contracts & Partnerships:

State Contracts

Wisconsin Department of Agriculture, Trade & Consumer Protection

- Conduct GMP inspections at licensed feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food sanitation, seafood HACCP, and juice HACCP inspections.
- Conduct follow–up inspections of first time violators of tissue residues in food animals.

Wisconsin Department of Health and Social Services

- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Wyoming

FDA Presence

- Wyoming is covered by the Denver District Office in Colorado. Denver District Office reports to Southwest Regional Office in Dallas, Texas
- Wyoming is the only state in the union without any permanently stationed FDA employees

Industry Presence in State – 276 FDA–regulated establishments

- Food establishments – includes cosmetics – 51 percent
- Human Drug establishments – 21 percent
- Medical Device and Radiological establishments – 14 percent
- Animal drug and feed establishments – 11 percent
- Biological establishments – includes blood banks – 3 percent

Industry Highlights

- Components of Wyoming's economy differ significantly from those of other states. The mineral extraction industry and the travel and tourism sector are the main drivers behind Wyoming’s economy.
- Federal government owns 50% of its landmass, while 6% is controlled by the state.

- Wyoming's mineral commodities include coal, natural gas, coal bed methane, crude oil, and trona. Wyoming ranks highest in mining employment in the U.S.
- The main agricultural commodities produced in Wyoming include livestock (beef), hay, sugar beets, grain (wheat and barley), and wool. Over 91% of land in Wyoming is classified as rural.

Contracts, Partnerships & Local Activities

State Contracts

Wyoming Department of Agriculture

- Conduct 35 food sanitation inspections

Wyoming Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Wyoming Department of Agriculture

- Share oversight & authority of regulated dairy manufacturing facilities.

Wyoming State Board of Pharmacy

- Conduct inspections of medical gas manufacturing facilities and share reports with the Denver District Office.

BLANK PAGE

Glossary of Acronyms

510k	Premarket Notification
AABB	American Association of Blood Banks
AAP	American Academy of Pediatrics
ABIG	Animal Biotechnology Interdisciplinary Group
ACA	Affordable Care Act
ACBSA	(HHS) Advisory Committee on Blood Safety and Availability
ACOMS	Advisory Committee Oversight and Management Staff
ADE	Adverse Drug Experience
ADRC	Animal Drugs Research Center
ADUFA	Animal Drug User Fee Act (or Amendments)
AED	Automatic External Defibrillator
AER	Adverse Experience Reports
AERS	Adverse Event Reporting System
AFSS	Animal Food Safety System
AGDUFA	Animal Generic Drug User Fee Act
AHRQ	Agency for Healthcare Research and Quality
ALM	Automated Laboratory Management
AMP	Real Property Asset Management Plan
AMS	Agricultural Marketing Service
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
APDS	Artificial Pancreas Device Systems
APEC	Asia Pacific Economic Cooperation
APHIS	Animal & Plant Health Inspection Service
API	Active Pharmaceutical Ingredient
ARL	Arkansas Regional Laboratory
ATF	Bureau of Alcohol, Tobacco, Firearms and Explosives
ATI	Analytical Tools Initiative
B&F	Buildings and Facilities Program
BA	Budget Authority
BA	Base Amount
BARDA	Biomedical Advanced Research and Development Authority
BIMO	Bioresearch Monitoring
BLA	Biologic License Application
BMAR	Backlog of Maintenance and Repair
BPA	Bisphenol A
BPCA	Best Pharmaceuticals for Children Act
BPCI	Biologics Price Competition and Innovation Act
BRF	Beltsville Research Laboratory
BSE	Bovine Spongiform Encephalopathy
BTA	Bioterrorism Act
CAP	Corrective action plan
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CBPR	Community-Based Participatory Research
CBRN	Chemical, Biological, Radiological or Nuclear
CCM	Common Communications Module
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health

CERS	Centers of Excellence in Regulatory Science
CeSub	CDRH Electronic Submissions
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CGMP	Current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
CJD	Crueutzfeldt-Jacob Disease
CLIA	Clinical Laboratory Improvement Amendments of 1988
CML	Chemical Mobile Laboratory
CMP	Civil Money Penalties
CMS	Centers for Medicare and Medicaid Services
CMS	Compliance Management System
COFEPRIS	Federal Commission for the Protection against Sanitary Risks
COMPACT	Compendium of Microbiological Protocols and Chemical Tests
CORE	Coordinated Outbreak Response and Evaluation
CPG	Compliance Policy Guide
CRADA	Cooperative Research and Development Agreement
CRT	Cardiac Resynchronization Therapy
CSTARS	Center Submission Tracking and Reporting System
CT	Computed Tomography
CTAC	Commercial Trade Analytical Center
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
CVS	Cardiovascular Systems
CY	Calendar Year
DARPA	Defense Advanced Research Projects Agency
DARRTS	Document Archiving, Reporting, and Regulatory Tracking System
DCIS	Defense Criminal Investigative Service
DEHP	di(2-ethylhexyl)phthalate
DFFC	Dedicated Foreign Food Cadre
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DICI	Direct Impact Corona Ionization
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOJ	Department of Justice
DRC	Direct Recall Classification
DTC	Direct-To-Consumer
DWPE	Detention Without Physical Examination
DX	Direct Expansion
eBPDR	Electronic Biological Product Deviation Reports
ECM	Energy Conservation Measure
eLEXNET	Electronic Laboratory Exchange Network
EMA	European Medicines Agency
EMS	Emergency Medical Services
EPA	Environmental Protection Agency
ERA	End-Review Amendments
eSAF	Electronic State Access to Field Accomplishment and Compliance Tracking System
EST	Embryonic Stem Cell Test
ETASU	Elements to Assure Safe Use
EU	European Union
EUA	Emergency Use Authorizations

FAC	Food Advisory Committee
FACA	Federal Advisory Committee Act
FACTS	Field Accomplishment and Compliance Tracking System
FAO	Food and Agriculture Organization
FCC	Forensic Chemistry Center
FCI	Facility Condition Index
FD&C Act	Food, Drug and Cosmetic Act
FDA	Food and Drug Adminstration
FDAAA	Food and Drug Administration Amendments Act
FDAMA	Food and Drug Administration Modernization Act
FERN	Food Emergency Response Network
FFDCA	Federal Food, Drug and Cosmetic Act
FOIA	Freedom of Information Act
FPTF	Food Protection Task Force
FR	Federal Register
FREE-B	Food Related Emergency Exercise Boxed Set
FSIS	Food Safety Inspection Service
FSMA	Food Safety Modernization Act
FSPTCA	Family Smoking Prevention and Tobacco Contract Act (Tobacco Control Act)
FTC	Federal Trade Commission
FTE	Full-Time Equivalent
FVM	Foods and Veterinary Medicine Program
FY	Fiscal Year
GBM	Glioblastoma Multiforme
GDUF	Generic Drug User Fee
GE	Genetically Engineered
GIS	Geographic Information System
GMP	Good Manufacturing Practices
GPhA	Generic Pharmaceutical Association
GRAS	Generally Recognized As Safe
GSA	General Services Administration
H1N1	Influenza A
HACCP	Hazard Analysis Critical Control Point
HBV	Hepatitis B Virus
HC	Health Canada
HCT	Human Cells, Tissues
HCT/Ps	Human Cells, Tissues, and Cellular and Tissue-based Products
HCV	Hepatitis C Virus
HDE	Humitarian Device Exemption
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HPHC	Harmful tobacco product constituent
HSP	Human Subject Protection
HTLV I/II	Human T-lymphotropic virus
HVAC	Heating, Ventilation, Air Conditioning
ICCR	International Cooperation on Cosmetic Regulation
ICD	Implantable Cardioverter Defibrillator
ICE	Immigration and Customs Enforcement
ICH	International Conference on Harmonization
ICOR	International Consortium of Orthopedic Registries
IDE	Investigational Device Exemption
IFSTL	International Food Safety Training Laboratory

IIWA	International Internet Week of Action
IMG	Incident Management Group
INAD	Investigational New Animal Drug
IND	Investigational New Drug
INTERPOL	International Criminal Police Organization
IOM	Institution of Medicine
IPRG	Interdisciplinary Pharmacogenomics Review Group
IPT	International Programs Team
IRAC	Interagency Risk Assessment Consortium
IRB	Institutional Review Board
IT	Information Technology
IUD	Intrauterine Devices
IVD	In-Vitro Diagnostic
IVET	InnoVation Exploration Team
JAMA	Journal of the American Medical Association
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JINAD	Generic Investigational New Animal Drug
JLC	Jefferson Laboratories Complex
LACF	Low-Acid Canned Foods
LCSD	Lake County Indiana Sheriff's Department
LGS	Low Glucose Suspend
LIMS	Laboratory Information Management System
LLC	Limited Liability Company
LMS	Learning Management System
LTKB	Liver Toxicity Knowledge Base
MAQC	MicroArray Quality Control
MARCS	Mission Accomplishment and Regulatory Compliance Services
MCM	Medical Countermeasurers
MCMi	Medical Countermeasures Initiative
MDR	Medical Device Reporting
MDUFA	Medical Device User Fee Amendments of 2007
MDUFMA	Medical Device User Fee and Modernization Act of 2002
MFRPS	Manufactured Foods Regulatory Program Standards
MMWR	*Morbidity and Mortality Weekly Report*
MOD1	Module One Research Laboratory
MOD2	Module Two Research Laboratories
MOU	Memorandum of Understanding
MQSA	Mammography Quality Standards Act
MRC	Muirkirk Road Complex
MRI	Magnetic Resonance Imaging
MRS	Magnetic Resonance Spectroscopy
MSD	Mitigation Strategies Database
MSM	Men who have sex with men
MUMS	Minor Use and Minor Species
NADA	New Animal Drug Applications
NAFLD	Nonalcoholic Fatty Liver Disease
NARMS	National Antimicrobial Resistance Monitoring System
NASH	Nonalcoholic Steatohepatitis
NCF	Nanotechnology Core Facility
NCTR	National Center for Toxicological Research
NDA	New Drug Application

NDI	New Dietary Ingredients
NHLBI	National Heart, Lung and Blood Institute
NIAID	National Institute for Allergy and Infectious Diseases
NIDA	National Institute of Drug Addiction (NIH)
NIH	National Institutes of Health
NOAA	National Oceanic and Atmospheric Administration
NRSA	National Research Service Award
NSTA	National Science Teachers Association
NTP	National Toxicology Program
OA	Office of Acquisitions
OASH	Office of the Assistant Secretary for Health
OB	Office of Budget
OC	Office of the Commissioner
OCC	Office of Chief Counsel
OCD	Office of the Center Director (CTP)
OCE	Office of Compliance and Enforcement (CTP)
OCET	Office of Counterterrorism and Emerging Threats
OCI	Office of Criminal Investigations
OCP	Office of Combination Products
OCR	Optical Character Resolution
OCS	Office of Chief Scientist
OCT	Optical Coherence Tomography
OCTC	Office of the Counselor to the Commissioner
ODA	Orphan Drug Act
OE	Office of Enforcement
OEA	Office of External Affairs
OECD	Organization for Economic Co-Operation and Development
OEEO	Office of Equal Employment Opportunity
OES	Office of Executive Secretariat
OF	Office of Finance
OF	Office of Foods
OFBA	Office of Finance, Budget and Acquisition
OGCP	Office of Good Clinical Practice
OGD	Office of Generic Drugs
OGROP	Office of Global Regulatory Operations and Policy
OHCE	Office of Health Communication and Education (CTP)
OHRP	Office for Human Research Protections
OIM	Office of Information Management
OIP	Office of International Programs
OIP	Office of International Programs
OL	Office of Legislation
OM	Office of Management
OMB	Office of Management and Budget
OMH	Office of Minority Health
OMPT	Office of Medical Products and Tobacco
OND	Office of New Drugs
OO	Office of Operations
OOPD	Office of Orphan Product Development
OP	Office of Policy (CTP)
OPP	Office of Policy and Planning
OPT	Office of Pediatric Therapeutics
OR	Office of Regulations (CTP)
OR	Office of Research
ORA	Office of Regulatory Affairs

ORO	Office of Regional Operations
ORSI	Office of Regulatory Science and Innovation
OS	Office of Science (CTP)
OSHA	Occupational Safety and Health Administration
OSHI	Office of Special Health Issues
OSI	Office of Scientific Integrity
OSMP	Office of Special Medical Programs
OSPD	Office of Scientific and Professional Development
OTC	Over-the-Counter
OWH	Office of Women's Health
P.L.	Public Law
PAC	Pediatric Advisory Committee
PAD	Program Activity Data
PAH	Polycyclic Aromatic Hydrocarbons
PAHO	Pan American Health Organization
PAHs	Polycyclic Aromatic Hydrocarbons
PAS	Post-Approval Studies
PATH	Program for Appropriate Technology in Health
PATH	Population Assessment of Tobacco and Health
PCR	Polymerase Chain Reaction
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PERC	Pediatric review Committee
PES	Program Evaluation and Executive Support
PET	Positron Emission Tomography
PETNet	Pet Event Tracking Network
PFGE	Pulsed Field Gel Electrophoresis
PFIPC	Permanent Forum on International Pharmaceutical Crime
PGx	Pharmacogenomics
PHAP	Public Health Action Plan
PHSAT	Public Health and Security Action Teams
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PM	Personalized Medicine
PMA	Premarket Approval
PMDA	Pharmaceuticals and Medical Devices Agency
PNC	Prior Notice Center
POP	Pelvic Organ Prolapse
PPP	Public Private partnerships
PREA	Pediatric Research Equity Act
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
PRISM	Postlicensure Rapid Immunization Safety Monitoring
QSIT	Quality Systems Inspection Technique
RAPID-B	Rapid Identification of Bacterial Pathogens
RBIS	Regulatory Business Information Services
REMS	Risk Evaluation Mitigation Strategies
RFD	Request for Designation
RFR	Reportable Food Registry
RiskMAP	Risk Minimization Action Plan
RNA	Recombinant DNA
RPM	Regulatory Procedures Manual
RPS	Regulated Product Submissions
RRT	Rapid Response Teams

RSF	Rentable Square Feet
RTE	Ready-To-Eat
SAP	Single Audit Program
SE	Salmonella Enteritidis
SENASICA	National Service for Agroalimentary Public Health, Safety and Quality
SEQC	Sequencing Quality Control
SNPT	Single Nucleotide Polymorphism Track
SOP	Standard Operating Procedure
SSC	Small Scientific Conference
STD	Sexually Transmitted Diseases
SW	Southwest
TCA	Tobacco Control Act
TIMS	Tobacco Inspection Management Systems
TPSAC	Tobacco Product Scientific Advisory Committee
U.S.C.	United States Code
UCSF	University of California, San Francisco
UDI	Unique Device Identification
UESC	Utility Energy Service Contract
UF	User Fee
UFMS	Unified Financial Management System
US	United States
USAO	United States Attorney's Offices
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
vCJD	Variant Crueutzfeldt-Jacob Disease
VCRP	Voluntary Cosmetic Ingredient Review
Vet-LRN	Veterinary-Laboratory Response Network
VICH	Veterinary International Conference on Harmonization
VXDS	Voluntary Exploratory Data Submission
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization
WNV	West Nile Virus
WTO	World Trade Organization

BLANK PAGE