DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2012

Food and Drug Administration

Justification of Estimates for Appropriations Committees

The FY 2012 Congressional Justification is one of several documents that fulfill the Department of Health and Human Services' (HHS) performance planning and reporting requirements. HHS achieves full compliance with the Government Performance and Results Act of 1993 and Office of Management and Budget Circulars A-11 and A-136 through the HHS agencies' FY 2012 Congressional Justifications and Online Performance Appendices, the Agency Financial Report, and the HHS Citizens' Report. These documents are available at http://www.hhs.gov/asrt/ob/docbudget/index.html.

The FY 2012 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2010 Annual Performance Report and FY 2012 Annual Performance Plan. The Agency Financial Report provides fiscal and high-level performance results. The HHS Citizens' Report summarizes key past and planned performance and financial information.

The Food and Drug Administrations Congressional Justification and Online Performance Appendix can be found at http://www.fda.gov/oc/oms/ofm/budget/documentation.htm.

Message from the FDA Commissioner

I am pleased to present the Administration's FY 2012 budget request for the Food and Drug Administration (FDA).

FDA protects and promotes the health of all Americans through every stage of life. The breadth of this mandate means that FDA responsibilities continue to grow. For example, in December 2010, Congress enacted important new food safety authorities and instructed FDA to establish a new system for food safety oversight.

The FDA FY 2012 budget supports many urgent public health priorities. It contains the needed resources to achieve fundamental public health responsibilities entrusted to FDA. The budget recommends new resources for FDA to transform America's food safety and nutrition, speed the development of medical countermeasures to meet critical national security priorities, protect patients, and advance FDA regulatory science. The FDA FY 2012 budget includes the following priorities:

Transforming Food Safety and Nutrition: The Transforming Food Safety and Nutrition Initiative allows FDA to implement the landmark Food Safety Modernization Act. FDA will establish a prevention-focused food safety system and leverage the valuable work of FDA's state and local food safety partners. The resources in this initiative will also empower Americans to make more healthful food choices through nutrition labeling for menu and vending machine items.

Advancing Medical Countermeasures (MCM): The Advancing MCM Initiative strengthens FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear threats, and to respond to naturally emerging diseases such as pandemic influenza. With this initiative, FDA will enhance the review of MCMs and develop new tools and standards to speed the development of MCMs. To improve public health response, FDA will also strengthen the legal, regulatory and policy framework that governs MCM development and availability. These efforts will accelerate development of MCM products for pressing public health and national security needs.

Protecting Patients: The Protecting Patients Initiative allows FDA to develop a pathway for approving biosimilars. Establishing a pathway for biosimilars offers the potential of significant savings for government and private sector health care systems that provide care to millions of Americans. This initiative also strengthens FDA efforts to modernize and improve safety throughout the foreign and domestic supply chain of medical products and includes other measures to assure the safety of medical products.

FDA Regulatory Science and Facilities: The FY 2012 budget will allow FDA to strengthen its core regulatory scientific capacities. The Advancing Regulatory Science Initiative will help FDA review and approve products that rely on new and emerging technologies and that offer promising new opportunities to diagnose, treat, cure and prevent disease.

FDA is responsible for overseeing more than $2 trillion worth of foods, drugs, biologics, medical devices, cosmetics, dietary supplements, tobacco products and consumer goods. As I quickly learned since coming to FDA, our role in protecting public health and overseeing these products is unique, and there is no one to backstop us. The initiatives and resources that FDA recommends for FY 2012 will allow us to act more quickly and strategically to protect consumers from food safety threats and help deliver safer, more effective medical therapies to the American people.

Margaret A. Hamburg, M.D.

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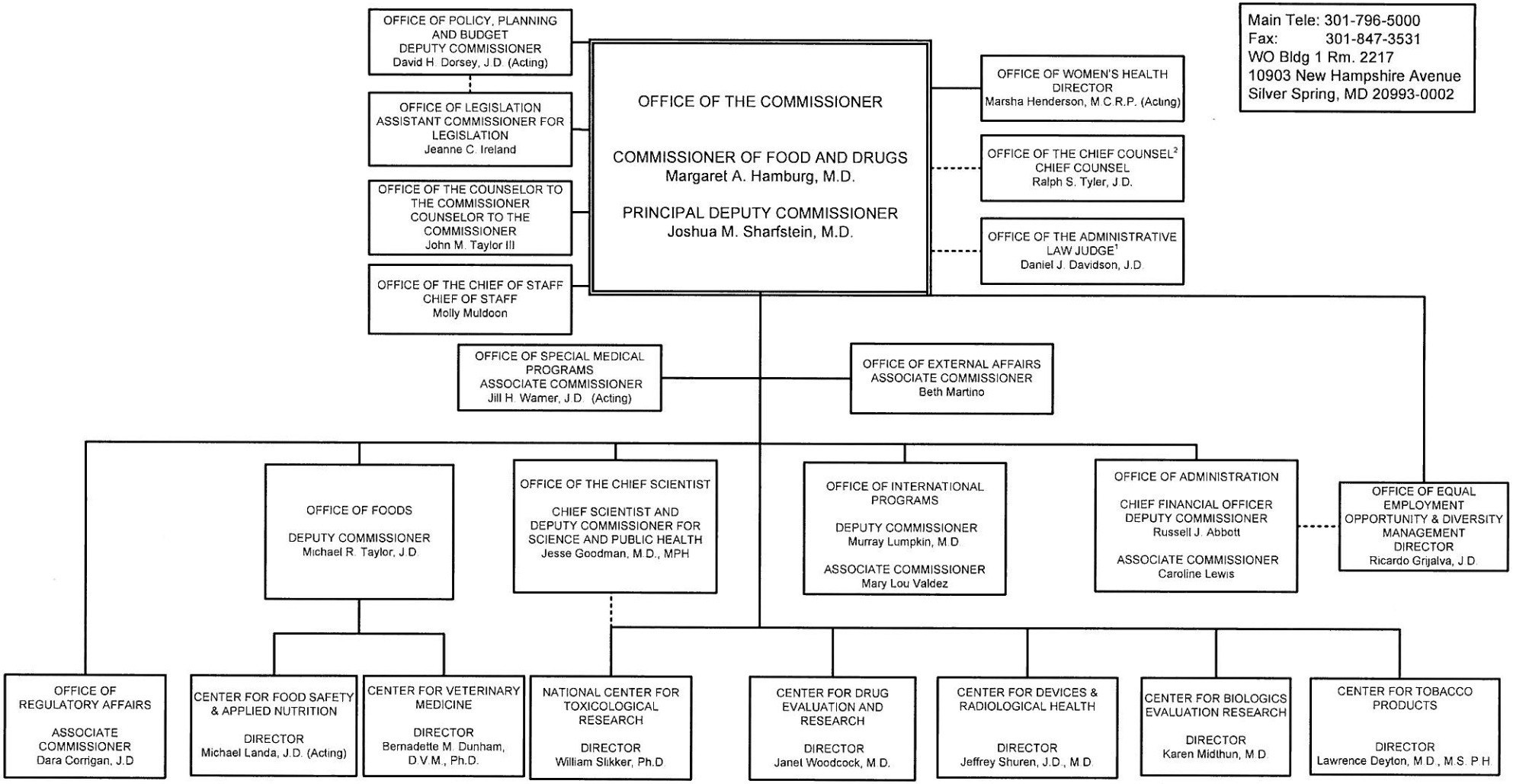

[1] Reports Directly to the Secretary, HHS
[2] Reports to the General Counsel of the HHS, advises the Commissioner of Food and Drugs

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Approved by the FDA Reorganization Coordinator and Principal Delegation Control Officer

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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.

Finally, FDA 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 2012 Budget Overview

The fiscal year (FY) 2012 President's Budget request for FDA is $4,360,281,000. This represents a total program level increase of $1,076,215,000 above the amount enacted into law for FY 2010. The FDA total program level includes new budget authority, current law user fees, and new proposed user fees.

The FY 2012 increase for user fees is $694,036,000, including $59,568,000 in proposed new user fees. The FY 2012 increase in budget authority is $382,179,000, of which $4,896,000 is for the cost of living pay increase.

The following information summarizes the FDA budgets for fiscal years 2010, 2011, and 2012.

FY 2012 Overview Table Food and Drug Administration (Dollars in thousands)						
Program[1]	FY 2010 Enacted[2]	FY 2010 Adjusted Enacted	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 PB request	+/- FY 2010 Adjusted Enacted
Budget Authority	$2,363,786	$2,361,786	$2,369,396	$2,361,786	$2,743,965	$382,179
User Fees	$922,280	$922,280	$748,265	$1,011,175	$1,616,316	$694,036
Total	$3,286,066	$3,284,066	$3,117,661	$3,372,961	$4,360,281	$1,076,215
FTE	12,335	12,335	12,381	12,381	14,436	2,101

[1] FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include $1.3 million for CRADA.

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

FDA FY 2012 Budget Request

The initiatives and resources for FY 2012 will allow FDA to achieve fundamental public health priorities in the following areas:

A. Transforming Food Safety and Nutrition +$218,424,000 / 435 FTE

The Transforming Food Safety and Nutrition Initiative allows FDA to implement the landmark Food Safety Modernization Act. FDA will establish a prevention-focused food safety system and leverage the valuable work of FDA's state and local food safety partners. The resources in this initiative will also empower Americans to make more healthful food choices through nutrition labeling for menu and vending machine items.

The FY 2012 budget does not include any legislative proposals for new food safety user fees. However, FDA plans to work with Congress during FY 2013 to enact additional food safety fees to support the full implementation of the FDA Food Safety Modernization Act.

B. Advancing Medical Countermeasures +$70,000,000 / 165 FTE

The Advancing MCM Initiative strengthens FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear threats, and to respond to naturally emerging diseases such as pandemic

influenza. With this initiative, FDA will enhance the review of MCMs and develop new tools and standards to speed the development of MCMs. To improve public health response, FDA will also strengthen the legal, regulatory and policy framework that governs MCM development and availability. These efforts will accelerate development of MCM products for pressing public health and national security needs.

C. Protecting Patients
+$56,323,000 / 118 FTE

The Protecting Patients Initiative allows FDA to develop a pathway for approving biosimilars. Establishing a pathway for biosimilars offers the potential of significant savings for government and private sector health care systems that provide care to millions of Americans. This initiative also strengthens FDA efforts to modernize and improve safety throughout the foreign and domestic supply chain of medical products and includes other measures to assure the safety of medical products.

D. FDA Regulatory Science and Facilities
+$48,675,000 / 50 FTE

The FY 2012 budget will allow FDA to strengthen its core regulatory scientific capacities. The Regulatory Science and Facilities Initiative will help FDA review and approve products that rely on new and emerging technologies and that offer promising new opportunities to diagnose, treat, cure and prevent disease. This initiative also contains resources for FDA to outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex to ensure that the facilities are operational and ready for occupancy in FY 2014.

E. Contract and Administrative Savings
-$29,723,000 / -46 FTE

During FY 2012, FDA will achieve contract and administrative savings by increasing competition, using FDA-wide contracts to combine resources and reduce cost, replacing traditional classroom training with online training, achieving savings on information technology procurement, and reducing administrative support FTE.

F. FDA Current Law User Fees
+$634,468,000 / +1,229 FTE

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, and medical devices and reviews of other FDA-regulated products. 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

services for 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 food recalls, food reinspections, and the voluntary qualified importers program. The budget request includes inflationary increases for FDA user fee programs authorized by law.

Details of the FDA FY 2012 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 2012 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 2012. In an increasingly global economy, and facing revolutionary advances in science and technology, FDA recognizes the need to modernize and transform our 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 we regulate
- 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.

FDA has changed the format of this Performance Budget to make it more useful and to focus on our commitment to achieving improved public health outcomes

and performance results at the subprogram level. This change in format mirrors a more fundamental change in how FDA will be measuring and reporting on our 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 Summary of Targets and Results Table

The Summary of Targets and Results Table provides an overview of all targets established for each corresponding fiscal year.

Fiscal Year	Total Targets	Targets with Results Reported	Percent of Targets with Results Reported	Total Targets Met	Percent of Targets Met
2007	51	51	100%	49	96%
2008	45	45	100%	41	90%
2009	47	46	98%	44	95%
2010	76	60	79%	54	89%
2011	80				
2012	80				

FDA Linkages to HHS Strategic Plan

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

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
1 Transform Health Care					
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			X		

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
1.C Emphasize primary and preventive care linked with community prevention services					
1.D Reduce the 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 of health information technology					
2 Advance Scientific Knowledge and Innovation					
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 and medical product safety	X				
2.D Increase our understanding of what works in public health and human service practice					
3 Advance the Health, Safety and Well-Being of the American People					
3.A Ensure the safety, well-being, 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					
3.D Promote prevention and wellness		X		X	
3.E Reduce the occurrence of infectious diseases		X			

HHS Strategic Goals	**FDA Goal 1:** Advance Regulatory Science and Innovation	**FDA Goal 2:** Advance Food Safety and Nutrition	**FDA Goal 3:** Advance the Safety and Effectiveness of Medical Products	**FDA Goal 4:** Establish an Effective Tobacco Regulation, Prevention, and Control Program	**FDA Goal 5:** Manage for Organizational Excellence and Accountability
3.F Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies		X	X		
4 Increase Efficiency, Transparency, and Accountability of HHS Programs					
4.A Ensure program integrity and responsible stewardship of resources					X
4.B Fight fraud and work to eliminate improper payments					
4.C Use HHS data to improve the health and well-being of the American people					
4.D Improve HHS environmental, energy, and economic performance to promote sustainability					X
5 Strengthen the Nation's Health and Human Service Infrastructure and Workforce					
5.A Invest in the HHS workforce to meet America's health and human services needs today and tomorrow					X
5.B Ensure that the Nation's health care workforce can meet increased demands					
5.C Enhance the ability of the public health workforce to improve public health at home and abroad					
5.D Strengthen the Nation's human services workforce					
5.E Improve national, state, and local surveillance and epidemiology capacity		X			

Advancing Medical Countermeasures
+$70,000,000 / 165 FTE

The following table displays the FDA budget authority for the Advancing Medical Countermeasures Initiative for the FY 2012 Congressional Justification.

Advancing Medical Countermeasures

(Dollars in Millions)

Program	FY 2010 / FY2011 Budget Amendment (non-add)[1]	FY 2012 Request	+/- FY 2010 Enacted
Budget Authority:			
Human Drugs	**$28.017**	**$12.688**	**+$12.688**
Center	27.144	12.033	+$12.033
Field Activities	0.873	0.655	+$0.655
Biologics	**$27.362**	**$11.790**	**+$11.790**
Center	26.489	11.353	+$11.353
Field Activities	0.873	0.437	+$0.437
Devices and Radiological Health	**$17.099**	**$8.428**	**+$8.428**
Center	16.661	8.210	+$8.210
Field Activities	0.438	0.218	+$0.218
Headquarters and Office of the Commissioner	**$90.234**	**$33.463**	**$33.463**
Other Rent and Rent Related	**$2.603**	**$1.320**	**$1.320**
GSA Rental Payments	**$4.685**	**$2.311**	**$2.311**
Total Advancing Medical Countermeasures	**$170.000**	**$70.000**	**+$70.000**

[1] Under the President's August 20, 2010, budget amendment and a related announcement by Secretary Sebelius, FDA will receive $170 million from amounts appropriated under Public Laws 111-8 and 111-117. The President's budget amendment also expands the availability of the FDA funding to support a broad array of FDA MCM activities.

1. Initiative Summary:

The Advancing Medical Countermeasures (MCM) Initiative contains resources to meet America's national security and public health requirements for MCM readiness. With these resources in the FY 2012 budget, FDA will take action to overcome obstacles that prevent the successful development and approval of the most critical MCMs.

The Advancing MCM Initiative strengthens FDA's ability to support the development of MCMs to respond to chemical, biological, radiologic and nuclear (CBRN) threats, and to respond to naturally emerging infectious diseases such as pandemic influenza. With this initiative, FDA will enhance the review of MCMs and develop new tools and standards to speed the development of MCMs.

FDA will also strengthen the legal, regulatory and policy framework that governs MCM development and availability to improve the Nation's ability to provide an effective and timely public health response. These FDA efforts will accelerate

development of MCM products for pressing public health and national security needs.

2. Why is this funding necessary?

Background: In recognition of our Nation's vulnerability to deliberate terrorist threats and naturally emerging infectious diseases, President Obama announced a new Medical Countermeasure Initiative in his January 2010 State of the Union Address:

> "[W]e are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease – a plan that will counter threats at home and strengthen public health abroad."

In May 2010, the Administration reaffirmed this priority in the President's National Security Strategy of 2010.[1]

On August 19, 2010, HHS released a report of an extensive review of the Federal government's system to develop MCMs. MCMs include drugs, vaccines, diagnostic tests, and medical equipment and supplies to respond to a public health emergency. The HHS report contains key steps the Federal government must take to modernize the nation's MCM Enterprise.[2] In particular, the report highlighted how critical FDA is to the success of the MCM Enterprise.

To allow FDA to immediately commence the MCM Initiative, HHS released funds to FDA in October 2010 from an existing HHS pandemic influenza appropriation.[3]

Even prior to the events of September 11, 2001, preparing for CBRN threats against the United States has been a paramount concern for the leadership of HHS, FDA, and other Federal agencies. Yet the government's collective readiness to respond to these threats remains is limited.

In December 2009, on the heels of the influenza pandemic, HHS Secretary Sebelius called for a comprehensive review of the Nation's readiness to defend against CBRN threats. The HHS review was prompted by recognition that influenza vaccine became available only *after* pandemic influenza was already widespread across the United States. The HHS review called on the expertise of the scientific leadership of all Federal agencies that work with medical

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[1] http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf
[2] http://www.hhs.gov/news/press/2010pres/08/20100819a.html
[3] HHS allocated $170 million to FDA from the appropriations in P.L. 111-8 and P.L 111-117. The Administration also submitted a budget amendment to Congress on August 20, 2010, that would expand FDA's use of these funds to address the full range of threats, including chemical, biological, radiological, and nuclear weapons.

countermeasures, as well as State and local health departments, the National Biodefense Science Board, and the Institute of Medicine.

During the review, the National Biodefense Science Board (NBSB) emphasized the clear need for significant additional resources for FDA, stating in its March 2010 report:

> **Give Special Attention to FDA Resources:** . . .[T]he Board concludes that the FDA has not been able to fulfill its implicit national security mission, in large part because of lack of resources . . . . It is clear from the NBSB's review, the recent IOM workshop, and other advisory panels that the FDA is drastically under-resourced. It is imperative for America's health and progress for the FDA to be provided adequate resources to bring its regulatory science into the 21st century. Doing so will greatly enhance the FDA's ability to support MCM development and licensing.

The review, released on August 19, 2010, identified the barriers to MCM development, as well as significant opportunities to improve the path for successful MCM development. The review identified FDA as critical to the success of the MCM Enterprise, primarily because FDA evaluation of product safety and efficacy can significantly affect the course of product development.

The report further recognized that robust FDA engagement from the earliest stages of product development can significantly increase the odds of successful approval. In the eyes of many industry and government experts who participated in this review, increased support for FDA MCM activities was considered one of the most critical steps the Federal government could take to transform the MCM Enterprise.

Subsequently, many stakeholders have continued to express unwavering support for a better resourced FDA in this area. Notably, during Congressional testimony on September 29, 2010, the Alliance for Biosecurity stated:

> The Alliance was also pleased with the emphasis placed on enhancing FDA regulatory innovation, science, and capacity in the Review, as well as the recognition of the importance of optimizing the legal and policy framework for MCM oversight and approval. Therefore, we support the Administration’s August 20th budget amendment request to make available balances from prior pandemic influenza appropriations to modernize FDA “regulatory science.” We believe that this new approach to regulatory science must focus on the agency’s “animal rule” in order to make it an effective mechanism for the approval of needed countermeasures in the numerous instances where human testing of drugs and vaccines is unfeasible and/or unethical. This focus requires the addition of substantial manpower to the agency to meet the complex needs of this space, and the training of regulatory personnel to facilitate

their understanding of the unique national security and public health issues that chemical, biological, and nuclear threats represent.

History: The United States Government has expended an unprecedented level of human and financial resources to prepare for CBRN threats. Federal civilian biodefense funding has been estimated to exceed $54 billion from FY 2001 through FY 2010.[4]

Despite these investments, our Nation lacks the range of MCMs listed in the HHS Public Health Emergency MCM Enterprise Implementation Plan.[5] For example, there are no countermeasures to treat acute radiation syndrome that would affect millions in the aftermath of a nuclear event. Moreover, no FDA-cleared, rapid, point-of-care diagnostics exist for any of the biothreat agents of greatest concern. Such diagnostic tests are needed to guide the public health response, to ensure that patients receive the most appropriate treatment, and to ensure appropriate use of the limited supplies of MCMs available during a public health emergency.

Furthermore, some of the available MCMs, such as the anthrax vaccine, exist only in limited quantities. Moreover, there is virtually no capability to rapidly develop a new countermeasure in response to a new threat and only limited capability to ramp-up production of existing countermeasures once an event is detected.

The Threat: Dozens of government reports since 9/11 and the October 2001 anthrax attack have affirmed the clear risk of terrorist groups wielding biological weapons. Terrorists wielding CBRN materials could cause suffering, death, and social and economic disruption on a monumental scale.

The Robb-Silverman Report on Weapons of Mass Destruction (WMD) Intelligence Capabilities documented that "Al Qaeda had a major bioweapons effort [in Afghanistan]" as of 2003.[6] Al Qaeda has asserted their right to kill up to four million Americans and, in 2003, they issued a fatwa authorizing the use of biological, chemical, and nuclear weapons against infidels.[7] In 2005, the National Intelligence Council noted that, "Our greatest concern is that terrorists might acquire biological agents, or less likely, a nuclear device, either of which could cause mass casualties."[8] And, most recently, the National Security Strategy of 2010[9] warned:

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[4] http://www.upmc-biosecurity.org/website/resources/publications/2009/2009-09-22-billionsforbiodefense.html

[5] 2007 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for Chemical, Biological, Radiological and Nuclear Threats, at https://www.medicalcountermeasures.gov/BARDA/documents/phemce_implplan_041607final.pdf

[6] U.S. Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction, *Report to the President of the United States*, March 31, 2005

[7] http://www.foreignpolicy.com/articles/2010/01/25/al_qaedas_pursuit_of_weapons_of_mass_destruction?page=full

[8] National Intelligence Council 2020 Project, *Mapping the Global Future;* Jan. 2005

[9] http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

> The 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.

According to the November 2009 National Security Council report,[10] the economic cost of a well-executed bioterrorist attack on American soil could exceed one trillion dollars. In addition, such an attack could have profound consequences for our way of life, for trust in government, and for our society and political order.

The 2009 H1N1 influenza pandemic further highlighted the Nation's vulnerability to public health threats. Despite dedicated and multi-year pandemic preparedness efforts by the Federal government, robust financial support from the Administration and Congress, and a strong public-private partnership that harnessed the expertise and commitment of some of the best vaccine manufacturers in the world, the public health response to the pandemic encountered substantial challenges. Although a safe vaccine was produced in record time, the six months from pandemic onset to vaccine availability would be unacceptable and destabilizing for a more severe pandemic or a deliberate CBRN event.

The Vulnerable MCM Enterprise: The path for successful medical product development has not been short or simple. Today, the long time required to develop an MCM is exemplified by the following example, which is considered an MCM development success. In September 2000, the Federal government issued a contract for the production of a smallpox vaccine. This vaccine was almost identical to the smallpox vaccine used in the global smallpox eradication program. Despite the highest priority placed on addressing the potential terrorist threat following September 11, 2001, the smallpox vaccine development process extended for seven years, from the first contract awarded to Acambis (Sept. 2000) to licensure of the ACAM2000 vaccine (Sept. 2007).

Efforts to prepare for the threat of an anthrax attack have also been challenging. The Federal government has not yet fulfilled the requirement for a second-generation anthrax vaccine. Despite early predictions of the likelihood of success and substantial Federal government investments, the effort to develop a more modern anthrax vaccine has not been successful. The contract for vaccine purchase that was awarded by HHS in 2004 had to be cancelled in 2006 because the sponsor was unable to resolve serious stability problems that plagued product development.

Priority countermeasures under the MCM Initiative include products as diverse as anthrax monoclonal antibodies, antivirals to treat smallpox, and drugs and

[10] See the *National Strategy for Countering Biological Threats* http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

cellular therapies to treat radiation injury. However, the path for developing such countermeasures is uncertain.

Examples of products that face difficulty progressing through the regulatory pathway are the large number of MCM applications that require approval under the Animal Rule. The Animal Rule amends the new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products when human efficacy studies are not ethical and field trials are not feasible.

MCM development and regulatory assessment using the Animal Rule is complex. Applications for products submitted under the Animal Rule currently take longer to evaluate than those pursued through normal regulatory mechanisms. This is due to the complexities of identifying the appropriate animal model and the significant difficulty in bridging animal data to humans. There often is no suitable animal model that mimics human disease.

FDA published the Animal Rule in 2002. To date, FDA has not licensed any biologic products using this regulatory pathway. Nor has FDA approved any *new* drugs have under the Animal Rule. The two New Drug Applications approved under the Animal Rule were for adding a CBRN indication to two previously developed products: Cyanokit (2006), for the treatment of cyanide poisoning and pyridostigmine bromide (2003), as a pretreatment to the nerve agent Soman.

Generally, products pursuing approval under the Animal Rule require more frequent and early development interactions between FDA and the sponsor, compared to products for non-MCM indications. Therefore, one major use of the resources in the FDA MCM Initiative will be to permit early interaction and extensive problem solving for products being developed under the Animal Rule.

Promising countermeasures will continue to meet obstacles if FDA does not receive the resources to commence a program that will assist sponsors of the highest priority MCMs. A 2008 analysis of MCM development costs and the likelihood for MCM success estimated the failure rate for developing critical MCMs at more than 85 percent.[11] Such high failure rates are not only unacceptable and expensive, but also leave the Nation vulnerable to CBRN attacks by our adversaries. The goal of FDA's MCM Initiative is to reverse this pattern, making it possible to better protect Americans' health in the aftermath of a CBRN attack or a naturally emerging infectious disease threat.

The FDA Role: As the National Biodefense Science Board emphasized, FDA is one of the most critical components of the MCM Enterprise. FDA has the most comprehensive understanding of the methodical steps required for successful drug, vaccine, biologic products, and device development and manufacture.

[11] http://www.nature.com/nbt/journal/v26/n9/pdf/nbt0908-981.pdf

Only FDA can build the regulatory science base to provide clear, efficient pathways for developing and manufacturing critical countermeasures and to help the MCM Enterprise overcome challenges that will predictably occur in the development process. In addition, FDA's scientific engagement is critical to realizing the promise of new technologies for flexible, rapidly scalable development and manufacture of drugs, vaccines and other biologics. These transformative technologies are essential for a rapid response to emerging threats, such as pandemic influenza, and to unforeseen agents, including response to the nefarious use of synthetic biology to create new biologic agents.

In summary, FDA is essential to reducing the slow development time and reversing the high failure rates associated with MCM development. FDA is also essential to transforming the MCM Enterprise so it can respond faster and more nimbly to emerging threats.

The FDA MCM Initiative: The MCM initiative will enable FDA to enhance MCM regulatory review, develop new tools and standards to evaluate the performance of MCM products, and optimize the legal, regulatory, and policy framework for MCM development and availability.

FDA will also support technologies that serve as a broad platform for MCM development. FDA actions under the MCM Initiative will support the development of products to better protect Americans' health in the aftermath of a chemical, biological, radiological, or nuclear attack, or a naturally emerging infectious disease threat.[11] These efforts are all necessary to accelerate development of critical MCM products for pressing public health and national security needs.

3. What activities will the funds support?

The funds in the MCM Initiative will enable FDA to implement and sustain the FDA Public Health and Security Action Plan for high-priority countermeasures.

A. Medical Countermeasures (+$66,369,000 / 165 FTE)

As a one-time investment, FDA received $170 million from Public Laws 111-8 and 111-117 to launch and build the necessary infrastructure and begin implementing its MCM Initiative during FY 2010 and 2011. For FY 2012, FDA will use the amounts in this initiative to fully implement and sustain the FDA Public Health and Security Action Plan for MCMs.

FDA's plan advances a strategy of three objectives to develop the highest priority medical countermeasures and to strengthen the MCM Enterprise. An outline of the FDA three objectives of the MCM strategy appears below.

Advancing Medical Countermeasures

FDA MCM Objective 1 – Enhance the Review Process for MCM by Establishing Public Health and Security Action Teams (PHSATs) (+$24,199,000 / 85 FTE)

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 PHSATs and provide support to PHSATs with investments in the following areas:

- drugs, vaccines, monoclonal and polyclonal antibodies for biological threats
- drugs for chemical threats
- advanced, flexible, scalable manufacturing methods for MCMs
- therapeutic approaches to radiation injury protection and response
- advanced methods for in vitro diagnostics for biological threats and flu
- biodosimetry methods for radiological or nuclear threats
- protective and emergency equipment, such as respirators and ventilators
- enhanced inspection and technical assistance for MCM manufacturing
- MCM Initiative leadership, implementation, coordination, tracking, and reporting
- advanced training for FDA staff in CBRN issues and MCM development, including support for special educational requirements for members of FDA PHSATs for MCMs

CDER +$7,276,000 / 26 FTE
CBER +$6,559,000 / 26 FTE
CDRH +$3,864,000 / 16 FTE
ORA +$1,310,000 / 6 FTE
OC +$5,190,000 / 11 FTE, including Program Support

FDA MCM Objective 2 – Advance Regulatory Science for MCM Development and Evaluation (+$36,903,000 / 60 FTE)

FDA will establish robust collaborations with MCM Enterprise partners including the Department of Defense. FDA will also establish an MCM regulatory science program. To accomplish these objectives, FDA will make investments in the following areas:

- animal models for developing and evaluating MCMs
- clinical biomarkers and immunology to accelerate MCM approval using human surrogate markers
- MCM product quality

- risk communication strategies for MCM public health emergencies
- radiation injury protection and response
- diagnostic platforms for CBRN and other emerging threats
- health informatics infrastructure to assess MCM safety and efficacy during public health emergencies
- MCM regulatory science leadership, implementation, coordination, tracking, and reporting for program success
- MCM intramural science and extramural partnerships

CDER +$3,918,000 / 14 FTE
CBER +$4,036,000 / 16 FTE
CDRH +$3,622,000 / 15 FTE
OC +$25,327,000 / 15 FTE, including Program Support

FDA MCM Objective 3 – Modernize the Legal, Regulatory, and Policy Framework for Effective Public Health Response (+$5,267,000 / 20 FTE)

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.

CDER +$840,000 / 3 FTE
CBER +$757,000 / 3 FTE
CDRH +$724,000 / 3 FTE
OC +$2,946,000 / 11 FTE, including Program Support

B. Rent Activities for Advancing Medical Countermeasures Initiative (+$3,631,000 / 0 FTE*)*

The $3,631,000 increase in budget authority will enable FDA to pay the GSA Rent and Other Rent and Rent-Related costs for the facilities that support MCM program activities and the new employees hired under the FY 2012 Advancing Medical Countermeasures initiative. Funding these rent activities will reduce the need for FDA to redirect resources from core, mission-critical public health activities to pay rent costs.

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

The FDA Medical Countermeasures Initiative supports important national security and public health priorities. Through this Initiative, FDA will help ensure that Americans have access to the medicines and vaccines they need after a deliberate CBRN attack or a naturally occurring epidemic.

The FDA MCM Initiative 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. The FDA MCM initiative will also protect American's health and foster resilience in response to emergencies.

The MCM Initiative also implements FDA priorities articulated in the HHS Public Health Emergency Medical Countermeasures Enterprise Review, released on August 19, 2010.[12] FDA will promote medical countermeasure 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.

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

Not proceeding with the FDA MCM Initiative poses genuine risks for the health of Americans and the security of our nation:

- The progress of FDA's MCM Initiative, launched in August 2010, will be significantly constrained if the Initiative will not be sustained in FY 2012.
- The Nation's ability to respond to natural or deliberate infectious disease outbreaks and CBRN threats will remain limited and insufficient.
- The Federal government cannot fulfill its responsibility to protect the nation's health and keep Americans safe during public health emergencies.
- America cannot realize the fruits of the multibillion-dollar investments it has made in biodefense during the past decade.
- The Nation will remain vulnerable to CBRN attacks; adversaries who hope to unleash CBRN threats on the United States will be emboldened as they observe America's continued vulnerability.

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

With this initiative, FDA will robustly support the need for "rapid and reliable development of medical countermeasures to respond to public health threats,"

[12] https://www.medicalcountermeasures.gov/documents/MCMReviewFinalcover-508.pdf

articulated in the National Security Strategy of 2010. Investing in Medical countermeasures development will help protect American's health and safety during emergencies and foster resilience in response to emergencies.

Funding this initiative will result in:

- 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 countermeasures
- an MCM regulatory science program to speed MCM development
- an improved legal framework and improved regulatory and policy approaches to MCM development and use
- faster development and availability of medical countermeasures
- a resilient Nation able to cope with the CBRN and infectious disease threats
- stronger national security.

FY 2012 Advancing Medical Countermeasures Performance

FDA is using FDA-TRACK, the agency's program performance management system, to track, analyze, and report performance measures, progress, and accomplishments for FDA's most important initiatives. FDA is implementing the initiatives showcased in the following FY 2012 performance tables using FDA-TRACK.

When FDA receives these resources, FDA will publish quarterly progress and accomplishments on performance under the MCM initiative at: http://www.fda.gov/AboutFDA/Transparency/track/default.htm

Performance Measures	FY 2011 President's Budget Performance Level	FY 2012 Request Performance Level +/- FY 2011 PB	Most Recent Actual
Establish Public Health and Security Action Teams (PHSATs) to support enhanced review of medical countermeasures and novel manufacturing approaches, based on the HHS highest priorities	N/A	Establish PHSAT teams to work on 6 priority countermeasures and/or platform technologies selected in consultation with HHS	N/A

Performance Measures	FY 2011 President's Budget Performance Level	FY 2012 Request Performance Level +/- FY 2011 PB	Most Recent Actual
Improve medical countermeasures development and evaluation pathways by incorporating advances in life science into the regulatory process	N/A	• Develop a strategic plan to advance MCM regulatory science • Engage with industry and Federal partners to address challenges with the development of animal models needed for the regulatory assessment of MCMs • Establish MCM Regulatory Science Program to conduct mission-directed research to simplify or speed product development and regulatory assessment. Examples of priority areas include: o Animal Models for MCM Development & Evaluation o Novel Diagnostic Platforms o Radiation Injury Protection and Response o Product Quality and Testing, such as: (a) developing potency assays, (b) developing methods for rapid sterility testing, and (c) applying cutting-edge science to develop methods to detect covert adventitious agents and oncogenic factors that may contaminate vaccine products, components, or cell substrates, including novel cell substrates proposed for vaccine production. o Health informatics to assess MCM safety and efficacy during public health emergencies	NA
Evaluate laws and policies and develop new approaches to medical countermeasures that ensure that the legal and policy framework support preparedness and response activities	N/A	• Establish a MCM Legal and Policy Review and Implementation Team to assess existing legal, regulatory and policy approaches to MCMs and develop new approaches, where necessary • Conduct an assessment to determine if additional authorities are needed to authorize or conditionally approve products that may be placed in the national stockpile and used in emergencies, but are not otherwise approved for marketing • Develop a policy to enable FDA to provide technical assistance to U.S. government-sponsored developers of highest priority MCMs	NA

Transforming Food Safety and Nutrition
+$325,971,000 / 829 FTE

The following table displays the budget authority and user fees for Transforming Food Safety and Nutrition Initiative in the FY 2012 request.

FY 2012 Resource Table
(Dollars in Millions)

Program[1]	FY 2010 Enacted[2]	FY 2011 Continuing Resolution	FY 2012 Request[3]	+/- FY 2010 Enacted
Budget Authority:				
Foods	**$783.449**	**$781.449**	**$959.617**	**+$178.168**
Center	236.542	236.000	300.795	+64.795
Field Activities	546.907	545.449	658.822	+113.373
Animal Drugs and Feeds	**$106.743**	**$106.743**	**$118.196**	**+$11.453**
Center	56.566	56.566	64.916	+8.350
Field Activities	50.177	50.177	53.280	+3.103
National Center for Toxicological Research	**$9.725**	**9.725**	**$10.162**	**+$0.437**
Headquarters and Office of the Commissioner	**$50.142**	**50.142**	**$65.741**	**+$15.599**
Other Rent and Rent Related	**$31.271**	**31.271**	**$39.745**	**+$8.474**
GSA Rental Payments	**$70.034**	**70.034**	**$81.721**	**+$11.687**
Total, Budget Authority, Salaries and Expenses	**$1,051.364**	**$1,049.364**	**$1,275.182**	**+$225.818**
Voluntary Qualified Importer Program (VQIP) User Fe	**$0.000**	**$0.000**	**$71.066**	**$71.066**
Food Export Certification User Fee[4]	**$0.000**	**$0.000**	**$1.267**	**$1.267**
Food Reinspection User Fee[4]	**$0.000**	**$0.000**	**$14.700**	**$14.700**
Food Recall User Fee	**$0.000**	**$0.000**	**$12.364**	**$12.364**
International Courier User Fee[5]	**$0.000**	**$0.000**	**$0.756**	**$0.756**
Total, Program Level	**$1,051.364**	**$1,049.364**	**$1,375.335**	**$325.971**

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

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the +/- FY 2010 Enacted column.

[3] Includes the $8M for the Administration's budget amendment of February 12, 2010.

[4] FY 2012 reflects FDA's estimate of the amount it will collect as FDA begins to implement the Food Safety Modernization Act

[5] FY 2012 Proposed user fee. The justification appears in the Protecting Patients Business Case Paper.

1. Initiative Summary:

The Transforming Food Safety and Nutrition Initiative reflects the vision of a strong, reliable food safety system for American consumers and a commitment to improving the health of Americans through better nutrition.

The resources in this initiative will allow FDA to implement the landmark FDA Food Safety Modernization Act. FDA will establish a prevention-focused domestic and import food safety system and leverage the valuable food safety work of FDA's state and local food safety partners. FDA will also empower Americans to make more healthful food choices through menu and vending machine labeling.

This initiative also contains resources to support the increased pay cost for U.S. Public Health Service Commissioned Corps officers and others who serve at FDA. Finally, this initiative also includes the increased rent costs for FDA food safety and nutrition programs.

2. Why is this funding necessary?

A. Implementing the FDA Food Safety Modernization Act

The passage of the FDA Food Safety Modernization Act (FFSMA), the first major overhaul of our food safety law in more than 70 years, transforms FDA's food safety program by establishing new public health mandates and enhanced tools for ensuring the safety of the food supply in the 21st century. The central purpose of FFSMA is to better protect public health by preventing food safety problems, rather than primarily reacting to problems after they occur.

FFSMA closes significant and longstanding gaps in FDA's current authority that hinder FDA's ability to protect the U.S. food supply. FFSMA provides FDA with new powers to set and achieve high rates of compliance with prevention-oriented food safety standards. FFSMA also contains new powers to allow FDA to better respond to and contain food safety problems when they do occur. FFSMA gives FDA important new tools to ensure that imported foods are as safe as domestic foods and directs FDA to build an integrated national food safety system in partnership with state, local and tribal authorities.

In its FY 2012 budget, FDA is organizing its food and feed safety programs and investments to implement FFSMA.

For the first time under FFSMA, FDA has a legislative mandate to require science-based preventive controls on the farm and during processing. FFSMA also provides FDA with important new tools for inspection, compliance, and response. These tools include mandated inspection frequency, records access, suspension of registration, administrative detention, mandatory recall, and third party laboratory testing.

FFSMA gives FDA unprecedented authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include importer accountability through a foreign supplier verification program and third party certification.

FFSMA also calls for HHS and FDA to build a formal system to collaborate with other government agencies, both domestic and foreign. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals.

In addition to strong public health benefits, the focus on prevention in FFSMA offers the opportunity for a dramatic return on the Federal government's investment. A 2007 study[1] estimated that the average hospital stay for each case of foodborne illness requiring hospitalization was 5.8 days [Roberts, American Journal of Agricultural Economics]. The study estimated the average cost per case at between $16,100 (adult) and $26,700 (child). A 2010 study estimates that the health-related cost of these foodborne illness at $152 billion per year [R Scharff, for the Pew Charitable Trust and Georgetown University].

Estimates of the cost of individual food safety events demonstrate the burden that consumers, industry and the economy suffer. In the case of the 2006 spinach recall, the Institute of Food Technologists estimated the cost of recalled spinach, lost sales, lost productivity, and other costs at $129 million. In the case of the 2008 PCA peanut product recall, one major manufacturer (Kellogg) estimated its costs to recall peanut-containing products at $65 million to $70 million. FDA believes that industry-wide costs from that incident exceeded $1 billion. FDA expended more than 100 staff years to protect consumers and conduct PCA-related inspection and recall activities.

B. Nutrition for Better Health

Excess intake of calories, dietary fat, sodium, certain carbohydrates, and certain micronutrients 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 – 60 million people – is obese and one out of every three children is overweight or obese.

With the investments in this initiative, FDA will also address the public health problems of obesity and chronic disease. FDA will improve nutrition labeling on restaurant menus and vending machines as a tool for consumers to construct healthier diets. This will empower consumers to make better nutritional choices and will motivate food producers to develop healthier foods.

Americans have steadily increased their reliance on away-from-home food. Restaurants serve more than 40 percent of Americans (130 million meals) every day. Research has shown that most individuals systematically and significantly underestimate the caloric content of restaurant meals, and they do so by a large margin. Moreover, studies show that even experts – American nutritionists – underestimate caloric content at fast food restaurants, coming in 200 to 600 calories below the mark.

A study of 241 adults examined the likelihood of purchasing certain food items before and after they received caloric content information. Providing calorie content data for items where participants were likely to underestimate calories

[1] CDC has revised its estimate of the annual number of foodborne illness in the United States on which the study was based.

decreased the likelihood that they would purchase the product from 37 to 24 percent. Even modest changes in behavior that result from access to information at the point of purchase can have large impact on health outcomes and health costs.

The experience following the introduction of the Nutritional Labeling and Education Act of 1990 (NLEA) demonstrates the potential of achieving results through enhanced information to consumers. The NLEA prompted industry to significantly reformulate their products, resulting in foods that offered improved dietary options across America.

Enhanced nutrition information for consumers is an essential component of a multi-faceted approach to controlling obesity in America. A 2009 analysis estimates the medical costs of obesity at $147 billion per year [Finkelstein, et al., Health Affairs]. The analysis also found that Medicare costs are $1,700 greater per obese patient than for a non-obese patient. Controlling obesity goes hand-in-hand with controlling health care costs.

3. What activities will the funds support?

FDA will conduct high priority food safety and nutrition activities with the resources in this initiative. In addition to relying on the new FDA authorities enacted in the FDA Food Safety Modernization Act (FFSMA), FDA will also rely on related authorities in the Food, Drug and Cosmetic Act to conduct the food safety activities in this FY 2012 budget initiative.

A. Implementing the FDA Food Safety Modernization Act +$183,006,000 / 399 FTE

Preventive Controls on Farms – FFSMA Section 105
+$10,596,000 / 21 FTE

This investment will support efforts by FDA and Federal, State and local partners to improve food safety from farm to table. To improve produce safety on the farm, FDA will assess the value of specific preventive controls for safe produce growing and packing. FDA will also establish standards for key food safety risk factors to enhance produce safety and protect the health of consumers. FDA will develop practical risk-based preventive controls for small-scale agriculture operations.

With this investment, FDA will conduct food safety outreach, education and technical assistance to produce growers. FDA will develop a curriculum to train personnel assigned to produce safety compliance, inspection and enforcement activities. FDA will also provide training to FDA laboratory personnel on new methods and detection protocols developed by FDA science programs. These protocols relate to produce safety on farms and to environmental sampling to

identify contamination. FDA will provide this training to FDA field personnel and other Federal, state, local, tribal, and territorial regulatory and public health partners.
CFSAN $7,059,000 / 15 FTE
ORA $3,537,000 / 6 FTE

Preventive Controls for Food and Feed Processing – FFSMA Sections 101, 103, 104, 110, 204, 405
+$30,614,000 / 61 FTE

This investment will allow FDA to implement preventive food and feed safety controls in food and feed processing facilities. FDA will develop and issue standards to ensure that the food and feed industries properly implement science and risk-based preventive controls for food and feed safety.

With this investment, FDA will develop performance standards to control significant food and feed hazards and validate the effectiveness of process controls that are widely used to meet food and feed safety standards. FDA will conduct outreach and education activities to industry on new standards, and will develop preventive controls-based inspection training and administer training on preventive controls to FDA and other Federal, state, local, tribal, and territorial regulatory and public health partners. Finally, FDA will modernize inspection practices to improve inspection efficiency and ensure high rates of compliance with food and feed safety preventive controls.

FDA will expand surveillance and monitoring under the National Antimicrobial Resistance Monitoring System (NARMS) to test additional high-priority commodities such as seafood and animal feeds as well as expand the number of retail meat testing sites.
CFSAN $16,414,000 / 46 FTE
CVM $4,100,000 / 11 FTE
HQ/OC $508,000 / 2 FTE
ORA $9,592,000 / 2 FTE

Integrated Food Safety System – FFSMA Sections 202, 204, 205, 209, 210
+$49,740,000 / 59 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. These investments will provide more uniform coverage and safety oversight of the food supply.

Specifically, FDA will assess the processes, data systems, and analytical capabilities needed to develop and manage a national work plan to coordinate federal and state inspection resources for maximum coverage of the food

industry with the least amount of duplication of effort. FDA will share Federal and State regulated establishment inventories to create a comprehensive inventory and reconcile multiple names for the same establishment, which will result in complete, consolidated inspection and outbreak information.

With this investment, FDA will develop and begin to implement standard laboratory practices, procedures and national accreditation standards. These investments will ensure that Federal and State laboratories develop and rely on consistent and meaningful data to support compliance, surveillance and environmental sampling for food and feed safety.

With these resources, FDA will improve rapid response and recovery by strengthening FDA preparedness, surveillance and outbreak detection, outbreak response and investigation, and post response activities under the FDA Foodborne Outbreak Team. FDA will improve food and feed safety response by integrating the capabilities of Federal, State, and local partners. FDA will also pursue pilot studies with industry using track and trace technology. The track and trace studies will guide FDA as it develops food product tracing regulation that provides for rapid tracing without overly burdening industry.

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

FDA will develop and administer food safety certification programs for inspectors, investigators, and analysts at FDA, and for its regulatory partners. This investment will improve food and feed safety by 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.
CFSAN $6,014,000 / 19 FTEs
CVM $1,500,000 / 6 FTEs
HQ/OC $778,000 / 1 FTE
ORA $24,330,000 / 28 FTEs

Safe Food Transport – FFSMA Section 111
+$2,197,000 / 4 FTE

This investment will improve preventive controls for the safe transport of food. FDA will evaluate safety and protection issues specific to food transportation, such as sanitation, pest control, employees training, and safeguards against tampering, establish a training curriculum that addresses these issues for food

transportation workers. FDA will draft a standard to address transportation-related food safety risks.
CFSAN $2,197,000 / 4 FTE

Retail Food Safety – FFSMA Section 209, 210
+$5,595,000 / 6 FTE

To improve compliance with the Food Code at retail and food service outlets, FDA will promote widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards. FDA will fund contracts, cooperative agreements, or grants for state, local, territorial, and tribal agencies that seek to institute innovative compliance and enforcement strategies that promote improved and sustained control of key operational risk factors designed to improve food safety.
CFSAN $2,640,000 / 4 FTE
ORA $2,955,000 / 2 FTE

Import Oversight – FFSMA Sections 201, 211, 301-308
+$40,576,000 / 147 FTE

This FDA investment supports a comprehensive prevention-focused import food and feed safety program. The import program will place greater responsibility on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. FDA will develop programs to obtain these assurances and will periodically audit these programs and those who participate in the programs. FDA will use information supplied through these programs to make risk based decisions for food and feed import entry. FDA will also use this information to make decisions on where FDA will conduct border exams and where it will target import sampling.

With this investment, FDA will supplement its import activities, border exams and import sampling by performing additional foreign inspections in countries that do not have comparable food safety oversight systems, robust export systems, or that do not participate in certification programs. In particular, FDA will focus greatest attention on facilities that produce higher risk food and feed commodities.

With these resources, FDA will develop and begin to implement foreign supplier verification, voluntary qualified importer, import certification and third party accreditation programs. FDA will conduct assessments to determine which countries have comparable food and feed safety systems or robust commodity-specific export programs. FDA will establish programs to recognize and accredit third-party certification programs. FDA will conduct initial assessments and periodic audits of comparable countries, export programs, and recognized third

party certification programs to ensure that they meet US food and feed safety standards. FDA will also establish partnerships with other public health agencies to execute international outreach, training, technical support, and capacity building.

FDA will use a risk-based strategy to target inspections of foreign establishments. FDA will also develop and implement rapid field tests to better target sampling at the border.

FDA will continue to develop the infrastructure and processes to enable timely enforcement action. FDA will develop processes and procedures to implement the new enforcement authorities provided by FFSMA, including suspension of registrations, administrative detention and the refusal of goods from foreign firms that refuse inspection.
CFSAN $12,609,000 / 41 FTE
CVM $2,621,000 / 8 FTE
ORA $25,346,000 / 98 FTE

Critical Capacity for Implementing FFSMA
+$35,688,000 / 101 FTE

To support FDA's farm-to-table prevention measures, FDA will invest in risk analysis, laboratory capacity, and scientific methods. FDA will improve risk analysis and research for food and feed safety by expanding its capacity to identify products at highest risk for contamination. This will allow FDA to better target and prioritize food safety efforts and sampling and inspection priorities.

With this investment, FDA will also expand laboratory capacity and establish a new mobile laboratory for remote, on-site testing. FDA will increase its capacity to analyze and assess patterns in test results. FDA will develop and deploy rapid tests to identify food and environmental contamination. Finally, FDA will configure existing office space to accommodate additional food safety employees to support the FFSMA requirements.
CFSAN $14,770,000 / 18 FTEs
HQ/OC $1,320,000 / 2 FTE
NCTR $414,000 / 1 FTEs
ORA $19,184,000 / 80 FTEs

Food Safety Training – FFSMA Sections 209
ORA +$8,000,000 / 0 FTE

FDA will spend $8.0 million on food safety training. FDA will develop and implement a national food safety training system to provide the knowledge and skills required for regulators and public health partners at all levels of government. FDA will also develop a related certification system to ensure the competency of the workforce. This investment will help ensure that FDA

maintains a skilled national workforce to ensure that the food industry is meeting food safety standards.

B. Nutrition for Better Health
+$8,808,000 / 7 FTE

Menu and Vending Machine Labeling
+$8,808,000 / 7 FTE
FDA will support new standards for restaurant menu and vending machine nutrition labeling through education, outreach, and compliance activities FDA will also conduct extensive outreach and education on menu and vending machine nutrition labeling to industry and consumers. With these resources, FDA will review regulatory issues associated with the final rule on restaurant menu and vending labeling. Moreover, FDA will partner with state and local governments to establish inspection programs to evaluate compliance with the new menu labeling standards.
CFSAN $2,519,000 / 5 FTE
ORA $6,289,000 / 2 FTE

C. Program Support for the Transforming Food Safety and Nutrition Initiative
+$11,691,000 / 29 FTE

The Transforming Food Safety and Nutrition Initiative includes resources to ensure that the food programs that participate in this initiative receive the support necessary to achieve their public health outcomes. Support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communications, ethics, headquarters coordination and related support functions.

D. Pay Costs for FDA Food Safety Programs: +$2,151,000 / 0 FTE

FDA regulates a diverse and complex portfolio of products that accounts for 20 percent of U.S. consumer spending. FDA can only fulfill its responsibilities if it has sufficient resources to pay the scientific, professional and technical workforce required to conduct FDA food safety programs. To maintain its workforce, FDA must continue to meet the cost of payroll for the commissioned corps employees and for the first three months of the pay increases incurred for fiscal year 2011.

For food safety programs, the FY 2012 budget authority funding for pay costs is $2.1 million. For all FDA programs, the budget authority for pay costs is $4.9 million during FY 2012.

E. Rent Activities for FDA Food Safety and Nutrition Programs
+$20,161,000 / 0 FTE

The $20,161,000 increase in budget authority will allow FDA to pay the GSA Rent and the Other Rent and Rent-Related costs for the facilities that support the program activities and the new employees hired under the FY 2012 Food Safety and Nutrition Initiative. These funds will also allow FDA to pay the increasing cost of GSA Rent and Other Rent and Rent-Related activities for the activities of FDA's base program without redirecting resources away from core, mission-critical public health activities. The increase in rental payments is essential for FDA food safety programs to maintain performance and achieve their public health goals.

The GSA Rent account includes funds for FDA payments to the General Services Administration (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 inventory of buildings.

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

The Transforming Food Safety and Nutrition Initiative will allow FDA to begin efforts to implement the FDA Food Safety Modernization Act. The initiative also supports key priorities developed by the Food Safety Working Group that are consistent with the new food safety authorities in FFSMA.

The initiative also implements elements of the Nutrition Labeling and Education Act and the Nutrition Labeling of Standard Menu Items in Chain Restaurants under section 403(q)(5)(H) the Federal Food, Drug, and Cosmetic Act (21 U.S.C.14 343(q)(5)(H).

Finally, the initiative implements the following strategic priorities:

- implementing a 21st century food safety system
- protecting Americans' health and safety during emergencies
- helping Americans achieve and maintain healthy weight
- promoting early childhood health.

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

The resources in this initiative will promote public health in the United States by increasing the safety of America's food supply. The resources will also empower Americans to achieve and maintain a healthy weight and make more healthful food choices.

With these resources, FDA will implement landmark new authorities that will better protect public health by preventing food safety problems, rather than primarily react to problems after they occur. Not funding this initiative will result in an inability of FDA to take full advantage of the new authorities it was granted under FFSMA to protect public health. 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.

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

- reduce the number of foodborne illnesses
- identify sources of risk in the food and feed safety systems
- improve industry compliance with food and feed safety standards
- reduce the time required to detect and respond to outbreaks
- strengthen oversight of imported food and feed
- enhance integration between Federal, State, local, 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.

Although FDA is not proposing food safety inspection fees for FY 2012, the Administration will work with Congress to enact these fees for FY 2013.

Funding the Nutrition element of the Initiative will enable better dietary choices as a strategy for Americans to reduce the risk for chronic diseases and the health care cost burden associated with these conditions. Two-thirds of Americans are overweight or obese. Likewise, diet and lifestyle choices affect the major causes

of morbidity and mortality in the U.S., including type-2 diabetes and cardiovascular disease.

With these resources, FDA will also address the public health problems of obesity and chronic disease by empowering consumers to make better nutrition choices. If this initiative is not funded, rates of chronic disease, including hypertension, heart disease, stroke, diabetes, and obesity, will continue to rise at an alarming pace.

6. What will FDA accomplish with the initiative?

This initiative will allow FDA to deliver on its promise of improved food safety and nutrition for the American people. Accomplishing these objectives will provide a foundation for substantially reducing foodborne illnesses caused by contamination of the food supply for years to come and substantially reducing obesity and chronic diseases linked to poor nutrition.

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

- lead to an increased focus on every participant in the food system performing their food safety responsibilities
- allow FDA to leverage the work of our Federal, state, local, tribal, and territorial partners to address gaps in the food safety system
- improve investigation, control and prevention of outbreaks to reduce foodborne illness
- increase assurance that food and feed imported into the U.S. is as safe as domestically produced food and feed
- enhance the ability of consumers using food labels to improve the nutritional quality of their food choices when dining away from home.

FY 2012 Transforming Food Safety and Nutrition Performance –

FDA is using FDA-TRACK, the agency's program performance management system, to track, analyze, and report performance measures, progress, and accomplishments for FDA's most important initiatives. FDA is implementing the initiatives showcased in the following FY 2012 performance tables using FDA-TRACK.

When FDA receives these resources, FDA will publish quarterly progress and accomplishments on performance under the Transforming Food Safety and Nutrition Initiative at: http://www.fda.gov/AboutFDA/Transparency/track/default.htm

The following tables contain information about performance commitments associated with FDA's proposed increase for Transforming Food Safety and Nutrition, including accomplishments expected during Fiscal Year 2012 and proposed program outputs during Fiscal Year 2012.

Food Safety through Prevention

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Initiation of IFSS Grants/Cooperative Agreements	N/A	+20	N/A
Expand the number of retail meat testing sites	11	+4	FY 2010: 11
Percent of US population that resides in an enrolled jurisdiction with direct inspection authority at retail	N/A	60% (+13%)	April 2010: 47%
3rd Party Assessments and Performance Audits	53	+15 FTE – hire and train in 2012. +127 audits full performance in 2015	FY 2010: 53
Foreign Food Inspections	600	+19 FTE – hire and train in 2012. +264 full performance in 2015	FY 2010: 354
Foreign Feed Inspections	10	+1 FTE – hire and train in 2012. +12 full performance in 2015	FY 2010: 3
Importer Verification Inspections	N/A	+22 FTE – hire and train in 2012. +731 full performance in 2014	N/A
The number of assessments/ questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the US relative to public health outcomes	N/A	+9	N/A
The average number of days to serotype priority pathogens in food (Screening Only)	9 working days	4 workings days (-5 days)	FY 2010: 10 working days

Nutrition for Better Health

Performance Measures	FY 2011 President's Budget Performance Level	FY 2012 Request Performance Level +/- FY 2011 PB	Most Recent Actual
Menu Labeling Inspections	N/A	+12,000	N/A

Protecting Patients Initiative
+$123,617,000 /265 FTE

The following table displays the FDA budget authority and user fees for the Protecting Patients Initiative for the FY 2012 President's Budget Justification.

Protecting Patients

(Dollars in Millions)

Program	FY 2010 Enacted	FY 2011 Continuing Resolution	FY 2012 Request	+/- FY 2010 Enacted
Budget Authority:				
Human Drugs	**$461.862**	**$461.862**	**$487.752**	**+$25.890**
Center	334.188	334.188	356.018	+21.830
Field Activities	127.674	127.674	131.734	+4.060
Biologics	**$205.563**	**$205.563**	**$214.236**	**+$8.673**
Center	165.490	165.490	173.024	+7.534
Field Activities	40.073	40.073	41.212	+1.139
Animal Drugs and Feeds	**$28.055**	**$28.055**	**$28.808**	**+$0.753**
Center	25.414	25.414	25.975	+0.561
Field Activities	2.641	2.641	2.833	+0.192
Devices and Radiological Health	**$313.935**	**$313.935**	**$320.516**	**+$6.581**
Center	233.932	233.932	238.654	+4.722
Field Activities	80.003	80.003	81.862	+1.859
National Center for Toxicological Research	**$49.020**	**49.020**	**$49.131**	**+$0.111**
Headquarters and Office of the Commissioner	**$90.706**	**90.706**	**$94.458**	**+$3.752**
Other Rent and Rent Related	**$33.589**	**33.589**	**$44.761**	**+$11.172**
GSA Rental Payments	**$75.226**	**75.226**	**$83.099**	**+$7.873**
Total, Budget Authority, Salaries and Expenses	**$1,257.956**	**$1,257.956**	**$1,322.761**	**+$64.805**
Generic Drug User Fee[1]	**$0.000**	**$0.000**	**$40.122**	**$40.122**
Reinspection Fee[1]	**$0.000**	**$0.000**	**$14.108**	**$14.108**
International Courier User Fee[1]			**$4.582**	**$4.582**
Total, Program Level	**$1,257.956**	**$1,257.956**	**$1,381.573**	**$123.617**

[1] Proposed User Fees

1. Initiative Summary:

The Protecting Patients Initiative will allow FDA to develop a pathway for approving follow-on biological products, also know as biosimilars. Establishing a pathway for approving biosimilars will generate a high return on investment, and will produce significant savings for Medicare and Medicaid and for the health care systems of the Department of Veterans Affairs and the Department of Defense.

Private sector health plans that millions of Americans depend on will also experience savings from the approval of biosimilars. Achieving the promise of biosimilars will reduce health care costs while promoting high value, accessible, effective care. FDA must receive these funds in FY 2012, because the timing of the investment in biosimilars will determine the how soon the savings from biosimilars begin to flow.

In addition to investing in biosimilars, the initiative also invests in new scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, vaccines and other biological products. FDA is launching this initiative at a time when the number of medical products manufactured abroad is increasing dramatically, which present greater challenges for product and manufacturing safety.

With the resources in this initiative, FDA can modernize its approach to assuring safety across the supply chain for medical products. The initiative expands FDA's capacity to conduct medical product safety assessments and to strengthen the safety of vaccines and the blood supply.

The proposals in this initiative offer a high rate of return for the investment of Federal dollars. They can reduce the cost of care and promote safe, high quality and accessible health care that Americans deserve.

Finally, this initiative also contains resources to support the increased pay cost for U.S. Public Health Service Commissioned Corps officers and other employees who serve at FDA. The initiative also contains funds to support increased rent costs for FDA medical product programs. Therefore, funding this initiative will help ensure that FDA retains professional staff to perform essential drug, device and biologic safety activities to protect the American public.

2. Why is this funding necessary?

A. Biosimilars: Section 351 of the Public Health Service Act (42 U.S.C. 262) requires FDA to establish a regulatory pathway for approving biosimilars. Biosimilars are therapies produced by another manufacturer when the patent life on an innovator's biologic product expires.

Biological products include many life important therapies. These include blockbuster products such as rituximab, trastuzumab, bevacizumab, and cetuximab to treat a wide array of cancers. They also include erythropoietin to treat anemia associated with debilitating diseases such as certain cancers, renal dialysis and HIV. Biological products also include ranibizumab to treat age-related macular degeneration and etanercept and similar therapies to treat rheumatoid arthritis and a wide range of rheumatologic diseases.

Biological products cost $15,000 to $150,000 or more per patient per year – prices that are far in excess of those charged for traditional small molecule drugs. These high prices represent a disproportionately high share of Federal government and private sector pharmaceutical costs. Because the number and importance of biological products used to manage serious diseases is steadily increasing, the Federal and non-Federal costs for these complex biological products will continue to rise.

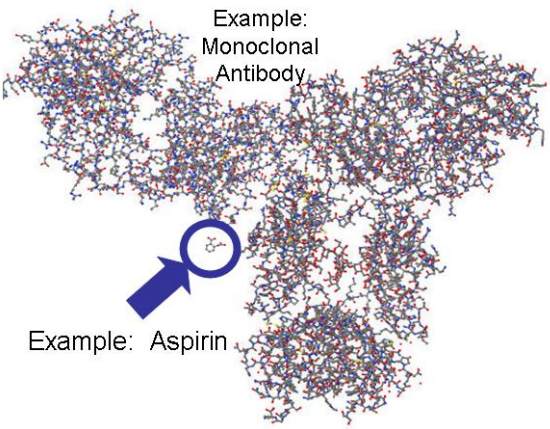
In the United States, patents have expired on biological products whose annual sales amount to more than $15 billion. Approving biosimilar versions of these products offers the potential for substantial savings.

The Congressional Budget Office estimates that Federal savings associated with biosimilars could equal $7 billion from FY 2010 through 2019. Private sector health plans will experience similar savings from the approval of biosimilars. However, these savings will not materialize unless FDA has the resources to establish a clear regulatory pathway for approving biosimilars.

To be successful, FDA must first develop technical standards and criteria to resolve the scientific and legal complexities associated with biosimilars. Establishing a regulatory pathway for approving biosimilars requires a strong scientific foundation due to the nature of biological products. For example, a simple change in the product manufacturing process has resulted in life-threatening complications that were not present in the innovator biological product.

The illustration below demonstrates the complexity of biological products and offers some insight into the complex work required to establish a regulatory pathway to approve biosimilars.

Complexity of Drugs vs. Biological Products



Recent evidence suggests that patients who are not able to afford expensive biological products may suffer severe health consequences. An August 2010 article in the New England Journal of Medicine described the unfortunate fate of patients who developed progressive cancer because they discontinued their treatment with a biological product.[1] The patients were not able to afford a life saving oral biological product that could extend their life expectancy up to several years. Whereas life expectancy without the therapy was measured in months, the median survival for patients with access to the expensive biological product now approaches five years.

B. Other Protecting Patients Priorities

The safe development, production, and use of medical products bring tremendous health benefits to the American people. However, these benefits cannot be taken for granted. The contamination of heparin, an essential drug widely used in hospitals across the United States, led to hundreds of adverse reactions and several deaths. It also signaled the dawn of a new era for the safety of medical products.

To protect America's public health, FDA must be vigilant about imported medical products, have modern scientific safety tools for pre- and postmarket safety assessment, and build strong partnerships with the private sector and our global regulatory partners. The Protecting Patients Initiative is critical for FDA to meet the safety challenges of the 21st century.

[1] Robin K. Kelley, M.D., Alan P. Venook, M.D. N Engl J Med. August 5, 2010; 363:6.

C. International Courier User Fees:

For FY 2012, 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 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 during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of FDA import operations to support international courier activities.

3. What activities will the funds support?

A. Biosimilars: (+$11,560,000 / 30 FTE)

FDA will begin to establish a regulatory path for biosimilar products. FDA will also conduct the research required to develop biosimilar reference standards to assure manufacturing quality.

To establish this pathway, FDA must expand its scientific, regulatory and legal capacity. Specifically, FDA will begin the following work to establish a new pathway for developing and marketing less-costly biological products:

- develop scientific and regulatory policies to facilitate the review and availability of biosimilars; FDA will hire investigators to conduct an additional eight domestic and thirteen foreign pre-approval inspections per year (all BA). Based on training requirements, the full performance year for domestic inspections will be FY 2014 and for foreign inspections it will be FY 2015.
  CDER +$840,000 / 3 FTE
  CBER +$576,000 / 2 FTE
  ORA +$630,000 / 3 FTE
  OC +157,000 / 0.5 FTE
- establish the criteria to determine what types of biological products will be eligible for an abbreviated biosimilars pathway designed to speed the development and marketing of less-costly biological products
  CDER +$840,000 / 3 FTE
  CBER +$576,000 / 2 FTE
- develop a work plan for implementing the new biosimilars authority
  CDER +$560,000 / 2 FTE
  OC +$157,000 / 0.5 FTE
- develop regulations and guidance documents to facilitate development of biosimilars

CDER +$560,000 / 2 FTE
OC +$314,000 / 1 FTE

- establish the capacity to facilitate development of physical reference standards for biosimilar review and for assuring manufacturing quality
  CDER +$2,142,000 / 2 FTE
- develop information systems that support the requirements of the new regulatory pathway
  CDER +$1,900,000 / 1 FTE
- establish pharmacovigilance procedures to monitor the safety of new biosimilar products after they are approved
  CDER +$280,000 / 1 FTE
- establish the capacity to address urgent inquiries from sponsors, including requests for meetings to clarify the potential impact of FDA's biosimilars authority on existing and new development programs
  CDER +$280,000 / 1 FTE
  OC +$157,000 / 0.5 FTE
- meet with stakeholders, experts, regulated industry and the public regarding key scientific and regulatory issues associated with biosimilars
  CDER +$560,000 / 2 FTE
  OC +$314,000 / 1 FTE
- address other issues to clarify the regulatory pathway, including standards for naming biosimilars, clarifying the statutory requirement of publicly available information to support a biosimilar application and complex new marketing exclusivity provisions for biosimilars.
  CDER +$560,000 / 2 FTE
  OC +$157,000 / 0.5 FTE

B. Import Safety: +$11,576,000 / 39 FTE

Thousands of critical medical products are manufactured outside of the United States. New investments for import safety are vital to FDA's ability to understand and respond to the growing challenge of foreign manufacturing and globalization.

- **FDA will launch an electronic drug registration and listing system to stop illegal drug imports.** FDA will begin to build and validate a system that will permit the efficient screening of drug imports at the border.
  CDER +$3,300,000 / 6 FTE

- **FDA will work closely with foreign drug regulatory authorities to monitor facilities in their countries.** FDA will collaborate and train other countries on U.S. manufacturing standards, gain better access to foreign manufacturing sites, and engage in bilateral and multilateral information sharing.

CDER +$730,000 / 3 FTE

- **FDA will expand foreign inspections.** FDA will identify the most critical and highest risk international facilities. FDA will hire investigators to conduct an additional 115 foreign GMP surveillance, tissue, and radiological health inspections per year (all BA). Based on training requirements, the full performance year for foreign inspections will be FY 2015.
  CDER +$500,000 / 2 FTE
  ORA +$4,425,000 / 19 FTE

- **FDA will expand efforts to protect human subjects in trials across the world.** This effort will involve taking a risk-based approach to targeting clinical site inspections and increasing the number of site inspections in the United States and around the world. FDA will hire investigators to conduct an additional 15 foreign generic drug bioequivalence laboratory inspections per year (all BA). Based on training requirements, the full performance year for foreign inspections will be FY 2015.
  CDER +$500,000 / 1 FTE
  ORA $621,000 / 3 FTE

- **FDA will prepare for international collaboration on key medical device safety issues.** FDA will train its staff to effectively review and use third party International Organization for Standardization (ISO) audits of foreign device manufacturer facilities for compliance. As a result, FDA will leverage device inspections conducted on behalf of foreign governments.
  CDRH +$1,500,000 / 5 FTE

C. Safety of High-Risk Products: +$8,621,000 / 20 FTE

Drugs, devices and biologics are becoming more complex. To protect the public, FDA must develop the capacity for effective pre-and postmarket risk assessment.

- **FDA will improve the safety of the blood supply.** To counter an array of threats to the blood supply, FDA will improve the prevention, detection, monitoring, analysis and response to manufacturing deviations, as well as observed and potential adverse events and adverse reactions.
  CBER +$2,500,000 / 3 FTE

- **FDA will improve the safety of vaccines.** FDA will improve vaccine safety through guidance for industry, scientific knowledge and new technologies. FDA will develop biological markers and other approaches to evaluate the safety of vaccine components, adjuvants for enhancing immune response, and related products. FDA will also explore the mechanisms of vaccine-related adverse events, and explore ways to

mitigate these mechanisms and identify biomarkers for predisposition to adverse events.
CBER +$1,000,000 / 2 FTE

- **FDA will improve the safety of human tissue and cord blood.** FDA will increase outreach to improve industry practices and performance. Specifically, FDA will continue to build additional capacity to identify and respond to adverse events, thereby reducing the risk of disease transmission caused by infected human tissues.
CBER +$2,500,000 / 6 FTE

- **FDA will begin to build a national Medical Device Registry.** FDA will design and begin to build a system to link unique identifiers for medical devices and electronic health data to create a national Medical Device Registry. The science component to support a national Medical Device Registry appears as a $2.3 million investment in FDA's Regulatory Science and Facilities Initiative.
CDRH +$1,667,000 / 4 FTE

- **FDA will increase inspections of high-risk medical products.** FDA will conduct an additional 99 domestic inspections each year (all BA). Based on training requirements, the full performance year for the additional domestic inspections will be FY 2014.
ORA +$954,000 / 5 FTE

D. Expand Partnerships for Patient Safety: +$7,575,000 / 20 FTE

To meet its public health responsibilities, FDA must interact and collaborate with many public and private entities in a medical system that is committed to safety.

- **FDA will expand postmarketing surveillance systems in collaboration with private partners that have access to extensive patient data.** This investment includes support for the next stage in FDA's Sentinel Initiative. The goal of the Sentinel Initiative is to access data from 100 million Americans to better assess the safety of medical products.
CDER +$5,000,000 / 9 FTE

- **FDA will work with the private sector to reduce medical radiation exposure.** Developing a National Imaging Dose Registry is an important component of an effort to prevent cancer by reducing unnecessary exposure to radiation from medical imaging tests.
CDRH +$250,000 / 1 FTE

- **FDA will partner with public and private organizations and businesses to reduce unnecessary adverse events, focused on special populations.** By working with others in the healthcare system,

FDA can reduce the number of childhood poisonings, elderly overdoses, and drug interactions.
CDER +$500,000 / 1 FTE
HQ/OC +$325,000 / 2 FTE

- **FDA will improve pediatric drug and device safety.** Working with international and domestic partners, FDA will identify medical products that are safe for children and those that pose special risks.
CDRH +$750,000 / 3 FTE
HQ/OC +$250,000 / 1 FTE

- **FDA will improve postmarketing safety in animal drugs.** FDA will hire and train scientific staff to review adverse experience reports and allow FDA to require prompt corrective action before safety problems reach a crisis stage.
CVM +$500,000 / 3 FTE

E. Generic Drug Review: BA +$2,000,000 / 4 FTE; UF +$40,122,000 / 73 FTE

- **FDA will Increase its Capacity to Review Generic Drugs Applications:** FDA will hire additional staff to support the review of abbreviated new drug application for generic drugs and inspections of generic drug manufacturing facilities. In the case of user fees, by the end of the first five years of the Generic Drug User Fee Program, the additional user fees will result in a complete review and response for an estimated 80 percent of applications within 12 months of receipt, other than applications excluded because of exclusivity or challenges. Generic drug user fees will support premarket and postmarket activities to ensure the safety and efficacy of generic drug products.

- FDA will also hire 6 new investigators with user fees to conduct inspections of generic drug manufacturing facilities. *(BA = 0 FTE; UF = 6 FTE)* When fully trained, the new investigators will conduct an additional 54 domestic inspections of generic drug manufacturing facilities to support the review process. Based on training requirements, the full performance year for the increase in domestic inspections is FY 2014.

  FDA will hire four new staff to conduct generic drug reviews. *(BA = 4 FTE; UF = 0 FTE)* When fully trained, the new staff will be able to conduct 18 additional application reviews per year. FDA expects that the reviewers will be fully trained after 24 months.
  CDER BA +$2,000,000 / 4 FTE
  Generic Drug UF +$40,122,000 / 73 FTE

F. Reinspection User Fee: +$14,108,000 / 56 FTE

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 the 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.

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.

Of the total FTE increase for this activity, FDA will hire 21 new investigators *(BA = 0 FTE; UF = 21 FTE)*. When the new investigators are fully trained, FDA will have the capacity to conduct an estimated 329 domestic medical product reinspections (BA = 0 / UF = 329)

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 extend to FDA food programs.

G. International Courier User Fee: +$5,338,000 / 21 FTE

For FY 2012, FDA is proposing a new International Courier User Fee to support activities associated with increased surveillance of FDA-regulated commodities, predominantly medical products, at express courier hubs. The user fee will address the growing volume of imports that enter through international couriers and the cost of FDA import operations to support international courier activities. 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 release of unsafe products
- establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

H. Program Support for Initiative Priorities +$1,687,000 / 5 FTE

The Protecting Patients Initiative includes resources to ensure that the FDA medical product programs participating in this initiative receive the support

needed to achieve the public health outcomes for the initiative. Support activities include finance and budgeting, contracting, billing, human resource assistance, legal counsel, communication, ethics, headquarters coordination and related support functions.

I. Pay Costs for FDA Medical Product Safety Programs: +$2,741,000 / 0 FTE

The pay amounts in this initiative support the FDA Centers and Offices that perform FDA medical product activities. FDA regulates a diverse and complex portfolio of products that account for 20 percent of U.S. consumer spending. FDA can only fulfill its responsibilities if it has sufficient resources to pay the scientific, professional and technical workforce required to protect patients and conduct the operations of FDA medical product safety programs. Therefore, funding this initiative will help ensure that FDA retains professional staff that performs essential drug, device, biologic and toxicological safety activities to protect the American public.

For medical product safety programs, the FY 2011 budget authority amount for higher pay costs is $2.7 million. For all FDA programs, pay costs will increase by $4.9 million.

J. Rent Activities for FDA Medical Product Programs: +$19,045,000 / 0 FTE

The $19,045,000 increase in budget authority will allow FDA to pay the GSA Rent and the Other Rent and Rent-Related costs for the facilities that support the program activities and the new employees hired under the FY 2012 Protecting Patients Initiative. These funds will also allow FDA to pay the increasing cost of GSA Rent and Other Rent and Rent-Related activities for the activities of FDA's base program without redirecting resources from core, mission-critical public health activities. The increase in rental payments is essential for FDA medical product programs to maintain performance and achieve their public health goals.

The GSA Rent account includes funds for FDA payments to the General Services Administration (GSA) for FDA 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 inventory of buildings.

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

The FDA Protecting Patients Initiative supports core public health priorities including:

- improving access to health care

- making health care more affordable
- improving health care quality and patient safety
- promoting high-value, efficient care.

The investment associated with biosimilars and other Protecting Patients priorities will generate important savings that will foster improved health care in America.

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

A. Biosimilars

Failure to fund this initiative will result in significant delays in defining the scientific and regulatory criteria that sponsors need to invest in and develop biosimilar products. If FDA funding is not sufficient at the outset, the path for developing biosimilars will lack certainty. This will lead to less investment, which will slow product development. In addition, FDA will likely face a significantly higher risk of litigation, which may further stymie the development of biosimilars by industry.

Furthermore, without these resources the Federal government will miss an important opportunity to generate significant savings, estimated by CBO at $7 billion, during the next 10 years. In the United States, patents have expired on biological products whose annual sales amount to more than $15 billion. Biosimilar versions of these products could produce savings for patients of at least 10 to 30 percent. These savings will only be realized after FDA establishes a regulatory pathway for approving biosimilars.

Until such a pathway is developed and implemented, regulated industry will face such regulatory and scientific uncertainty that investment in biosimilars will be stunted, if they occur at all.

B. Other Protecting Patients Priorities

This initiative meets the need for a strong and smart regulator to handle the safety challenges of the 21st century.

FDA's Science Board – an external advisory group to FDA – and the Government Accountability Office have documented the urgent need for a major investment in FDA's safety efforts. Not funding this initiative would leave America with the medical product safety system we have now – vulnerable to unsafe imports, unable to identify serious safety issues, and unable to respond to key advances in technology.

As the approval and use of medical products continues to grow, if FDA does not receive the resources in this initiative, FDA will face a diminished ability to:

- identify and respond to adverse events
- to identify and analyze medical product safety signals
- to communicate safety concerns to patients and the medical community.

In summary, failing to provide these resources will lead to preventable injuries and patient deaths.

International Courier User Fee:

Without the resources authorized by the proposed International Courier User Fee, FDA cannot adequately protect the health of Americans and the health of the U.S. animal population. 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
- minimize the time between detection and appropriate risk management response.

C. Pay and Rent Activity Costs for FDA Medical Product Safety Programs

For medical product programs, the FY 2012 budget authority increase for higher pay costs is $2,741,000 and the increase for rent activities for medical product programs is $19,045,000. Payroll, rent, utilities and other costs to support the FDA workforce account for 80 percent of the FDA budget. These are fixed costs that FDA does not control. If FDA does not receive the full amount for increased pay and rent costs, FDA will absorb the higher pay and rent costs by reducing essential staff. As a result, FDA will fail to hire or replace investigators, epidemiologists, safety experts and other professionals that are the backbone of FDA's medical product safety workforce.

6. What will FDA accomplish with the initiative?

A. Biosimilars: This initiative will enable FDA to begin to reduce much of the scientific, legal and regulatory uncertainty surrounding the development of biosimilars. Reducing this uncertainty will increase the investment in this promising area and lead to quicker development and launch of biosimilar products, leading to lower costs of life-saving treatments for many Americans. Reducing these costs will improve access to care among those who currently cannot afford it. Savings will accrue not only to patients, but also to other parts of the health care system such as the Centers for Medicare and

Medicaid Services, the Department of Veterans Affairs and the Department of Defense. The timing of FDA's investment in the development of biosimilars will determine the timing of Federal savings.

B. Additional Protecting Patients Priorities: FDA's Protecting Patients Initiative will have a significant, beneficial impact on public health in the United States. This science-based strategy will continue to build new and greater safety capabilities into the future, resulting in:

- reduced number of import safety emergencies
- fewer serious adverse events linked to medical products
- earlier identification of major safety problems with drugs, devices, and biologics.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. The initiative supports critical international efforts, important internal upgrades to FDA capacity, and essential partnerships with the private sector. With the proposed resources, the Protecting Patients Initiative will lead to:

- improved import safety program for medical products
- increased capacity to conduct inspections
- improved safety of blood, tissue and vaccines
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

C. 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 establishment of import controls to prevent unsafe products from entering the United States.

Performance for FY 2012 Protecting Patients Initiative

The following table contains information about performance commitments associated with FDA's proposed increase for Protecting Patients Initiative, including accomplishments expected in Fiscal Year 2011 and proposed program outputs to be achieved in Fiscal Year 2012.

FDA-TRACK, the Agency's program performance management system, is being used to track, analyze and report performance measures, progress and accomplishments for FDA's most important initiatives. FDA is currently implementing the initiatives showcased in this year's performance tables in FDA-TRACK. FDA will post quarterly progress and accomplishments on the performance for this initiative at http://www.fda.gov/AboutFDA/Transparency/track/default.htm

Protecting Patients Initiative

Biosimilars

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Begin to establish an abbreviated regulatory review pathway for biosimilar and interchangeable biological products	N/A	Begin to identify scientific, legal and policy issues related to biosimilar and interchangeable biological products	N/A

Import Safety

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Number of clinical investigator sites inspected within required timelines (targeting as highest-priority those identified by the Good Clinical Practice inspection prioritization model)	N/A	0 (+30% of sites by FY 2013)	Develop the Good Clinical Practice inspection prioritization model
Percentage of FDA database entries that validate against the Dun & Bradstreet[2] (D&B) database	N/A	0 (90% by FY 2012)	Develop capability to validate against D&B database

[2] Dun & Bradstreet maintains the world's largest business database containing information on more than 100 million businesses, and they continuously update their information (on average 1.5 million times each business day) to ensure it is the most accurate and up to date.

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Number of generic drug manufacturing sites identified as high risk that will be inspected by staff with appropriate pharmaceutical product expertise	N/A	0 (75% by FY 2015)	Develop-mental
Number of foreign GMP surveillance human drug process inspections	N/A	0 (+13 FTEs resulting in +46 inspections by FY 2015)	FY 2010: 380
Number of foreign human drug BIMO inspections, including PEPFAR	N/A	0 (+3 FTEs resulting in +15 inspections by FY 2015)	FY 2010: 214
Number of foreign human tissue establishment inspections	N/A	0 (+1 FTE resulting in +2 inspections by FY 2015)	FY 2010: 13
Number of foreign Medical Device GMP surveillance inspections	N/A	0 (4+ FTEs resulting in +53 inspections by FY 2015)	FY 2010: 251
Number of foreign Rad Health inspections	N/A	0 (+1 FTEs resulting in +14 inspections by end of FY 2015)	FY 2010: 33

Safety for High-Risk Products

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Blood Safety: Reduce adverse events and adverse reactions	N/A	Improve the prevention, detection, monitoring, analysis and response to manufacturing deviations, as well as observed and potential adverse events and adverse reactions	N/A
Tissue and Cord Blood Safety: Reduce adverse events	N/A	Continue to build a capacity to identify and respond to adverse events	N/A
Number of domestic human tissue establishment inspections	N/A	0 (+3 FTEs resulting in +68 inspections by FY 2014)	FY 2010: 552
Number of domestic high risk animal drug inspections	N/A	0 (+1 FTE resulting in +17 by FY 2014)	FY 2010: 229
Number of domestic Medical Device GMP surveillance inspections	N/A	0 (+1 FTEs resulting in +14 inspections by FY 2014)	FY 2010: 1,672

Expand Partnerships for Patient Safety

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Number of people for whom FDA is able to evaluate product safety through miniature Sentinel* pilots	N/A	+15 million (total of 70 million patients by FY 2012)	FY 2010: 60 million
Review adverse experience reports received to detect animal product hazards early	N/A	+5%	FY 2010: 22%

FDA Regulatory Science and Facilities
+$48,730,000 / 50 FTE

The following table displays the FY 2012 budget authority for the FDA Regulatory Science and Facilities Initiative.

FDA Regulatory Science and Facilities

(Dollars in Millions)

Program	FY 2010 Enacted	FY 2011 Continuing Resolution	FY 2012 Request	+/- FY 2010 Enacted
Budget Authority:				
Foods	**$0.000**	**$0.000**	**$2.377**	**$2.377**
Center	0.000	0.000	$2.100	$2.100
Field Activities	0.000	0.000	$0.277	$0.277
Human Drugs	**$0.000**	**$0.000**	**$2.753**	**$2.753**
Center	0.000	0.000	$2.476	$2.476
Field Activities	0.000	0.000	$0.277	$0.277
Biologics	**$0.000**	**$0.000**	**$1.425**	**$1.425**
Center	0.000	0.000	$1.425	$1.425
Field Activities	0.000	0.000	$0.000	$0.000
Animal Drugs and Feeds	**$0.000**	**$0.000**	**$2.151**	**$2.151**
Center	0.000	0.000	$2.151	$2.151
Field Activities	0.000	0.000	$0.000	$0.000
Devices and Radiological Health	**$0.000**	**$0.000**	**$4.010**	**$4.010**
Center	0.000	0.000	$3.734	$3.734
Field Activities	0.000	0.000	$0.276	$0.276
National Center for Toxicological Research	**$0.000**	**$0.000**	**$1.700**	**$1.700**
Headquarters and Office of the Commissioner	**$0.000**	**$0.000**	**$9.558**	**$9.558**
FDA White Oak Consolidation	**$0.000**	**$0.000**	**$23.675**	**$23.675**
Other Rent and Rent Related	**$0.000**	**$0.000**	**$0.386**	**$0.386**
GSA Rental Payments	**$0.000**	**$0.000**	**$0.695**	**$0.695**
Total FDA Regulatory Science	**$0.000**	**$0.000**	**$48.730**	**$48.730**

1. Initiative Summary:

The FDA Regulatory Science and Facilities Initiative will allow FDA to establish the scientific infrastructure on the White Oak, Maryland campus that is essential for FDA to fulfill its public health responsibilities. The initiative also will allow FDA to develop standards for new and emerging technologies, modernize the standards for evaluating products, and accelerate the development of essential medical therapies for the American public.

Regulatory science at FDA is unique compared to the science conducted by industry and academia. Regulatory science focuses on developing tools to properly assess the safety, effectiveness and quality of products that are being developed or are already on the market. Regulatory science focuses on tools and knowledge that will help products advance from concept to market safely and efficiently.

With the FDA Regulatory Science and Facilities Initiative resources, FDA will make important advances in regulatory science, which serves as the foundation for FDA regulation of foods, medical products and other products. Industry will more efficiently develop new products and FDA will more efficiently assess new product safety and effectiveness.

With the FDA Regulatory Science and Facilities Initiative resources FDA will address scientific gaps identified in *FDA Science and Mission at Risk*, the 2007 report of the Subcommittee on Science and Technology of the FDA Science Board. The FDA Science Board is an Advisory Committee to the FDA Commissioner. FDA will harness the power of science for America's benefit.

With the FDA Regulatory Science and Facilities Initiative resources, FDA will also outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex. On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction work is underway. FDA must make this investment in FY 2012 to ensure that the laboratory is operational and ready for occupancy in FY 2014.

2. Why is this funding necessary?

During the past two decades, an unprecedented level of investment has led to revolutionary advances in the biomedical sciences. However, FDA's scientific expertise and infrastructure have not kept pace with these advances. Today, FDA is relying on 20th century regulatory science to evaluate 21st food and medical products.

In 2007, *FDA Science and Mission at Risk* concluded that FDA is unable fulfill its mission, in part because it lacks modern scientific expertise. The number of new medical products approved by FDA since 1950 has remained constant. Drugs entering phase 1 clinical trials today are no more likely to reach the market than those entering phase 1 trials more than 20 years ago – in part because methods to anticipate product safety and test product efficacy during development are inefficient and outmoded. The lack of core scientific capacities for new and emerging technologies has hampered regulatory review at FDA, delayed the development of promising new therapies, and handicapped FDA's ability to promote and preserve public health.

Funding the CBER-CDER Life Sciences-Biodefense Laboratory will provide FDA with safe, certified laboratory capacity for FDA to perform its medical product responsibilities. This laboratory complex is the cornerstone of FDA support for national and global preparedness for annual influenza and pandemic influenza. The laboratory also is essential to protect the nation's blood supply and other biological products from emerging threats. Emerging threats include SARS, dengue virus, and Chagas' disease. Finally, the laboratory will provide the facilities to support the science necessary to implement the new FDA

requirements related to biosimilar products under section 351 of the Public Health Service Act (42 U.S.C. 262).

The Life Sciences-Biodefense Laboratory will also ensure that FDA is technologically ready to test vaccines, drugs and other medical countermeasures MCMs that will protect Americans against the threat of bioterrorism and other emerging threats in support our national defense. The Life Sciences-Biodefense Laboratory is an essential facility for FDA to develop, test and license MCM vaccines and immunoglobulins to prevent and treat illnesses due to exposure to bioterrorist pathogens. Examples of these threats include anthrax, smallpox, botulism, tularemia, plague and hemorrhagic fever viruses.

Finally, this initiative also contains resources to support the increased pay cost for the commissioned corps officers who serve at FDA and the increased rent costs to support regulatory science activities. Therefore, funding this initiative will help ensure that FDA retains professional staff that performs essential drug, device and biologic safety activities to protect the American public.

3. What activities will the funds support?

FDA will use the funds in this initiative to modernize regulatory science, which is essential to FDA actions to protect patients and consumers and successfully accomplish its public health mission. FDA will begin to build essential scientific capacity and close the gap in the emerging science and technology areas where FDA is most handicapped. The investment in regulatory science will benefit new product development in areas such as personalized medicine and systems biology – including genomics. The investment will also support new products that rely on nanotechnology, medical imaging, wireless healthcare devices, cell- and tissue-based products, regenerative medicine, and other complex products, such as combination products.

The investment will allow FDA to develop regulatory standards to provide pathways for developing products that rely on new and emerging technologies. FDA will support applied science that focuses on developing methods and tools to characterize a new generation of products, as well as biomarkers to assess product safety and effectiveness. With this investment, FDA can accelerate the development and evaluation of products that can address unmet health needs.

The investment will allow the FDA Chief Scientist to provide FDA-wide leadership and coordination on cross-cutting issues in emerging sciences. The Chief Scientist will also oversee efforts to maintain FDA's core scientific infrastructure.

In this initiative, FDA will focus on the emerging technologies and medical products in three broad areas: leadership and coordination, core capacities, and modern product evaluation standards.

FDA Regulatory Science and Facilities

A. CBER-CDER Life Sciences-Biodefense Lab: +$23,675,000 / 0 FTE

- FDA can only succeed in its public health mission if it operates with modern laboratories and supporting facilities to enable sound, science-based regulatory decisions that protect public heath. With this investment, FDA will pay the costs to make the GSA-constructed CBER-CDER Life Sciences-Biodefense Laboratory operational. FDA must make this investment in FY 2012 to ensure that the laboratory is functioning and ready for occupancy in FY 2014. The new laboratory complex will have an essential role in fulfilling FDA responsibilities for drug and biologic safety, medical countermeasures development, annual influenza and other threats.

B. Leadership and Coordination: +$2,480,000 / 5 FTE

- **FDA will strengthen scientific leadership.** The Office of the Chief Scientist (OCS) will provide FDA and its centers with dedicated and expert scientific leadership. OCS will work with the centers to define and establish a vision, develop a structure, and prioritize, oversee, support, and coordinate key scientific investments at FDA.

  By establishing the Office of Science and Innovation, OCS will provide scientific support, leadership and coordination. The Office of Science and Innovation will be a core resource of scientific expertise in emerging areas. It will scan the horizon for new technologies, promote innovation in regulatory science and review, and serve as a nucleus for internal and external collaboration.

  OCS will also establish collaborations to support regulatory science research. The collaborations will allow FDA to continuously access expertise in emerging science, harness existing external resources, and strengthen knowledge and skills within the FDA workforce.

  These efforts will focus on emerging technologies and respond to key needs identified by the FDA Science Board. The Chief Scientist will coordinate key professional development programs in emerging sciences and support scientists in FDA centers who are engaged in peer reviewed, high priority, collaborative, and mission-focused applied regulatory research. This investment begins to respond to concerns of the FDA Science Board, which described FDA research as ". . . critical because it is not conducted by other public or private entities . . . [and is] fundamental to the discharge of FDA's statutory responsibilities to protect and promote the public health."
  HQ/OC: +$2,480,000 / 5 FTE

C. Core Capacities – Infrastructure, Workforce, Collaboration: +$15,562,000 / 26 FTE

- **FDA will acquire core scientific capacities in emerging technologies.** FDA will build core scientific capacity and expertise in nanotechnology, which holds great promise for advances in medical products and foods. FDA will establish collaborations with scientific institutions and other regulatory agencies and support collaborative regulatory science research in nanotechnology. Nanotechnology efforts will focus on critical product characterization and safety issues given the field's potentially unanswered safety concerns. With this investment, FDA seeks to support innovation while protecting consumers.
  CFSAN: +$750,000 / 2 FTE
  CDER: +$475,000 / 1 FTE
  CBER: +$475,000 / 1 FTE
  CVM: +$300,000 / 0 FTE
  CDRH: +$900,000 / 2 FTE
  NCTR: +$1,700,000 / 4 FTE
  ORA: +$830,000 / 3 FTE
  HQ/OC: +$1,899,000 / 4 FTE

  FDA will also support the evaluation of products that result from stem cell innovation so that the results of Federal investment in stem cell research can transfer from the bench to the bedside.
  CBER: +$950,000 / 2 FTE

- **FDA will recruit next generation scientific staff.** FDA and the Science Board have identified essential areas of emerging science where FDA lacks expertise. The budget will allow the Center for Devices and Radiological Health to enhance expertise in two forward-looking areas for which there is an urgent and critical need: 1) smart devices for a wide range of applications, including in the development of next generation high-technology orthopedic prosthetic devices and 2) innovative analytic methods that will allow FDA to more efficiently acquire and translate medical data into usable information. FDA will apply these methods to a national medical device registry.
  CDRH: +$500,000 / 2 FTE

- **FDA will address science issues for creating a national medical device registry.** FDA will begin to link unique device identifiers (UDIs) to health-related electronic data to create a national medical device registry to improve our understanding of the risk-benefit profile of higher risk devices.
  CDRH: *+$2,333,000 / 4 FTE*

- **FDA will promote scientific collaboration and exchange.** Through enhanced support of partnerships and collaboration, FDA will develop

tools to modernize product development and evaluation. Additional investments in FDA's Critical Path Program will position FDA to foster focused partnerships to transform product development and evaluation sciences, advance personalized medicine, and develop novel diagnostic and medical products. The goal is to speed translation of research discoveries into marketed medical products, while reducing risks and costs by identifying ineffective products and potential safety risks early in development.
HQ/OC: +$4,450,000 / 1 FTE

D. Update medical product regulatory standards: +$5,200,000 / 16 FTE

- **FDA will update review standards and provide regulatory pathways for new technologies.** FDA will establish regulatory guidance to provide a scientifically sound and safe pathway to better characterize and develop biosimilars. In addition to the amounts requested in the FDA Regulatory Science and Facilities Initiative, FDA is requesting $13,000,000 (program, rent and support) for biosimilars in the Protecting Patients Initiative.
CDER: +$2,000,000 / 4 FTE

- Given the tremendous potential for biotechnology to improve health and reduce illness, FDA will refine its guidance to industry and regulatory pathway for animal biotechnology products.
CVM: *+$1,850,000 / 10 FTE*

- **FDA will promote development of healthy foods and encourage healthy food choices.** FDA will encourage and support food industry efforts to modify food products and give consumers more healthful food choices. FDA will use data from well-designed studies to support a modernized food label to encourage Americans to eat healthier diets and potentially reduce the prevalence of obesity and its associated health care costs in the United States.
CFSAN: +$1,350,000 / 2 FTE

E. Pay and Rent Costs for FDA Regulatory Science and Facilities Activities: +$1,085,000 / 0 FTE

This initiative contains $4,000 to support the increased pay cost for the commissioned corps officers who serve at FDA. FDA regulates a diverse and complex portfolio of products that accounts for 20 percent of U.S. consumer spending. FDA can only fulfill its responsibilities if it has sufficient resources to pay the scientific, professional and technical workforce required to conduct FDA regulatory science activities.

In addition, a $1,081,000 increase in budget authority will allow FDA to pay the GSA Rent and the Other Rent and Rent-Related costs for the facilities that support regulatory science activities and the new employees hired under the FDA

Regulatory Science and Facilities Initiative. These funds will allow FDA to pay the increasing cost of GSA Rent and Other Rent and Rent-Related activities for the activities of FDA's base program without redirecting resources away from core, mission-critical public health activities. The increase in rental payments is essential for FDA regulatory science programs to maintain performance and achieve their public health goals.

The GSA Rent account includes funds for FDA payments to the General Services Administration (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 inventory of buildings.

F. Program Support for the FDA Regulatory Science and Facilities Initiative: +$728,000 / 3 FTE

To ensure that FDA program offices that conduct the FDA Regulatory Science and Facilities Initiative receive the support necessary to achieve the proposed public health priorities, the initiative includes resources for essential support activities. Support activities include finance and budgeting, contracting, billing, human resource assistance, legal counsel, communications, ethics, coordination and related support functions.
HQ/OC: +$728,000 / 3 FTE

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

The FDA Regulatory Science and Facilities Initiative will allow FDA to harness the power of science to improve the health of Americans. The FDA Regulatory Science and Facilities Initiative supports important priorities such as

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

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

A. CBER-CDER Life Sciences-Biodefense Lab:

Without this investment, FDA must 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. FDA will lack the capacity to fulfill its expanding responsibilities related to drug and biologic

safety, medical countermeasures, annual influenza, and pandemic influenza and other naturally emerging and intentional threats.

B. FDA Regulatory Science Leadership and Coordination:

Funding the Advancing Regulatory Science Initiative will strengthen FDA's capacity and expertise in mission-critical areas. Specifically, FDA will achieve the scientific expertise necessary to support product development through strong science leadership and coordination, core support for targeted research at FDA, and strategic collaboration and partnerships through Critical Path and other academic and government partners. This investment will allow FDA to support sound development, evaluation and access to innovative new products that promise to revolutionize medicine and public health. The investment will help FDA be better equipped to assess safety and efficacy throughout a product's lifecycle, including post approval safety monitoring.

Failure to fund this initiative will result in the continued erosion of excellence at FDA and deeply affect FDA's core competency. FDA will not be able to attract, recruit or retain the review, laboratory and population scientists needed to help our country harvest the fruits of revolutionary developments in science and informatics. The risks of failures will continue to increase as the gaps between demands on FDA and its capacity to respond continue to grow.

As the Science Board noted, "[t]he imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system and hence the safety of the public." This initiative begins to plug those gaps. Not funding this initiative will mean that FDA and the U.S. biotechnology, pharmaceutical and device industries will see their global influence wane, with adverse impacts to the U.S. economy and the health and quality of life for all Americans.

C. Pay and Rent Costs for the FDA Regulatory Science and Facilities Initiative:

For regulatory science activities, the FY 2012 budget authority increase for higher pay costs for Commissioned Corps Officers and other FDA professional staff is $4,000. The FY 2012 budget authority increase to support rent activities for regulatory science activities is $1,081,000. Payroll, rent, utilities and other costs to support the FDA workforce account for 78 percent of the FDA budget. These are fixed costs that FDA does not control. If FDA does not receive the full amount for increased pay and rent costs, FDA will absorb the higher pay and rent costs by reducing essential staff. As a result, FDA will fail to hire or replace the professionals that are the backbone of FDA's regulatory science workforce.

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

This initiative is critical for FDA to be an active participant in 21st century product development and to fulfill its mission to patients and consumers. The FDA

Regulatory Science and Facilities Initiative supports FDA efforts to develop and maintain a world-class science workforce and brings much needed core scientific capacities to FDA. With these resources, FDA can better maintain its position as a global leader in regulatory science. As a result, America will continue to be a global leader in biotechnology, food safety and medical product development.

The initiative will also generate significant benefits for public health in the United States. This initiative will allow for:

- faster food and medical product development and availability
- decreased product development costs
- new, more efficient regulatory pathways for emerging technologies.

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. As a result, U.S. consumers and the U.S. health care system will benefit from lower medical costs. Populations in other countries will also benefit, as the FDA remains the international "gold standard" for regulatory science.

This investment will support:

- strong FDA scientific leadership and coordination
- core science capacities at FDA and support for scientific partnerships and collaboration with academia
- new regulatory science tools, pathways and guidance for new and emerging technologies
- improved accuracy and efficiency of FDA review
- faster access to personalized medicine and new life-saving therapies.

FY 2012 FDA Regulatory Science Performance

FDA is using FDA-TRACK, the agency's program performance management system, to track, analyze, and report performance measures, progress, and accomplishments for FDA's most important initiatives. FDA is implementing the initiatives showcased in the following FY 2012 performance tables using FDA-TRACK.

When FDA receives these resources, FDA will publish information quarterly progress and accomplishments for its performance under the FDA Regulatory Science and Facilities initiative at:
http://www.fda.gov/AboutFDA/Transparency/track/default.htm

FDA Regulatory Science and Facilities

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Enhance the safety or efficacy of drugs, biologics, and devices by conducting state-of-art laboratory tests	N/A	• Support the development, testing and licensing of vaccines and immunoglobulins to prevent and treat illnesses due to exposure to emerging infections or bioterrorist pathogens • Develop improved assays, standards and tests for medical products • Evaluate blood and plasma products to ensure safety • Conduct research to enhance gene and cell therapy safety and effectiveness • Use state-of-the-art flow cytometry technologies to aid in medical product evaluation.	N/A
Establish organizational resources for strengthening science at FDA	N/A	• Develop staffing plans and hire key staff • OCS coordinate key professional development programs in emerging sciences • Establish Cross-Center Working Groups • Establish Scientific Challenge Grant programs for collaborative, mission critical, applied regulatory science research	• Established the Office of Chief Scientist (OCS, which includes a new Office of Science and Innovation
Enhance scientific capabilities in nanotechnology	N/A	• Acquire critically needed equipment and technical staff to conduct product assessment and safety research in support of regulatory decision-making • Establish a professional development program in nanotechnology • Establish collaborative programs in nanotechnology with universities, government agencies, and international regulatory counterparts	• Completed the initial setup of the NCTR/ORA Nanotechnology Core Facility • Limited scale effort at Centers to characterize nanotechnology-based products as they relate to human health • Provided science based guidance to those seeking to use nanomaterials in FDA regulated products
Strengthen FDA's scientific capacity to regulate products resulting from stem cell innovation	N/A	• Develop analytic tests for characterization of stem cells products • Conduct outreach activities to ensure the scientific community is aware of regulatory requirements	• Developed MRI imaging methods to track neural stem cells after transplantation into mouse brains

Performance Measures	FY 2011 Adjusted CR Performance Level	FY 2012 President's Budget Performance Level +/- FY 2011 Adjusted CR	Most Recent Actual
Improved tools for modernizing medical product assessment in areas such as clinical trail design and data analysis, and more accurate predictors of product safety and efficacy using biomarkers	N/A	• Fund projects to validate new biomarkers, enable personalized medicine, modernize and increase the efficiency of the clinical trial enterprise, improve tools to predict safety and effectiveness of medical products, modernize the methods used in toxicology studies	• Engaged public private partnerships to identify and qualify new biomarkers and to improve detection of serious adverse events in clinical trails
Enhanced continuing education and professional development programs for scientific staff, increased scientific exchanges	N/A	• Increase participation in continuing education, professional development, and scientific collaborative programs • Targeted increases in performance incentives	• Continued improvement of Center-specific professional development programs and enhanced online opportunities
Enhance capabilities to efficiently regulate new animal biotechnology products	N/A	• Hire and train staff to improve the knowledge base and expertise to facilitate review and potential approval of animal biotechnology products	• Developed baseline performance
Increase number of regulatory standards established to guide drug innovators in the application of technologies such as genomics, proteomics, and medical imaging to drug discovery and development	N/A	• Develop regulatory policy to clarify FDA expectations and requirements surrounding submission of applications for biosimilar products • Begin acquiring necessary equipment and expertise to evaluate biosimilar applications	• Provided scientific and strategic input to the Predictive Safety Testing Consortium to qualify biomarkers for drug-induced kidney toxicity in humans
Improve public health and reduce chronic disease by modernizing the food label, increasing consumer awareness, and reducing intake of sodium and trans fats	N/A	• Develop nutritional criteria for labeling on the front of food packages that consumers can rely on to make informed choices for healthy eating	• Program evaluation of nutrition labeling education for children ages 9-13

FDA Contract and Administrative Savings
- $29,723,000 / - 46 FTE

FY 2011 Resource Table

The following table displays the budget authority amounts for Contract and Administrative Savings in the FY 2012 President's Budget for each FDA program.

Contract and Administrative Savings

Dollars in Millions

Program	FY 2012 Request
Budget Authority:	
Foods	**-$6.707**
Center	-2.026
Field Activities	-4.681
Human Drugs	**-$5.659**
Center	-4.088
Field Activities	-1.571
Biologics	**-$2.518**
Center	-2.027
Field Activities	-0.491
Animal Drugs and Feeds	**-$1.257**
Center	-0.795
Field Activities	-0.462
Devices and Radiological Health	**-$3.852**
Center	-2.872
Field Activities	-0.980
National Center for Toxicological Research	**-0.699**
Headquarters and Office of the Commissioner	**-5.534**
Natural Products Center	**-3.497**
Total, Budget Authority	**-$29.723**

1. Initiative Summary:

The Contract and Administrative Savings Initiative will achieve savings of $29,723,000 across FDA during fiscal year 2012.

2. How will FDA achieve contract and administrative savings?

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

- reducing services provided by outside contractors
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting.

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

- limiting contracts through partnerships with academic institutions for epidemiological or adverse event research
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting
- reducing training and identifying lower-cost training options .

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

- reducing acquisition costs by conducting training to improve the skills of the acquisition workforce and program offices
- using technology to improve contract management and to manage contract costs
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting
- using FDA-wide contracts to combine resources and reduce cost, such as CBER joining with other FDA centers in contracts to support is activities on the NIH campus
- using more cost-effective contract types and ending contracts that do not fully meet program needs.

The Center for Veterinary Medicine (CVM) will achieve contract savings by:

- using existing FDA and center contracts and identifying other measures to award contracts that can reduce costs
- determining where outside source services can be accomplished internally
- using in-house expertise to teach training courses instead of paying contractor services
- streamlining activity time reporting processes to improve efficiency and productivity, which will reduce the need for contract support for this system

- using telework to increase productivity, improve efficiency, and reduce overhead costs for rental space.

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

- reducing travel by CDRH staff
- replacing traditional classroom training with online training
- reducing services provided by outside contractors
- using technology to further reduce high contractor costs associated with processing and data entry
- terminating contracts that do not fully meet program needs

The Office of Regulatory Affairs (ORA) will achieve savings by:

- reducing administrative support FTE, both in Headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA.

The National Center for Toxicological Research (NCTR) will achieve savings by:

- reviewing contracts for research support and identifying activities that NCTR workforce can perform.

Headquarters and the Office of the Commissioner (OC) will achieve savings by:

- reducing the OC enterprise contract spending related to financial services, recruitment and workforce management, and information technology including $4.0 million in savings related to the Medwatch Plus IT System

Contract and Administrative Savings

FDA Current Law User Fees
+$634,468,000 / 1,229 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 FDA-regulated products. 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 fee increases for many FDA user fee programs. The increases expand the available options for treating and curing diseases and addressing other important public health needs.

The following table displays funding for FY 2010 through FY 2012 for FDA current law user fees:

FDA Program Resources Table
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
PDUFA	$578,162	$573,258	$667,057	$856,041	$277,879
Tobacco	$235,000	$71,987	$235,000	$477,000	$242,000
Voluntary Qualified Importer Program	$0	$0	$0	$71,066	$71,066
MDUFMA	$57,014	$57,187	$57,014	$67,118	$10,104
ADUFA	$17,280	$16,601	$17,280	$21,768	$4,488
Reinspection	$0	$0	$0	$14,700	$14,700
Recall	$0	$0	$0	$12,364	$12,364
AGDUFA	$5,106	$4,737	$5,106	$5,706	$600
Food & Feed Export Certification	$0	$0	$0	$1,267	$1,267
MQSA	$19,318	$14,064	$19,318	$19,318	$0
Color Certification	$7,700	$6,768	$7,700	$7,700	$0
Export Certification	$2,700	$3,663	$2,700	$2,700	$0
	$922,280	**$748,265**	**$1,011,175**	**$1,556,748**	**$634,468**

2. What activities will the funds support?

PDUFA: +$277,879,000 / 584 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. Known as PDUFA IV, this authority is effective for five years.

PDUFA IV 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 authority to collect fees under PDUFA IV expires on October 1, 2012. Therefore, as authorized by Section 736(c)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379h(c)(3)], the FY 2012 PDUFA budget includes a final year adjustment to assure the availability of three months of user fee revenue.

PDUFA IV upgrades and broadens FDA's drug safety program and expands guidance for industry and FDA reviewers. The FY 2012 fee levels also allow FDA to invest in information technology that supports human drug review. The funds facilitate more efficient development of safe and effective new drugs and support FDA efforts to modernize the drug safety system for the American public.

The following table displays funding for FY 2010 through FY 2012 for PDUFA.

PDUFA Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CDER	$406,984	$414,877	$469,559	$602,590	$195,606
CBER	$83,747	$76,781	$96,624	$123,998	$40,251
Field Activities	$11,795	$8,024	$13,608	$17,463	$5,668
Headquarters/OC	$34,073	$28,953	$40,693	$52,222	$18,149
White Oak Consolidation	$2,960	$0	$3,415	$4,383	$1,423
GSA Rent and Rent Related	$38,603	$44,623	$43,158	$55,385	$16,782
Total	**$578,162**	**$573,258**	**$667,057**	**$856,041**	**$277,879**

Tobacco Act Program: +$242,000,000 / 216 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 2010 through FY 2012 for the Tobacco Program:

Tobacco Act Program Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CTP	$211,823	$62,355	$211,823	$448,501	$236,678
Field Activities	$4,700	$2,063	$4,700	$6,250	$1,550
Headquarters/OC	$14,336	$3,375	$14,336	$15,196	$860
GSA Rent and Rent Related	$4,141	$4,194	$4,141	$7,053	$2,912
Total	**$235,000**	**$71,987**	**$235,000**	**$477,000**	**$242,000**

Voluntary Qualified Importer Program (VQIP): +$71,066,000 / 280 FTE

This user fee supports important public health priorities by providing the FDA the ability to expedite the import of food that meets defined standards. This user fee program will help ensure that foods are safe for consumption thereby allowing FDA to focus other resources on targeting foods that have a higher risk of causing illness or have other public health consequences.

The following table displays funding for FY 2010 through FY 2012 for VQIP:

Voluntary Qualified Importer Program Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CFSAN	$0	$0	$0	$232	$232
Field Activities	$0	$0	$0	$61,000	$61,000
Headquarters/OC	$0	$0	$0	$3,674	$3,674
GSA Rent and Rent Related	$0	$0	$0	$6,160	$6,160
Total	**$0**	**$0**	**$0**	**$71,066**	**$71,066**

MDUFMA: +$10,104,000 / 34 FTE

In FDAAA, Congress renewed FDA's authority to collect user fees under the Medical Device User Fee and Modernization Act (MDUFMA). This authority is effective for five years and directs FDA to improve the quality and timeliness of medical device review. MDUFMA also provides funds to:

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

MDUFMA 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 authority to collect fees under MDUFMA expires on October 1, 2012.

The supplemental funding provided from MDUFMA collections is critical to FDA's ability to further strengthen the review processes and meet performance goals for the medical device program. Meeting these goals can reduce the time required to complete clinical trials and marketing application reviews, thereby speeding to market products that save lives, reduce suffering, and enhance quality of life.

The following table displays funding for FY 2010 through FY 2012 for MDUFMA:

MDUFMA Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CBER	$11,068	$ 7,039	$11,068	$13,030	$1,962
CDRH	$32,836	$ 41,283	$32,836	$38,655	$5,819
Field Activities	$1,556	$ 1,825	$1,556	$1,832	$276
Headquarters/OC	$5,914	$ 3,592	$5,914	$6,962	$1,048
GSA Rent and Rent Related	$5,640	$ 3,448	$5,640	$6,639	$999
Total	**$57,014**	**$57,187**	**$57,014**	**$67,118**	**$10,104**

ADUFA: +$4,488,000 / 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 October 1, 2013.

The following table displays funding for FY 2010 through FY 2012 for ADUFA:

ADUFA Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CVM	$15,290	$14,644	$15,290	$19,261	$3,971
Field Activities	$250	$546	$250	$315	$65
Headquarters/OC	$693	$631	$693	$873	$180
GSA Rent and Rent Related	$1,047	$780	$1,047	$1,319	$272
Total	**$17,280**	**$16,601**	**$17,280**	**$21,768**	**$4,488**

Food Reinspection: +$14,700,000 / 73 FTE

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foods and animal feed facilities to assess their compliance with Good Manufacturing Practice requirements. ORA inspects domestic and foreign facilities. 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 2010 through FY 2012 for Food Reinspection:

Food Reinspection Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Foods Field	$0	$0	$0	$6,825	$6,825
Animal Drugs & Feeds Field	$0	$0	$0	$2,550	$2,550
Headquarters/OC	$0	$0	$0	$3,395	$3,395
GSA Rent and Rent Related	$0	$0	$0	$1,930	$1,930
Total	**$0**	**$0**	**$0**	**$14,700**	**$14,700**

Recall Fees: +$12,364,000 / 31 FTE

These funds reimburse FDA for the cost of conducting a mandatory recall of an article of food that is adulterated or misbranded. These mandatory recalls, also knows 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 2010 through FY 2012 for Recall Fees:

Recall Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CFSAN	$0	$0	$0	$464	$464
Foods Field	$0	$0	$0	$9,397	$9,397
CVM	$0	$0	$0	$521	$521
Animal Drugs & Feeds Field	$0	$0	$0	$639	$639
Headquarters/OC	$0	$0	$0	$661	$661
GSA Rent and Rent Related	$0	$0	$0	$682	$682
Total	**$0**	**$0**	**$0**	**$12,364**	**$12,364**

AGDUFA: +$600,000 / 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 October 1, 2013.

The following table displays funding for FY 2010 through FY 20 for AGDUFA:

AGDUFA Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CVM	$4,382	$4,225	$4,382	$4,898	$516
Field Activities	$143	$144	$143	$160	$17
Headquarters/OC	$204	$158	$204	$228	$24
GSA Rent and Rent Related	$377	$210	$377	$420	$43
Total	**$5,106**	**$4,737**	**$5,106**	**$5,706**	**$600**

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

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 foods. These user fees will support activities associated with facilitating international trade by FDA issuing export certificates.

The following table displays funding for FY 2010 through FY 2012 for Food Export Certification:

Export Certification Increase for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CFSAN	$0	$0	$0	$1,185	$1,185
CVM	$0	$0	$0	$82	$82
Total	**$0**	**$0**	**$0**	**$1,267**	**$1,267**

MQSA: No change

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 there 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 by October 1994 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 of fees to cover the costs of MQSA inspections, record keeping, and annual reports. In FY 2012, FDA estimates the same funding level as in FY 2011.

The following table displays funding for FY 2010 through FY 2012 for MQSA:

MQSA Funding for FY 2012
(Dollars in Thousands)

Program	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
CDRH	$6,003	$4,284	$6,003	$6,003	$0
Field Activities	$13,077	$9,510	$13,077	$13,077	$0
Headquarters/OC	$238	$270	$238	$238	$0
Total	**$19,318**	**$14,064**	**$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 2012 as in FY 2011.

Export Certification (for Drugs, Biologics, and Devices): No change

FDA is required to issue certificates for the export of a drug, animal drug, or device. Certificates state that the product meets certain requirements of law. This applies to products approved for sale in the U.S. as well as unapproved products. The purpose of the certificates is to promote the export of products made in the United States. For FY 2012, FDA is estimating the same funding level as in FY 2011.

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

This initiative addresses a key priority of assuring the safety of essential food and medical products that benefit 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 VQIP User Fee supports Administration public health priorities by providing the FDA with the ability to expedite the review and import of food that meets specific standards to ensure it safe for public consumption. These fees allow FDA to focus appropriated resources on targeting foods that have a higher risk potential of causing illness or other public health consequences.

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 where 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 (MDUFMA) and 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 FDA 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 would have to spend budget authority to remove harmful products from public distribution and not impose these costs on the manufacturer or distributor (Recall User Fees).
- FDA would 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 high priority areas including food and animal drug safety matters (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).
- Rather than targeting higher risk, potentially unsafe products from sources that may fail to meet food quality standards, FDA would have to continue to spend appropriated resources to review all products (VQIP fees).
- FDA cannot adequately develop and implement effective public health strategies to reduce the burden of illness and death caused by tobacco products.

- 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 ensure that FDA meets performance commitments in FY 2012 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.

New user fees, such as VQIP, will allow FDA to expedite the review and import of safe food products. These user fees will enable FDA to better use appropriated resources to increase the ability 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 refuse to do so voluntarily.

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; $4,256,673,000: Provided, That of the amount provided under this heading, $856,041,000 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; $67,118,000 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 shall be derived from animal drug user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; $5,706,000 shall be derived from animal generic drug user fees authorized by 21 U.S.C. 379f, and shall be credited to this account and shall

remain available until expended; $477,000,000 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 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 added by the FDA Food Safety Modernization Act (Public Law 111-353), and shall be credited to this account and remain available until expended; $14,700,000 shall be derived from food reinspection fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act, as added by the FDA Food Safety Modernization Act, and shall be credited to this account and remain available until expended; and $71,066,000 shall be derived from voluntary qualified importer program fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act, as added by the FDA Food Safety Modernization Act, 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 user fees that exceed the fiscal year 2012 limitation 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, animal generic drug, and tobacco product assessments for fiscal year 2012 received during fiscal year 2012, including any such fees assessed prior to fiscal year 2012 but credited for fiscal year 2012, shall be subject to the fiscal year 2012 limitations: 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.

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, $13,055,000, to remain available until expended.

SALARIES AND EXPENSES

Contingent upon the enactment of authorizing legislation, the Secretary shall charge fees for generic drug review activities: Provided, That such fees, in an amount not to exceed $40,122,000, shall be credited to this account, to remain available until expended, for generic drug review activities.

In addition, contingent upon the enactment of authorizing legislation to charge reinspection fees for products other than food, the Secretary shall charge fees for such reinspections: Provided, That such fees, in an amount not to exceed $14,108,000, shall be credited to this account, to remain available until expended, for reinspections.

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge fees for international express courier import activities: Provided, That such fees, in an amount not to exceed $5,338,000, shall be credited to this account, to remain available until expended, for international express couriers import activities.

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 $40,122,000 in 2012, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Medical Products Reinspection User Fee	The Administration will propose legislation to allow FDA to collect fees to cover the costs of medical re-inspections and associated follow-up work. The additional resources, estimated at $14,108,000 in 2012, will ensure that facilities that fail to comply with health and safety standards bear the cost of reinspection.
International Express Couriers User Fees	The Administration will propose legislation to allow FDA to collect fees to cover the costs of increased surveillance at express courier hubs. The additional resources, estimated at $5,338,000 in 2012, will support FDA import operations to support international courier activities.

Food and Drug Administration
FY 2012 Congressional Budget Request
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Food and Drug Administration
FY 2012 Exhibit for Congressional Appropriations
Dollars in Thousands

FY 2012 Changes[1]	BUDGET AUTHORITY																					
	FY 2010 Enacted[2]		FY 2010 Adjusted Enacted		FDA 2012 President's Budget Request														Total Budget Authority Changes		FY 2012 TOTAL (Budget Authority)	
					Pay		Rent and Infrastructure		Transforming Food Safety and Nutrition		Advancing Medical Countermeasures		Protecting Patients		FDA Regulatory Science and Facilities		Administrative and Contract Savings					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	***3,486***	***783,449***	***3,486***	***781,449***	**0**	**1,795**	**0**	**0**	**363**	**176,373**	**0**	**0**	**0**	**0**	**5**	**2,377**	**-30**	**-6,707**	**338**	**173,838**	**3,824**	**955,287**
CFSAN	*981*	*236,542*	*981*	*236,000*	*0*	*573*	*0*	*0*	*152*	*64,222*	*0*	*0*	*0*	*0*	*4*	*2,100*	*0*	*-2,026*	*156*	*64,869*	*1,137*	*300,869*
Field Activities	*2,505*	*546,907*	*2,505*	*545,449*	*0*	*1,222*	*0*	*0*	*211*	*112,151*	*0*	*0*	*0*	*0*	*1*	*277*	*-30*	*-4,681*	*182*	*108,969*	*2,687*	*654,418*
Human Drugs	***2,085***	***461,862***	***2,085***	***461,862***	**0**	**1,095**	**0**	**0**	**0**	**0**	**46**	**12,688**	**63**	**24,796**	**6**	**2,752**	**-7**	**-5,659**	**108**	**35,672**	**2,193**	**497,534**
CDER	*1,399*	*334,188*	*1,399*	*334,188*	*0*	*779*	*0*	*0*	*0*	*0*	*43*	*12,033*	*45*	*21,052*	*5*	*2,475*	*0*	*-4,088*	*93*	*32,251*	*1,492*	*366,439*
Field Activities	*686*	*127,674*	*686*	*127,674*	*0*	*316*	*0*	*0*	*0*	*0*	*3*	*655*	*18*	*3,744*	*1*	*277*	*-7*	*-1,571*	*15*	*3,421*	*701*	*131,095*
Biologics	***858***	***205,563***	***858***	***205,563***	**0**	**481**	**0**	**0**	**0**	**0**	**47**	**11,790**	**20**	**8,192**	**3**	**1,425**	**-2**	**-2,518**	**68**	**19,370**	**926**	**224,933**
CBER	*637*	*165,490*	*637*	*165,490*	*0*	*382*	*0*	*0*	*0*	*0*	*45*	*11,353*	*15*	*7,152*	*3*	*1,425*	*0*	*-2,027*	*63*	*18,285*	*700*	*183,775*
Field Activities	*221*	*40,073*	*221*	*40,073*	*0*	*99*	*0*	*0*	*0*	*0*	*2*	*437*	*5*	*1,040*	*0*	*0*	*-2*	*-491*	*5*	*1,085*	*226*	*41,158*
Animal Drugs & Feeds	***636***	***134,798***	***636***	***134,798***	**0**	**309**	**0**	**0**	**35**	**11,214**	**0**	**0**	**4**	**684**	**10**	**2,150**	**-3**	**-1,257**	**46**	**13,100**	**682**	**147,898**
CVM	*361*	*81,980*	*361*	*81,980*	*0*	*191*	*0*	*0*	*25*	*8,221*	*0*	*0*	*3*	*500*	*10*	*2,150*	*0*	*-795*	*38*	*10,267*	*399*	*92,247*
Field Activities	*275*	*52,818*	*275*	*52,818*	*0*	*118*	*0*	*0*	*10*	*2,993*	*0*	*0*	*1*	*184*	*0*	*0*	*-3*	*-462*	*8*	*2,833*	*283*	*55,651*
Device & Radiological Products	***1,494***	***313,935***	***1,494***	***313,935***	**0**	**753**	**0**	**0**	**0**	**0**	**35**	**8,428**	**19**	**5,829**	**9**	**4,009**	**-4**	**-3,852**	**59**	**15,167**	**1,553**	**329,102**
CDRH	*1,048*	*233,932*	*1,048*	*233,932*	*0*	*556*	*0*	*0*	*0*	*0*	*34*	*8,210*	*13*	*4,167*	*8*	*3,733*	*0*	*-2,872*	*55*	*13,794*	*1,103*	*247,726*
Field Activities	*446*	*80,003*	*446*	*80,003*	*0*	*197*	*0*	*0*	*0*	*0*	*1*	*218*	*6*	*1,662*	*1*	*276*	*-4*	*-980*	*4*	*1,373*	*450*	*81,376*
NCTR	***210***	***58,745***	***210***	***58,745***	**0**	***134***	**0**	***0***	***1***	***414***	***0***	***0***	***0***	***0***	***4***	***1,700***	***0***	***-699***	***5***	***1,549***	**215**	**60,294**
Tobacco Act Program	***0***	***0***	***0***	***0***	*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*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Field Activities	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Other Activities	***644***	***140,848***	***644***	***140,848***	**0**	***329***	**0**	***0***	***36***	***15,505***	***37***	***33,463***	***12***	***3,518***	***13***	***9,557***	***0***	***-5,534***	***98***	***56,838***	**742**	**197,686**
Office of Regulatory Affairs [Non-Add]	***4,133***	***847,475***	***4,133***	***846,017***	***0***	***1,952***	***0***	***0***	***221***	***115,144***	***6***	***1,310***	***30***	***6,630***	***3***	***830***	***-46***	***-8,185***	***214***	***117,681***	***4,347***	***963,698***
White Oak Consolidation	***0***	***38,536***	***0***	***38,536***	**0**	**0**	**0**	**1,927**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**23,675**	**0**	**0**	***0***	***25,602***	**0**	**64,138**
Other Rent & Rent-Related	***0***	***64,860***	***0***	***64,860***	**0**	**0**	**0**	**3,335**	**0**	**6,804**	**0**	**1,320**	**0**	**9,525**	**0**	**368**	**0**	**0**	***0***	***21,352***	**0**	**86,212**
GSA Rent	***0***	***145,260***	***0***	***145,260***	**0**	**0**	**0**	**7,700**	**0**	**8,114**	**0**	**2,311**	**0**	**3,779**	**0**	**662**	**0**	**0**	***0***	***22,566***	**0**	**167,826**
Salaries & Expenses Increases	***9,413***	***2,347,856***	***9,413***	***2,345,856***	**0**	**4,896**	**0**	**12,962**	**435**	**218,424**	**165**	**70,000**	**118**	**56,323**	**50**	**48,675**	**-46**	**-26,226**	**722**	**385,054**	**10,135**	**2,730,910**
Non-Field	*5,280*	*1,251,725*	*5,280*	*1,251,183*	*0*	*2,944*	*0*	*0*	*214*	*88,362*	*159*	*65,059*	*88*	*36,389*	*47*	*23,140*	*0*	*-18,041*	*508*	*197,853*	*5,788*	*1,449,036*
Field	*4,133*	*847,475*	*4,133*	*846,017*	*0*	*1,952*	*0*	*0*	*221*	*115,144*	*6*	*1,310*	*30*	*6,630*	*3*	*830*	*-46*	*-8,185*	*214*	*117,681*	*4,347*	*963,698*
Rents		*248,656*		*248,656*	*0*	*0*	*0*	*12,962*	*0*	*14,918*	*0*	*3,631*	*0*	*13,304*	*0*	*24,705*	*0*	*0*	*0*	*69,520*		*318,176*
Buildings and Facilities	***0***	***12,433***	***0***	***12,433***	**0**	**0**	**0**	**622**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	***622***	**0**	**13,055**
Sec 725 Construction Grant		***3,497***		***3,497***	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-3,497**		**-3,497**		**0**
Total	***9,413***	***2,363,786***	***9,413***	***2,361,786***	**0**	**4,896**	**0**	**13,584**	**435**	**218,424**	**165**	**70,000**	**118**	**56,323**	**50**	**48,675**	**-46**	**-29,723**	**722**	**382,179**	**10,135**	**2,743,965**

[1] This table does not include resources for current indefinite user fees for MQSA ($19.318M); Medical Products Export Certification ($2.7M); Food Export Certification (1.267M); Color Certification ($7.7M).

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

Food and Drug Administration
FY 2012 Exhibit for Congressional Appropriations
Dollars in Thousands

FY 2012 Changes[1]	USER FEES																PROPOSED USER FEES						PROGRAM LEVEL	
	PDUFA		MDUFMA		ADUFA		AGDUFA		Tobacco		Voluntary Qualified Importer Program (VQIP) User Fee		Food Reinspection User Fee		Recall User Fee		Generic Drug User Fee (GDUFA)		Medical Products Reinspection User Fee		International Courier User Fee		FY 2012 TOTAL	
	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	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**266**	**61,232**	**48**	**6,825**	**25**	**9,861**	**0**	**0**	**0**	**0**	**3**	**690**	**4,166**	**1,033,895**
CFSAN	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*232*	*0*	*0*	*2*	*464*	*0*	*0*	*0*	*0*	*0*	*0*	*1,140*	*301,565*
Field Activities	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*265*	*61,000*	*48*	*6,825*	*23*	*9,397*	*0*	*0*	*0*	*0*	*3*	*690*	*3,026*	*732,330*
Human Drugs	**2,222**	**614,888**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**68**	**36,276**	**18**	**2,630**	**2**	**460**	**4,503**	**1,151,788**
CDER	*2,164*	*602,590*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*56*	*29,539*	*0*	*0*	*0*	*0*	*3,712*	*998,568*
Field Activities	*58*	*12,298*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*12*	*6,737*	*18*	*2,630*	*2*	*460*	*791*	*153,220*
Biologics	**405**	**129,163**	**36**	**13,627**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**537**	**0**	**0**	**1,370**	**368,260**
CBER	*399*	*123,998*	*32*	*13,030*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1,131*	*320,803*
Field Activities	*6*	*5,165*	*4*	*597*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*3*	*537*	*0*	*0*	*239*	*47,457*
Animal Drugs & Feeds	**0**	**0**	**0**	**0**	**68**	**19,576**	**21**	**5,058**	**0**	**0**	**0**	**0**	**18**	**2,550**	**4**	**1,160**	**0**	**0**	**1**	**134**	**0**	**0**	**794**	**176,376**
CVM	*0*	*0*	*0*	*0*	*66*	*19,261*	*20*	*4,898*	*0*	*0*	*0*	*0*	*0*	*0*	*2*	*521*	*0*	*0*	*0*	*0*	*0*	*0*	*487*	*116,927*
Field Activities	*0*	*0*	*0*	*0*	*2*	*315*	*1*	*160*	*0*	*0*	*0*	*0*	*18*	*2,550*	*2*	*639*	*0*	*0*	*1*	*134*	*0*	*0*	*307*	*59,449*
Device & Radiological Products	**0**	**0**	**258**	**39,890**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**3,424**	**15**	**3,450**	**1,850**	**375,866**
CDRH	*0*	*0*	*244*	*38,655*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1,347*	*286,381*
Field Activities	*0*	*0*	*14*	*1,235*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*24*	*3,424*	*15*	*3,450*	*503*	*89,485*
NCTR	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***215***	***60,294***
Tobacco Act Program	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	***392***	***454,751***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***392***	***454,751***
CTP	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*366*	*448,501*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*366*	*448,501*
Field Activities	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*26*	*6,250*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*26*	*6,250*
Other Activities	***201***	***52,222***	***24***	***6,962***	***4***	***873***	***1***	***228***	***34***	***15,196***	***14***	***3,674***	***7***	***3,395***	***2***	***661***	***5***	***1,325***	***10***	***5,902***	***1***	***276***	***1,045***	***288,400***
Office of Regulatory Affairs [Non-Add]	***64***	***17,463***	***18***	***1,832***	***2***	***315***	***1***	***160***	***26***	***6,250***	***265***	***61,000***	***66***	***9,375***	***25***	***10,036***	***12***	***6,737***	***46***	***6,725***	***20***	***4,600***	***4,892***	***1,088,191***
White Oak Consolidation	**0**	**4,383**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	***0***	***68,521***
Other Rent & Rent-Related	**0**	**29,841**	**0**	**1,620**	**0**	**204**	**0**	**80**	**0**	**1,550**	**0**	**2,240**	**0**	**592**	**0**	**248**	**0**	**578**	**0**	**455**	**0**	**168**	***0***	***123,788***
GSA Rent	**0**	**25,544**	**0**	**5,019**	**0**	**1,115**	**0**	**340**	**0**	**5,503**	**0**	**3,920**	**0**	**1,338**	**0**	**434**	**0**	**1,943**	**0**	**1,026**	**0**	**294**	***0***	***214,302***
Salaries & Expenses Increases	**2,828**	**856,041**	**318**	**67,118**	**72**	**21,768**	**22**	**5,706**	**426**	**477,000**	**280**	**71,066**	**73**	**14,700**	**31**	**12,364**	**73**	**40,122**	**56**	**14,108**	**21**	**5,338**	**14,335**	**4,316,241**
Non-Field	*2,764*	*778,810*	*300*	*58,647*	*70*	*20,134*	*21*	*5,126*	*400*	*463,697*	*15*	*3,906*	*7*	*3,395*	*6*	*1,646*	*61*	*30,864*	*10*	*5,902*	*1*	*276*	*9,443*	*2,821,439*
Field	*64*	*17,463*	*18*	*1,832*	*2*	*315*	*1*	*160*	*26*	*6,250*	*265*	*61,000*	*66*	*9,375*	*25*	*10,036*	*12*	*6,737*	*46*	*6,725*	*20*	*4,600*	*4,892*	*1,088,191*
Rents	*0*	*59,768*	*0*	*6,639*	*0*	*1,319*	*0*	*420*	*0*	*7,053*	*0*	*6,160*	*0*	*1,930*	*0*	*682*	*0*	*2,521*	*0*	*1,481*	*0*	*462*	*0*	*406,611*
Buildings and Facilities	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**13,055**
Sec 725 Construction Grant	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**		
Total	**2,828**	**856,041**	**318**	**67,118**	**72**	**21,768**	**22**	**5,706**	**426**	**477,000**	**280**	**71,066**	**73**	**14,700**	**31**	**12,364**	**73**	**40,122**	**56**	**14,108**	**21**	**5,338**	**14,335**	**4,329,296**

[1] This table does not include resources f[1] This table does not include resources for current indefinite user fees for MQSA ($19.318M); Medical Products Export Certification ($2.7M); Food Export Certification (1.267M); Color Certification ($7.7M).

[2] The FY 2010 Enacted column displays f[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

Food and Drug Administration
Amounts Available for Obligation
(Dollars in Thousands)

	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 President's Budget Request
General Fund Discretionary Appropriation:			
Appropriation (Enacted)	3,117,661	3,372,961	4,360,281
Across-the-board reductions (Enacted)	0	0	0
Subtotal, Adjusted Appropriation	**3,117,661**	**3,372,961**	**4,360,281**
Discretionary Appropriation: Color Certification			
Appropriation	6,768	7,700	7,700
Subtotal, appropriation	**6,768**	**7,700**	**7,700**
Total, Discretionary Appropriation	**3,117,661**	**3,372,961**	**4,360,281**
Offsetting collections (spending authority) from:			
Federal Funds	34,000	0	67,000
Trust Funds			
Non-Federal Sources	35,374	3,039	-67,000
Portion Precluded from obligation	(35)	0	0
Subtotal, offsetting collections	**69,339**	**3,039**	**0**
Unobligated balance, start of year	258,000	294,000	293,000
Recoveries of prior year obligations	0	-	-
Total Amounts Available for Obligation	**3,445,000**	**3,670,000**	**4,653,281**
Less Unobligated balance, end of year	(258,000)	(294,000)	(293,000)
Less Unobligated balance, lapsing			
Total obligations	**3,187,000**	**3,376,000**	**4,360,281**

FOOD AND DRUG ADMINISTRATION
Summary of Changes
FY 2012 Congressional Justification

	Budget Authority	User Fees	Program Level	Program Level FTE[1]
FY 2010 Enacted[2]	**$2,363,786,000**	**$922,280,000**	**$3,286,066,000**	**12,335**
FY 2010 Adjusted Enacted	**$2,361,786,000**	**$922,280,000**	**$3,284,066,000**	**12,335**
FY 2012 Program Changes:				
Budget Authority				
Pay Increase	*$4,896,000*		*$4,896,000*	*0*
Rent and Infrastructure Increase	*$12,962,000*		*$12,962,000*	*0*
Building and Facilities Increase	*$622,000*		*$622,000*	*0*
Administrative and Contract Savings	*(26,226,000)*		*(26,226,000)*	(46)
Natural Products Center Reduction for Contract Savings	*(3,497,000)*		*(3,497,000)*	*0*
Advancing Medical Countermeasures	$70,000,000		$70,000,000	165
Transforming Food Safety and Nutrition	$218,424,000		$218,424,000	435
Protecting Patients	$56,323,000		$56,323,000	118
FDA Regulatory Science and Facilities	$48,675,000		$48,675,000	50
Subtotal: Budget Authority Program Changes	**$382,179,000**		**$382,179,000**	**722**
Total Budget Authority Change from FY 2010 Adjusted Enacted to FY 2012 President's Budget Request	**$382,179,000**		**$382,179,000**	**722**
FY 2012 User Fee Changes:				
Current Law User Fees:				
PDUFA		$277,879,000	$277,879,000	584
MDUFMA		$10,104,000	$10,104,000	34
ADUFA		$4,488,000	$4,488,000	0
AGDUFA		$600,000	$600,000	0
Tobacco		$242,000,000	$242,000,000	216
MQSA		$0	$0	0
Color Certification		$0	$0	4
Export Certification		$0	$0	0
Food Export Certification User Fee		$1,267,000	1,267,000	7
Food Reinspection User Fee		$14,700,000	14,700,000	73
Voluntary Qualified Importer Program (VQIP) User Fee		$71,066,000	71,066,000	280
Recall User Fee		$12,364,000	12,364,000	31
Total Current Law User Fees:		**$634,468,000**	**$634,468,000**	**1,229**
Proposed User Fees:				
Generic Drug User Fee (GDUFA)		$40,122,000	$40,122,000	73
Medical Products Reinspection User Fee		$14,108,000	$14,108,000	56
International Courier User Fee		$5,338,000	$5,338,000	21
Total Proposed User Fees:		**$59,568,000**	**$59,568,000**	**150**
Total User Fee Changes from FY 2010 Enacted		**$694,036,000**	**$694,036,000**	**1,379**
Net Program Level Change from FY 2010 Adjusted Enacted	**$382,179,000**	**$694,036,000**	**$1,076,215,000**	**2,101**
Total FDA Request for FY 2012	**$2,745,965,000**	**$1,616,316,000**	**$4,362,281,000**	**14,436**

[1] FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include $1.3 million for CRADA.

[2] The FY 2010 Enacted row displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted row.

Food and Drug Administration

FY 2012 President's Budget Request All Purpose Table - Budget Authority

(Dollars in Thousands)

Program[1]	FY 2010						FY 2011		FY 2012 President's Budget Request			
	Enacted[2]		Adjusted Enacted		Actuals[3]		Continuing Resolution		Total		+/- FY 2010 Adjusted Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:												
Foods……	**3,486**	**$783,449**	**3,486**	**$781,449**	**3,387**	**$783,178**	**3,387**	**$781,449**	**3,824**	**$955,287**	**338**	**$173,838**
Center.....	981	$236,542	981	$236,000	871	$236,354	871	$236,000	1,137	$300,869	156	$64,869
Field Activities.....	2,505	$546,907	2,505	$545,449	2,516	$546,824	2,516	$545,449	2,687	$654,418	182	$108,969
**Human Drugs..... **	**2,085**	**$461,862**	**2,085**	**$461,862**	**1,937**	**$462,243**	**1,937**	**$461,862**	**2,193**	**$497,534**	**108**	**$35,672**
Center.....	1,399	$334,188	1,399	$334,188	1,248	$334,323	1,248	$334,188	1,492	$366,439	93	$32,251
Field Activities.....	686	$127,674	686	$127,674	689	$127,920	689	$127,674	701	$131,095	15	$3,421
**Biologics ..... **	**858**	**$205,563**	**858**	**$205,563**	**874**	**$205,542**	**874**	**$205,563**	**926**	**$224,933**	**68**	**$19,370**
Center.....	637	$165,490	637	$165,490	652	$165,596	652	$165,490	700	$183,775	63	$18,285
Field Activities.....	221	$40,073	221	$40,073	222	$39,946	222	$40,073	226	$41,158	5	$1,085
**Animal Drugs and Feeds..... **	**636**	**$134,798**	**636**	**$134,798**	**677**	**$134,360**	**677**	**$134,798**	**682**	**$147,898**	**46**	**$13,100**
Center.....	361	$81,980	361	$81,980	401	$81,918	401	$81,980	399	$92,247	38	$10,267
Field Activities.....	275	$52,818	275	$52,818	276	$52,442	276	$52,818	283	$55,651	8	$2,833
**Devices and Radiological Health..... **	**1,494**	**$313,935**	**1,494**	**$313,935**	**1,525**	**$313,452**	**1,525**	**$313,935**	**1,553**	**$329,102**	**59**	**$15,167**
Center.....	1,048	$233,932	1,048	$233,932	1,077	$233,584	1,077	$233,932	1,103	$247,726	55	$13,794
Field Activities.....	446	$80,003	446	$80,003	448	$79,868	448	$80,003	450	$81,376	4	$1,373
**National Center for Toxicological Research..... **	**210**	**$58,745**	**210**	**$58,745**	**246**	**$58,531**	**246**	**$58,745**	**215**	**$60,294**	5	**$1,549**
**Headquarters and Office of the Commissioner... **	**644**	**$140,848**	**644**	**$140,848**	**722**	**$141,321**	**722**	**$140,848**	**742**	**$197,686**	98	**$56,838**
**FDA White Oak Consolidation..... **	**0**	**$38,536**	**0**	**$38,536**	**0**	**$38,536**	**0**	**$38,536**	0	**$64,138**	0	**$25,602**
**Other Rent and Rent Related /4..... **	**0**	**$64,860**	**0**	**$64,860**	**0**	**$64,861**	**0**	**$64,860**	0	**$86,212**	0	**$21,352**
**GSA Rental Payments /4..... **	**0**	**$145,260**	**0**	**$145,260**	**0**	**$145,261**	**0**	**$145,260**	0	**$167,826**	0	**$22,566**
**SUBTOTAL, Salaries and Expenses..... **	**9,413**	**$2,347,856**	**9,413**	**$2,345,856**	**9,368**	**$2,347,285**	**9,368**	**$2,345,856**	**10,135**	**$2,730,910**	**722**	**$385,054**
**Buildings and Facilities..... **	**0**	**$15,930**	**0**	**$15,930**	**0**	**$22,111**	**0**	**$15,930**	0	**$13,055**	**0**	**($2,875)**
FDA Building and Facilities /5.....	0	$12,433	0	$12,433	0	$15,117	0	$12,433	0	13,055	0	$622
Natural Products Center /6.....	0	$3,497	0	$3,497	0	$6,994	0	$3,497	0	$0	0	($3,497)
**TOTAL ..... **	**9,413**	**$2,363,786**	**9,413**	**$2,361,786**	**9,368**	**$ 2,369,396**	**9,368**	**$2,361,786**	**10,135**	**$2,743,965**	**722**	**$382,179**
**Non-Field Activities..... **	5,280	$1,251,725	5,280	$1,251,183	5,217	$ 1,251,627	5,217	$1,251,183	5,788	$1,449,036	508	$197,853
**Field Activities..... **	4,133	$847,475	4,133	$846,017	4,151	$847,000	4,151	$846,017	4,347	$963,698	214	$117,681
Rent Activities, B&F, and White Oak	0	$264,586	0	$264,586	0	$ 270,769	0	$264,586	0	331,231	0	$66,645

[1] FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include $1.3 million for CRADA.

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

[3] FY 2010 Actuals include $1.458 million in spending from the $2 million Gulf Oil Spill supplemental appropriation. The FY 2010 S&E appropriation was $2,345 million. The actual is $.029 million lower due to lapsed funds.

[4] Infrastructure totals reflect the FY 2010 reprogramming.

[5] The FY 2010 Actuals for Building and Facilities includes $9.653 million in prior year funds expended during FY 2010.

[6] FY 2010 Appropriations includes a general provision appropriating $3.497 million to the National Center for Natural Products Research (NCNPR) for construction and renovation. The FY 2010 Actuals include $3.497 million from the FY 2009 appropriation for the NCNPR Grant.

Food and Drug Administration

FY 2012 President's Budget Request All Purpose Table - User Fees

(Dollars in Thousands)

Program	FY 2010 Enacted		FY 2010 Actuals		FY 2011 Continuing Resolution		FY 2012 President's Budget Request Total		+/- FY 2010 Adjusted Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses, Definite Appropriations:										
Prescription Drug User Fee Act (PDUFA)										
Human Drugs (PDUFA)	**1,732**	**$415,290**	**1,898**	**$421,216**	**1,898**	**$479,142**	**2,222**	**$614,888**	**490**	**$199,598**
Center	1,682	$406,984	1,849	$414,877	1,849	$469,559	2,164	$602,590	482	$195,606
Field	50	$8,306	49	$6,339	49	$9,583	58	$12,298	8	$3,992
Biologics (PDUFA)	**340**	**$87,236**	**346**	**$78,466**	**346**	**$100,649**	**405**	**$129,163**	**65**	**$41,927**
Center	335	$83,747	341	$76,781	341	$96,624	399	$123,998	64	$40,251
Field	5	$3,489	5	$1,685	5	$4,025	6	$5,165	1	$1,676
Headquarters and Office of the Commissioner (PDUFA)	**172**	**$34,073**	**172**	**$28,953**	**172**	**$40,693**	**201**	**$52,222**	**29**	**$18,149**
FDA Consolidation at White Oak	**0**	**$2,960**	**0**	**$0**	**0**	**$3,415**	-	**$4,383**	**0**	**$1,423**
Other Rent and Rent Related (PDUFA)	**0**	**$16,275**	**0**	**$18,991**	**0**	**$23,253**	-	**$29,841**	**0**	**$13,566**
GSA Rental Payments (PDUFA)	**0**	**$22,328**	**0**	**$25,632**	**0**	**$19,905**	-	**$25,544**	**0**	**$3,216**
Subtotal PDUFA	**2,244**	**$578,162**	**2,416**	**$573,258**	**2,416**	**$667,057**	**2,828**	**$856,041**	**584**	**$277,879**
Medical Device User Fee Act (MDUFMA)										
Biologics (MDUFMA)	**35**	**$11,575**	**30**	**$7,422**	**30**	**$11,575**	**36**	**$13,627**	**1**	**$2,052**
Center	31	$11,068	30	$7,039	30	$11,068	32	$13,030	1	$1,962
Field	4	$507	0	$383	0	$507	4	$597	0	$90
Devices and Radiological Health (MDUFMA)	**227**	**$33,885**	**245**	**$42,725**	**245**	**$33,885**	**258**	**$39,890**	**31**	**$6,005**
Center	220	$32,836	232	$41,283	232	$32,836	244	$38,655	24	$5,819
Field	7	$1,049	13	$1,442	13	$1,049	14	$1,235	7	$186
Headquarters and Office of the Commissioner (MDUFMA)	**22**	**$5,914**	**23**	**$3,592**	**23**	**$5,914**	**24**	**$6,962**	**2**	**$1,048**
Other Rent and Rent Related Activities (MDUFMA)	**0**	**$1,376**	**0**	**$1,087**	**0**	**$1,376**	-	**$1,620**	**0**	**$244**
GSA Rental Payments (MDUFMA)	**0**	**$4,264**	**0**	**$2,361**	**0**	**$4,264**	-	**$5,019**	**0**	**$755**
Subtotal (MDUFMA)	**284**	**$57,014**	**298**	**$57,187**	**298**	**$57,014**	**318**	**$67,118**	**34**	**$10,104**
Animal Drug User Fee Act (ADUFA)										
Animal Drugs and Feeds	**68**	**$15,540**	**67**	**$15,190**	**67**	**$15,540**	**68**	**$19,576**	**0**	**$4,036**
Center	66	$15,290	65	$14,644	65	$15,290	66	$19,261	0	$3,971
Field	2	$250	2	$546	2	$250	2	$315	0	$65
Headquarters and Office of the Commissioner (ADUFA)	**4**	**$693**	**4**	**$631**	**4**	**$693**	**4**	**$873**	**0**	**$180**
Other Rent and Rent Related Activities (ADUFA)	**0**	**$162**	**0**	**$121**	**0**	**$162**	-	**$204**	**0**	**$42**
GSA Rental Payments (ADUFA)	**0**	**$885**	**0**	**$659**	**0**	**$885**	-	**$1,115**	**0**	**$230**
Subtotal (ADUFA)	**72**	**$17,280**	**71**	**$16,601**	**71**	**$17,280**	**72**	**$21,768**	**0**	**$4,488**
Animal Generic Drug User Fee Act (AGDUFA)										
Animal Drugs and Feeds	**21**	**$4,525**	**23**	**$4,369**	**23**	**$4,525**	**21**	**$5,058**	**0**	**$533**
Center	20	$4,382	22	$4,225	22	$4,382	20	$4,898	0	$516
Field	1	$143	1	$144	1	$143	1	$160	0	$17
Headquarters and Office of the Commissioner (AGDUFA)	**1**	**$204**	**1**	**$158**	**1**	**$204**	**1**	**$228**	**0**	**$24**
Other Rent and Rent Related Activities (AGDUFA)	**0**	**$72**	**0**	**$105**	**0**	**$72**	-	**$80**	**0**	**$8**
GSA Rental Payments (AGDUFA)	**0**	**$305**	**0**	**$105**	**0**	**$305**	-	**$340**	**0**	**$35**
Subtotal (AGDUFA)	**22**	**$5,106**	**24**	**$4,737**	**24**	**$5,106**	**22**	**$5,706**	**0**	**$600**
Indefinite Appropriations:										
Mammography Quality and Standards Act (MQSA)										
Devices and Radiological Health	**34**	**$19,080**	**31**	**$13,794**	**31**	**$19,080**	**34**	**$19,080**	**0**	**$0**
Center	26	$6,003	23	$4,284	23	$6,003	26	$6,003	0	$0
Field Activities	8	$13,077	8	$9,510	8	$13,077	8	$13,077	0	$0
Headquarters and Office of the Commissioner (MQSA)	**2**	**$238**	**2**	**$270**	**2**	**$238**	**2**	**$238**	0	$0
Subtotal (MQSA)	**36**	**$19,318**	**33**	**$14,064**	**33**	**$19,318**	**36**	**$19,318**	**0**	**$0**
Export Certification/1	**18**	**$2,700**	**20**	**$3,663**	**20**	**$2,700**	**18**	**$2,700**	**0**	**$0**
Food Export Certification User Fee										
Foods	**0**	**$0**	**0**	**$0**	**0**	**$0**	**7**	**$1,185**	**7**	**$1,185**
Center	0	$0	0	$0	0	$0	7	$1,185	7	$1,185
Field	0	$0	0	$0	0	$0	0	$0	0	$0
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$82**	**0**	**$82**
Center	0	$0	0	$0	0	$0	0	$82	0	$82
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**7**	**$1,267**	**7**	**$1,267**
Color Certification Fund	**36**	**$7,700**	**38**	**$6,768**	**38**	**$7,700**	**40**	**$7,700**	**4**	**$0**
Indefinite Appropriations Total	**90**	**$29,718**	**91**	**$24,495**	**91**	**$29,718**	**101**	**$30,985**	**11**	**$1,267**
Family Smoking Prevention and Tobacco Control Act										
Center for Tobacco Products	**194**	**$216,523**	**90**	**$64,418**	**90**	**$216,523**	**392**	**$454,751**	**198**	**$238,228**
Center	174	$211,823	84	$62,355	84	$211,823	366	$448,501	192	$236,678
Field	20	$4,700	6	$2,063	6	$4,700	26	$6,250	6	$1,550
Headquarters and Office of the Commissioner	**16**	**$14,336**	**23**	**$3,375**	**23**	**$14,336**	**34**	**$15,196**	**18**	**$860**
Other Rent Related Activities	**0**	**$1,343**	**0**	**$503**	**0**	**$1,343**	**0**	**$1,550**	**0**	**$207**
GSA Rental Payments	**0**	**$2,798**	**0**	**$3,691**	**0**	**$2,798**	**0**	**$5,503**	**0**	**$2,705**
Subtotal	**210**	**$235,000**	**113**	**$71,987**	**113**	**$235,000**	**426**	**$477,000**	**216**	**$242,000**

Food and Drug Administration

FY 2012 President's Budget Request All Purpose Table - User Fees

(Dollars in Thousands)

Program	FY 2010 Enacted FTE	FY 2010 Enacted $000	FY 2010 Actuals FTE	FY 2010 Actuals $000	FY 2011 Continuing Resolution FTE	FY 2011 Continuing Resolution $000	FY 2012 President's Budget Request Total FTE	FY 2012 President's Budget Request Total $000	+/- FY 2010 Adjusted Enacted FTE	+/- FY 2010 Adjusted Enacted $000
Voluntary Qualified Importer Program (VQIP) User Fee[2]										
Foods	**0**	**$0**	**0**	**$0**	**0**	**$0**	**266**	**$61,232**	**266**	**$61,232**
Center	0	$0	0	$0	0	$0	1	$232	1	$232
Field	0	$0	0	$0	0	$0	265	$61,000	265	$61,000
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**14**	**$3,674**	**14**	**$3,674**
Other Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$2,240**	**0**	**$2,240**
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$3,920**	**0**	**$3,920**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**280**	**$71,066**	**280**	**$71,066**
Food Reinspection User Fee										
Office of Regulatory Affairs	**0**	**$0**	**0**	**$0**	**0**	**$0**	**66**	**$9,375**	**66**	**$9,375**
Foods Program Estimate	0	$0	0	$0	0	$0	48	$6,825	48	$6,825
Animal Drugs and Feeds Program Estimate	0	$0	0	$0	0	$0	18	$2,550	18	$2,550
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**7**	**$3,395**	**7**	**$3,395**
Other Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$592**	**0**	**$592**
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$1,338**	**0**	**$1,338**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**73**	**$14,700**	**73**	**$14,700**
Recall User Fee [3]										
Foods	**0**	**$0**	**0**	**$0**	**0**	**$0**	**25**	**$9,861**	**25**	**$9,861**
Center	0	$0	0	$0	0	$0	2	$464	2	$464
Field	0	$0	0	$0	0	$0	23	$9,397	23	$9,397
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**0**	**$0**	**4**	**$1,160**	**4**	**$1,160**
Center	0	$0	0	$0	0	$0	2	$521	2	$521
Field	0	$0	0	$0	0	$0	2	$639	2	$639
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**2**	**$661**	**2**	**$661**
Other Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$248**	**0**	**$248**
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$434**	**0**	**$434**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**31**	**$12,364**	**31**	**$12,364**
Proposed User Fees:										
Generic Drug User Fee (GDUFA)										
Human Drugs	0	$0	0	$0	0	$0	**68**	**$36,276**	**68**	**$36,276**
Center	0	$0	0	$0	0	$0	56	$29,539	56	$29,539
Field	0	$0	0	$0	0	$0	12	$6,737	12	$6,737
Headquarters and Office of the Commissioner (GDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$0**	**5**	**$1,325**	**5**	**$1,325**
Other Rent and Rent Related (Generic Drug)	**0**	**$0**	**0**	**$0**	**0**	**$0**	0	$578	0	$578
GSA Rental Payments (GDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$0**	0	$1,943	0	$1,943
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**73**	**$40,122**	**73**	**$40,122**
Medical Products Reinspection User Fee										
Office of Regulatory Affairs	**0**	**$0**	**0**	**$0**	**0**	**$0**	**46**	**$6,725**	**46**	**$6,725**
Human Drugs Program Estimate	0	$0	0	$0	0	$0	18	$2,630	18	$2,630
Biologics Program Estimate	0	$0	0	$0	0	$0	3	$537	3	$537
Animal Drugs Program Estimate	0	$0	0	$0	0	$0	1	$134	1	$134
Devices and Radiological Health Program Estimate	0	$0	0	$0	0	$0	24	$3,424	24	$3,424
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**10**	**$5,902**	**10**	**$5,902**
FDA White Oak Consolidation	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
Other Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$455**	**0**	**$455**
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$1,026**	**0**	**$1,026**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**56**	**$14,108**	**56**	**$14,108**
International Courier User Fee										
Office of Regulatory Affairs	**0**	**$0**	**0**	**$0**	**0**	**$0**	**20**	**$4,600**	**20**	**$4,600**
Foods Program Estimate	0	$0	0	$0	0	$0	3	$690	3	$690
Human Drugs Program Estimate	0	$0	0	$0	0	$0	2	$460	2	$460
Devices and Radiological Health Program Estimate	0	$0	0	$0	0	$0	15	$3,450	15	$3,450
Headquarters and Office of the Commissioner	0	$0	0	$0	0	$0	**1**	**$276**	**1**	**$276**
Other Rent and Rent Related	0	$0	0	$0	0	$0	**0**	**$168**	**0**	**$168**
GSA Rent	0	$0	0	$0	0	$0	**0**	**$294**	**0**	**$294**
Subtotal, International Courier Hubs User Fee	**0**	**$0**	**0**	**$0**	**0**	**$0**	**21**	**$5,338**	**21**	**$5,338**
Total Proposed User Fees	**0**	**0**	**0**	**$0**	**0**	**0**	**150**	**59,568**	**150**	**$59,568**
Total User Fees	**2,922**	**$922,280**	**3,013**	**$748,265**	**3,013**	**$1,011,175**	**4,301**	**$1,616,316**	**1,379**	**$694,036**

[1] FY 2010 Export Certification actuals include prior year carryover funds expended during FY 2010.

[2] FDA estimates that VQIP user fee collections will begin in FY 2012 but the full implementation of this program will occur during FY 2013.

[3] FY 2011 reflects FDA's estimate of the amount it will collect as FDA begins to implement the new Recall User Fee program.

Food and Drug Administration

FY 2012 President's Budget Request All Purpose Table - Total Program Level

(Dollars in Thousands)

Program[1]	FY 2010 Enacted[2]		FY 2010 Adjusted Enacted		FY 2010 Actuals[3]		FY 2011 Continuing Resolution		FY 2012 President's Budget Request Total		+/- FY 2010 Adjusted Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:												
Foods	**3,486**	**$783,449**	**3,486**	**$781,449**	**3,387**	**$783,178**	**3,387**	**$781,449**	**4,173**	**$1,035,080**	**687**	**$253,631**
Center	981	$236,542	981	$236,000	871	$236,354	871	$236,000	1,147	$302,750	166	$66,750
Field	2,505	$546,907	2,505	$545,449	2,516	$546,824	2,516	$545,449	3,026	$732,330	521	$186,881
Human Drug	**3,817**	**$877,152**	**3,817**	**$877,152**	**3,835**	**$883,459**	**3,835**	**$941,004**	**4,503**	**$1,151,788**	**686**	**$274,636**
Center	3,081	$741,172	3,081	$741,172	3,097	$749,200	3,097	$803,747	3,712	$998,568	631	$257,396
Field	736	$135,980	736	$135,980	738	$134,259	738	$137,257	791	$153,220	55	$17,240
Biologics	**1,233**	**$304,374**	**1,233**	**$304,374**	**1,250**	**$291,430**	**1,250**	**$317,787**	**1,370**	**$368,260**	**137**	**$63,886**
Center	1,003	$260,305	1,003	$260,305	1,023	$249,416	1,023	$273,182	1,131	$320,803	128	$60,498
Field	230	$44,069	230	$44,069	227	$42,014	227	$44,605	239	$47,457	9	$3,388
Animal Drugs and Feeds	**725**	**$154,863**	**725**	**$154,863**	**767**	**$153,919**	**767**	**$154,863**	**794**	**$176,458**	**69**	**$21,595**
Center	447	$101,652	447	$101,652	488	$100,787	488	$101,652	487	$117,009	40	$15,357
Field	278	$53,211	278	$53,211	279	$53,132	279	$53,211	307	$59,449	29	$6,238
Devices and Radiological Health	**1,755**	**$366,900**	**1,755**	**$366,900**	**1,801**	**$369,971**	**1,801**	**$366,900**	**1,884**	**$394,946**	**129**	**$28,046**
Center	1,294	$272,771	1,294	$272,771	1,332	$279,151	1,332	$272,771	1,373	$292,384	79	$19,613
Field	461	$94,129	461	$94,129	469	$90,820	469	$94,129	511	$102,562	50	$8,433
National Center for Toxicological Research	**210**	**$58,745**	**210**	**$58,745**	**246**	**$58,531**	**246**	**$58,745**	**215**	**$60,294**	**5**	**$1,549**
Tobacco Act Program	**194**	**$216,523**	**194**	**$216,523**	**90**	**$64,418**	**90**	**$216,523**	**392**	**$454,751**	**198**	**$238,228**
Center	174	$211,823	174	$211,823	84	$62,355	84	$211,823	366	$448,501	192	$236,678
Field	20	$4,700	20	$4,700	6	$2,063	6	$4,700	26	$6,250	6	$1,550
Headquarters and Office of the Commissioner	**861**	**$196,306**	**861**	**$196,306**	**947**	**$178,300**	**947**	**$202,926**	**1,047**	**$288,638**	**186**	**$92,332**
FDA White Oak Consolidation	**0**	**$41,496**	**0**	**$41,496**	**0**	**$38,536**	**0**	**$41,951**	**0**	**$68,521**	**0**	**$27,025**
Other Rent and Rent Related Activities/4	**0**	**$84,088**	**0**	**$84,088**	**0**	**$85,668**	**0**	**$91,066**	**0**	**$123,788**	**0**	**$39,700**
GSA Rent/4	**0**	**$175,840**	**0**	**$175,840**	**0**	**$177,709**	**0**	**$173,417**	**0**	**$214,302**	**0**	**$38,462**
TOTAL, Salaries & Expenses	**12,281**	**$3,259,736**	**12,281**	**$3,257,736**	**12,323**	**$3,085,119**	**12,323**	**$3,346,631**	**14,378**	**$4,336,826**	**2,097**	**$1,079,090**
Export Certification/5	**18**	**$2,700**	**18**	**$2,700**	**20**	**$3,663**	**20**	**$2,700**	**18**	**$2,700**	0	$0
Color Certification Fund	**36**	**$7,700**	**36**	**$7,700**	**38**	**$6,768**	**38**	**$7,700**	**40**	**$7,700**	4	$0
Buildings and Facilities	**0**	**$15,930**	**0**	**$15,930**	**0**	**$22,111**	**0**	**$15,930**	**0**	**$13,055**	**0**	**($2,875)**
FDA Building and Facilities /6	0	$12,433	0	$12,433	0	$15,117	0	$12,433	0	$13,055	0	$622
Natural Products Center /7	0	$3,497	0	$3,497	0	$6,994	0	$3,497	0	$0	0	($3,497)
TOTAL PROGRAM LEVEL	**12,335**	**$3,286,066**	**12,335**	**$3,284,066**	**12,381**	**$3,117,661**	**12,381**	**$3,372,961**	**14,436**	**$4,360,281**	**2,101**	**$1,076,215**
Non-Field Activities	8,105	$2,089,716	8,105	$2,089,174	8,146	$1,924,525	8,146	$2,171,246	9,536	$2,839,347	1,431	$750,173
Field Activities	4,230	$878,996	4,230	$877,538	4,235	$869,112	4,235	$879,351	4,900	$1,101,268	670	$223,730
Other Actions, Rent Activities, B&F, and White Oak	0	$317,354	0	$317,354	0	$324,024	0	$322,364	0	$419,666	0	$102,312
Less User Fees:												
Prescription Drugs (PDUFA)	2,244	$578,162	2,244	$578,162	2,416	$573,258	2,416	$667,057	2,828	$856,041	584	$277,879
Medical Devices (MDUFMA)	284	$57,014	284	$57,014	298	$57,187	298	$57,014	318	$67,118	34	$10,104
Animal Drugs (ADUFA)	72	$17,280	72	$17,280	71	$16,601	71	$17,280	72	$21,768	0	$4,488
Animal Generic Drug (AGDUFA)	22	$5,106	22	$5,106	24	$4,737	24	$5,106	22	$5,706	0	$600
Mammography Quality (MQSA)	36	$19,318	36	$19,318	33	$14,064	33	$19,318	36	$19,318	0	$0
Family Smoking Prevention and Tobacco Control Act	210	$235,000	210	$235,000	113	$71,987	113	$235,000	426	$477,000	216	$242,000
Export Certification	18	$2,700	18	$2,700	20	$3,663	20	$2,700	18	$2,700	0	$0
Color Certification Fund	36	$7,700	36	$7,700	38	$6,768	38	$7,700	40	$7,700	4	$0
Generic Drug (GDUFA)	0	$0	0	$0	0	$0	0	$0	73	$40,122	73	$40,122
Voluntary Qualified Importer Program (VQIP) User Fee	0	$0	0	$0	0	$0	0	$0	280	$71,066	280	$71,066
Export Certification User Fees	0	$0	0	$0	0	$0	0	$0	7	$1,267	7	$1,267
Food Reinspection User Fee	0	$0	0	$0	0	$0	0	$0	73	$14,700	73	$14,700
Food Inspection and Food Facility Registration User Fee	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0
Medical Products Reinspection User Fee	0	$0	0	$0	0	$0	0	$0	56	$14,108	56	$14,108
Recall User Fee:	0	$0	0	$0	0	$0	0	$0	31	$12,364	31	$12,364
International Courier User Fee	0	$0	0	$0	0	$0	0	$0	21	$5,338	21	$5,338
SUBTOTAL User Fees	**2,922**	**$922,280**	**2,922**	**$922,280**	**3,013**	**$748,265**	**3,013**	**$1,011,175**	**4,301**	**$1,616,316**	**1,379**	**$694,036**
TOTAL USER FEES	**2,922**	**$922,280**	**2,922**	**$922,280**	**3,013**	**$748,265**	**3,013**	**$1,011,175**	**4,301**	**$1,616,316**	**1,379**	**$694,036**
TOTAL BUDGET AUTHORITY	**9,413**	**$2,363,786**	**9,413**	**$2,361,786**	**9,368**	**$2,369,396**	**9,368**	**$2,361,786**	**10,135**	**$2,743,965**	**722**	**$382,179**

[1] FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include $1.3 million for CRADA.

[2] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

[3] FY 2010 Actuals include $1.458 million in spending from the $2 million Gulf Oil Spill supplemental appropriation. The FY 2010 S&E appropriation was $2,345 million. The actual is $.029 million lower due to lapsed

[4] Infrastructure totals reflect the FY 2010 reprogramming.

[5] FY 2010 Export Certification actuals include prior year carryover funds expended during FY 2010.

[6] The FY 2010 Actuals for Building and Facilities includes $9.653 million in prior year funds expended in FY 2010.

[7] FY 2010 Appropriations includes a general provision appropriating $3.497 million to the National Center for Natural Products Research (NCNPR) for construction and renovation. The FY 2010 Actuals include $3.497 million from the FY 2009 appropriation for or the NCNPR Grant.

Food and Drug Administration
FY 2012 President's Budget Request Crosswalk - Budget Authority
(Dollars in Thousands)

Program	FY 2010 Enacted [1]		FY 2010 Adjustment for Supp. (P.L. 112-212)	FY 2010 Adjusted Enacted		Budget Authority Initiatives														FY 2012 Request	
						Pay Increase	Rent and Infrastructure	Advancing Medical Countermeasures		Transforming Food Safety and Nutrition		Protecting Patients		FDA Regulatory Science and Facilities		Administrative and Contract Savings [2]		Sub-Total			
	FTE	$000	$000	FTE	$000	$000	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,486**	**$783,449**	**($2,000)**	**$3,486**	**$781,449**	**$1,795**	**$0**	**0**	**$0**	**363**	**176,373**	**0**	**0**	**5**	**$2,377**	**(30)**	**($6,707)**	**338**	**$173,838**	**3,824**	**$955,287**
Center	981	236,542	(542)	981	236,000	$573	$0	0	$0	152	64,222	0	0	4	2,100	0	($2,026)	156	64,869	1,137	300,869
Field Activities	2,505	546,907	(1,458)	2,505	545,449	$1,222	$0	0	$0	211	112,151	0	0	1	277	(30)	($4,681)	182	108,969	2,687	654,418
Human Drugs	**2,085**	**$461,862**	**$0**	**$2,085**	**$461,862**	**$1,095**	**$0**	**46**	**$12,688**	**0**	**0**	**63**	**24,796**	**6**	**$2,752**	**(7)**	**($5,659)**	**108**	**$35,672**	**2,193**	**$497,534**
Center	1,399	334,188	0	1,399	334,188	$779	$0	43	$12,033	0	0	45	21,052	5	2,475	0	($4,088)	93	32,251	1,492	366,439
Field Activities	686	127,674	0	686	127,674	$316	$0	3	$655	0	0	18	3,744	1	277	(7)	($1,571)	15	3,421	701	131,095
Biologics	**858**	**$205,563**	**$0**	**$858**	**$205,563**	**$481**	**$0**	**47**	**$11,790**	**0**	**0**	**20**	**8,192**	**3**	**$1,425**	**(2)**	**($2,518)**	**68**	**$19,370**	**926**	**$224,933**
Center	637	165,490	0	637	165,490	$382	$0	45	$11,353	0	0	15	7,152	3	1,425	0	($2,027)	63	18,285	700	183,775
Field Activities	221	40,073	0	221	40,073	$99	$0	2	$437	0	0	5	1,040	0	0	(2)	($491)	5	1,085	226	41,158
Animal Drugs and Feeds	**636**	**$134,798**	**$0**	**$636**	**$134,798**	**$309**	**$0**	**0**	**$0**	**35**	**11,214**	**4**	**684**	**10**	**$2,150**	**(3)**	**($1,257)**	**46**	**13,100**	**682**	**$147,898**
Center	361	81,980	0	361	81,980	$191	$0	0	$0	25	8,221	3	500	10	2,150	0	($795)	38	10,267	399	92,247
Field Activities	275	52,818	0	275	52,818	$118	$0	0	$0	10	2,993	1	184	0	0	(3)	($462)	8	2,833	283	55,651
Devices and Radiological Health	**1,494**	**$313,935**	**$0**	**$1,494**	**$313,935**	**$753**	**$0**	**35**	**$8,428**	**0**	**0**	**19**	**5,829**	**9**	**$4,009**	**(4)**	**($3,852)**	**59**	**$15,167**	**1,553**	**$329,102**
Center	1,048	233,932	0	1,048	233,932	$556	$0	34	$8,210	0	0	13	4,167	8	3,733	0	($2,872)	55	13,794	1,103	247,726
Field Activities	446	80,003	0	446	80,003	$197	$0	1	$218	0	0	6	1,662	1	276	(4)	($980)	4	1,373	450	81,376
National Center for Toxicological Research	**210**	**58,745**	**$0**	**210**	**58,745**	**$134**	**$0**	**0**	**$0**	**1**	**414**	**0**	**0**	**4**	**1,700**	**0**	**($699)**	**5**	1,549	**215**	**$60,294**
Headquarters and Office of the Commissioner	**644**	**140,848**	**$0**	**644**	**140,848**	**$329**	**$0**	**37**	**$33,463**	**36**	**15,505**	**12**	**3,518**	**13**	**9,557**	**0**	**($5,534)**	**98**	**$56,838**	**742**	**$197,686**
FDA White Oak Consolidation	-	**38,536**	**$0**	-	**38,536**	**$0**	**$1,927**	**0**		**0**	**0**	**0**	**0**	**0**	**$23,675**	**0**	**$0**	**0**	**25,602**	**0**	**$64,138**
Other Rent and Rent Related	-	**64,860**	**$0**	-	**64,860**	**$0**	**$3,335**	**0**	**$1,320**	**0**	**6,804**	**0**	**9,525**	**0**	**368**	**0**	**$0**	**0**	**21,352**	**0**	**$86,212**
GSA Rental Payments	-	**145,260**	**$0**	-	**145,260**	**$0**	**$7,700**	**0**	**$2,311**	**0**	**8,114**	**0**	**3,779**	**0**	**662**	**0**	**$0**	**0**	**22,566**	**0**	**$167,826**
SUBTOTAL, Salaries and Expenses	**9,413**	**$2,347,856**	**($2,000)**	**$9,413**	**$2,345,856**	**$4,896**	**$12,962**	**165**	**$70,000**	**435**	**218,424**	**118**	**56,323**	**50**	**$48,675**	**(46)**	**($26,226)**	**768**	**385,054**	**10,135**	**$2,730,910**
Buildings and Facilities	**0**	**$15,930**	**$0**	**$0**	**$15,930**	**$0**	**$622**	**0**	**$0**	**0**	**0**	**0**	**0**	**0**	**$0**	**0**	**($3,497)**	**0**	**($2,875)**	**0**	**$13,055**
FDA Building and Facilities	0	$12,433	0	$0	$12,433	$0	$622	0	$0	0	0	0	0	0	$0	0	$0	0	622	0	$13,055
Natural Products Center	0	$3,497	0	$0	$3,497	$0	$0	0	$0	0	0	0	0	0	$0	0	($3,497)	0	($3,497)	0	$0
TOTAL	**9,413**	**$2,363,786**	**($2,000)**	**$9,413**	**$2,361,786**	**$4,896**	**$13,584**	**165**	**$70,000**	**435**	**218,424**	**118**	**56,323**	**50**	**$48,675**	**(46)**	**($29,723)**	**722**	**382,179**	**10,135**	**$2,743,965**
Non-Field Activities	5,280	1,251,725	(542)	5,280	1,251,183	2,944	0	159	65,059	214	88,362	88	36,389	47	23,140	0	(18,041)	508	197,853	5,788	1,449,036
Field Activities	4,133	847,475	(1,458)	4,133	846,017	1,952	0	6	1,310	221	115,144	30	6,630	3	830	(46)	(8,185)	214	117,681	4,347	963,698
Other Actions, Rent Activities, B&F, and White Oak	0	264,586	0	0	264,586	0	13,584	0	3,631	0	14,918	0	13,304	0	24,705	0	(3,497)	0	66,645	0	331,231

[1] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the FY 2010 Adjusted Enacted column.

[2] Administrative and Contract Savings includes $4M in HQ/OC IT contract savings associated with MedWatch. Please note the Administrative and Contract savings does not disproportionately affect activities associated with Section 351 of the Public Health Service Act (42 U.S.C. 262), Food Defense, MCM, Life Science BT Lab, or the Regulatory Science Initiative.

Food and Drug Administration
FY 2012 President's Budget Request Crosswalk - User Fee
(Dollars in Thousands)

			Current law User Fees										Indefininte User Fees								Food Safety Modernization Act User Fees								Proposed User Fees											
Program	FY 2010 Enacted		PDUFA		MDUFMA		ADUFA		AGDUFA		Tobacco		MQSA		Color Certification		Export Cert		Food Export Certification User Fee		Food Reinspection User Fee		Voluntary Qualified Importer Program (VQIP) User Fee		Recall User Fee		Generic Drug User Fee (GDUFA)		Medical Products Reinspection User Fee		International Courier User Fee		Sub-total		FY 2012 Request	
	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	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**7**	**$1,185**	**48**	**$6,825**	**266**	**$61,232**	**25**	**$9,861**	**0**	**$0**	**0**	**$0**	**3**	**$690**	**349**	**$79,793**	**349**	**$79,793**
Center	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	1,185	0	0	1	232	2	464	0	0	0	0	0	0	10	1,881	10	1,881
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	48	6,825	265	61,000	23	9,397	0	0	0	0	3	690	339	77,912	339	77,912
Human Drugs	**1,732**	**$415,290**	**490**	**$199,598**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**68**	**$36,276**	**18**	**$2,630**	**2**	**$460**	**578**	**$238,964**	**2,310**	**$654,254**
Center	1,682	406,984	482	195,606	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	56	29,539	0	0	0	0	538	225,145	2,220	632,129
Field Activities	50	8,306	8	3,992	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	12	6,737	18	2,630	2	460	40	13,819	90	22,125
Biologics	**375**	**$98,811**	**65**	**$41,927**	**1**	**$2,052**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**3**	**$537**	**0**	**$0**	**69**	**$44,516**	**444**	**$143,327**
Center	366	94,815	64	40,251	1	1,962	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	65	42,213	431	137,028
Field Activities	9	3,996	1	1,676	0	90	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	537	0	0	4	2,303	13	6,299
Animal Drugs and Feeds	**89**	**$20,065**	**0**	**$0**	**0**	**$0**	**0**	**$4,036**	**0**	**$533**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$82**	**18**	**$2,550**	**0**	**$0**	**4**	**$1,160**	**0**	**$0**	**1**	**$134**	**0**	**$0**	**23**	**$8,495**	**112**	**$28,560**
Center	86	19,672	0	0	0	0	0	3,971	0	516	0	0	0	0	0	0	0	0	0	82	0	0	0	0	2	521	0	0	0	0	0	0	2	5,090	88	24,762
Field Activities	3	393	0	0	0	0	0	65	0	17	0	0	0	0	0	0	0	0	0	0	18	2,550	0	0	2	639	0	0	1	134	0	0	21	3,405	24	3,798
Devices and Radiological Health	**261**	**$52,965**	**0**	**$0**	**31**	**$6,005**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**24**	**$3,424**	**15**	**$3,450**	**70**	**$12,879**	**331**	**$65,844**
Center	246	38,839	0	0	24	5,819	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	24	5,819	270	44,658
Field Activities	15	14,126	0	0	7	186	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	24	3,424	15	3,450	46	7,060	61	21,186
National Center for Toxicological 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**
Tobacco	**194**	**$216,523**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**198**	**$238,228**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**198**	**$238,228**	**392**	**$454,751**
Center	174	211,823	0	$0	0	$0	0	$0	0	$0	192	236,678	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	192	236,678	366	$448,501
Field	20	4,700	0	$0	0	$0	0	$0	0	$0	6	1,550	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	0	$0	6	1,550	26	$6,250
Headquarters and Office of the Commissioner	**217**	**$55,458**	**29**	**18,149**	**2**	**1,048**	**0**	**180**	**0**	**24**	**18**	**860**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**0**	**7**	**3,395**	**14**	**$3,674**	**2**	**$661**	**5**	**$1,325**	**10**	**$5,902**	**1**	**$276**	**88**	**$35,494**	**305**	**90,952**
FDA White Oak Consolidation	**0**	**2,960**	**0**	**1,423**	**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**	**$1,423**	**0**	**$4,383**
Other Rent and Rent Related Activities	**0**	**19,228**	**0**	**13,566**	**0**	**244**	**0**	**42**	**0**	**8**	**0**	**207**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**0**	**0**	**592**	**0**	**$2,240**	**0**	**$248**	**0**	**$578**	**0**	**$455**	**0**	**$168**	**0**	**$18,348**	**0**	**$37,576**
GSA Rental Payments	**0**	**30,580**	**0**	**3,216**	**0**	**755**	**0**	**230**	**0**	**35**	**0**	**2,705**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**0**	**0**	**1,338**	**0**	**$3,920**	**0**	**$434**	**0**	**$1,943**	**0**	**$1,026**	**0**	**$294**	**0**	**$15,896**	**0**	**$46,476**
Export Certification	**20**	**$2,700**	**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**	**20**	**$2,700**
Color Certification	**36**	**$7,700**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**4**	**$0**	**0**	**$0**	**0**	**0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**4**	**$0**	**40**	**$7,700**
Total	**2,924**	**$922,280**	**584**	**$277,879**	**34**	**$10,104**	**0**	**$4,488**	**0**	**$600**	**216**	**$242,000**	**0**	**$0**	**4**	**$0**	**0**	**$0**	**7**	**$1,267**	**73**	**$14,700**	**280**	**$71,066**	**31**	**$12,364**	**73**	**$40,122**	**56**	**$14,108**	**21**	**$5,338**	**1,379**	**$694,036**	**4,303**	**$1,616,316**
Non-Field	2,827	837,991	575	254,006	27	8,829	0	4,151	0	540	210	237,538	0	0	4	0	0	0	7	1,267	7	3,395	15	3,906	6	1,646	61	30,864	10	5,902	1	276	923	552,320	3,750	1,390,311
Field	97	31,521	9	5,668	7	276	0	65	0	17	6	1,550	0	0	0	0	0	0	0	0	66	9,375	265	61,000	25	10,036	12	6,737	46	6,725	20	4,600	456	106,049	553	137,570
Rent Activities, B&F, and White Oak	0	52,768	0	18,205	0	999	0	272	0	43	0	2,912	0	0	0	0	0	0	0	0	0	1,930	0	6,160	0	682	0	2,521	0	1,481	0	462	0	35,667	0	88,435

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Food and Drug Administration
FY 2012 Congressional Budget Request
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FOODS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted [1]	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$783,449**	**$783,178**	**$781,449**	**$1,035,080**	**$253,631**
Center	$236,542	$236,354	$236,000	$302,750	$66,750
FTE	981	871	871	1,147	166
Field	$546,907	$546,824	$545,449	$732,330	$186,881
FTE	2,505	2,516	2,516	3,026	521
Program Level FTE	**3,486**	**3,387**	**3,387**	**4,173**	**687**
Budget Authority	**$783,449**	**$783,178**	**$781,449**	**$955,287**	**$173,838**
Center	$236,542	$236,354	$236,000	$300,869	$64,869
Field	$546,907	$546,824	$545,449	$654,418	$108,969
Pay Increase (non add)				*$1,795*	*$1,795*
Transforming Food Safety and Nutrition (non-add)				*$176,373*	*$176,373*
FDA Regulatory Science and Facilities (non-add)				*$2,377*	*$2,377*
Administrative and Contract Savings (non-add)				*-$6,707*	*-$6,707*
Budget Authority FTE	**3,486**	**3,387**	**3,387**	**3,824**	**338**
Center	981	871	871	1,137	156
Field	2,505	2,516	2,516	2,687	182
User Fees	**$0**	**$0**	**$0**	**$79,793**	**$79,793**
Voluntary Qualified Importer Program (VQIP) User Fee				**$61,232**	**$61,232**
Center				$232	$232
FTE				1	1
Field				$61,000	$61,000
FTE				265	265
Food Reinspection				**$6,825**	**$6,825**
Field				$6,825	$6,825
FTE				48	48
Export Certification				**$1,185**	**$1,185**
Center				$1,185	$1,185
FTE				7	7
Field				$0	$0
FTE				0	0
Recall User Fees				**$9,861**	**$9,861**
Center				$464	$464
FTE				2	2
Field				$9,397	$9,397
FTE				23	23
International Courier User Fee				**$690**	**$690**
Field				690	690
FTE				3	3
User Fee FTE	**0**	**0**	**0**	**349**	**349**

[1] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the +/- FY 2010 Enacted column.

The FDA Foods Program operates under the following legal authorities:

The Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
The 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 public health focus of the FDA Foods Program relies on 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. FDA's goal is to identify and counteract potential threats to the food supply before they harm American consumers.

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported foods, 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 is responsible for all domestic and imported food, with the

*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.

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.

Under the leadership of the Commissioner 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 — protects and promotes the public health by keeping the American food supply safe, sanitary, wholesome, and properly labeled and by ensuring that cosmetic products are safe and properly labeled.

The FDA Foods Program executes its regulatory responsibilities through five sub-programs:

- Prioritizing Prevention
- Strengthening Surveillance and Enforcement
- Improving Response and Recovery
- Nutrition & Labeling Strategies for Better Health
- Reinventing Cosmetics Safety.

Prioritizing Prevention - Center Activities
Base Amount: $61,798,880 (All BA)

Public Health Focus

The public health focus of the Prioritizing Prevention sub-program is to protect the American food supply from unintentional and deliberate contamination and prevent food safety problems before they occur. Prevention is the cornerstone of an effective, food safety strategy. Ensuring that industry implements preventive control measures is essential to prevent intentional or unintentional contamination of the American food supply.

Public Health Outcome

Driven by science and modern information technology, CFSAN detects, identifies, and counters potential hazards before they harm American consumers. CFSAN also develops and implements uniform, science-based standards to strengthen and better integrate the American food safety system at the federal, state, and local levels, as well as to increase assurance that imported food is as safe as domestic.

CFSAN base funding in this sub-program provides the resources to support industry and protect consumers 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 pre-market and post-market basis.

In the pre-market arena, CFSAN base programs protect the public health by assessing and evaluating the safety of infant formulas and assessing and evaluating 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 technologies that have the potential to reduce foodborne illness by decreasing levels of pathogens in food.

For example, FDA expanded the permitted use of irradiation as a treatment to reduce foodborne pathogens in iceberg lettuce and spinach. This irradiation provides producers with an additional tool to reduce levels of pathogens such as *E. coli* and *Salmonella* on these leafy greens. CFSAN also published guidance for manufacturers on microbiological considerations in preparing submissions for antimicrobial food additives. CFSAN issued several other authorizations for antimicrobial ingredients for fresh produce and for use in wash water during the processing of meat and poultry.

CFSAN base resources also support the evaluation of submissions for new and emerging technologies. 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.

CFSAN recently updated its guidance to petitioners for new food additives and food packaging components. For the first time, the updated guidance includes recommendations and considerations about changes in particle size. FDA also published a final rule requiring the labeling of the color additives carmine and cochineal extract to protect consumers who are allergic to these colors.

On a post-market basis, CFSAN base programs protect the public health by providing industry with information and requirements in the form of regulations and 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, from minimally processed foods, such as fresh produce, to processed foods, such as low-acid canned foods.

CFSAN also develops science-based safety standards that will reduce risk in a number of commodities. For example, CFSAN issued a new egg safety regulation, designed to prevent *Salmonella enteritidis* in shell eggs during production, transportation, and storage, that took effect in July 2009. The regulation requires preventive measures during the production of eggs in poultry houses and requires subsequent refrigeration during storage and transportation. These measures are expected to save thousands of lives from *Salmonella* over the next few years.

In April 2010, CFSAN launched a web site with information on the safe transportation of human food and animal feed. The site aggregates links to existing FDA regulations, guidances, and press releases providing a comprehensive information resource to commercial food transporters. Knowledge of and adherence to these regulations,

guidances, and press releases assists commercial food transporters in reducing the potential introduction of physical, chemical, biological, and other contaminants during the transportation of foods and feeds. CFSAN base resources also support activities to determine baseline levels of chemical contaminants in foods. Examples of such contaminants include furans, melamine, perchlorate, dioxins, lead, and pesticides. Base resources also allow CFSAN to protect public health by assessing potential problems, taking steps to remove products from the market that violate safety standards, and ensuring that manufacturers use appropriate control measures to reduce or eliminate contaminants in foods. For example, CFSAN base resources support annual data collection through the Total Diet Study (TDS) program to determine the levels of various contaminants and nutrients in foods. This is particularly important for estimating the dietary intake of substances such as pesticide residues, which may be reduced or increased as a result of washing, peeling and cooking.

During FY 2011, FDA will provide funding to the Center for Foodborne Illness Research and Prevention (CFIRP) to support food program activities, as noted in Section 728 of the FY 2010 Appropriations Act. The long-term health burden of acute foodborne disease is not well understood and there are few guidelines for long-term medical care. CFIRP will develop a framework for systematic follow-up of foodborne illness cases which will greatly enhance the ability to attribute long-term health problems resulting from acute foodborne illness.

Promoting Efficiency

Through the Prioritizing Prevention subprogram, CFSAN takes preventive action to protect consumers from food safety risks. In this subprogram, CFSAN also helps firms develop safe food packaging based on the latest science and avoid the risk and expense of recalling products that do not meet safety standards.

The CFSAN premarket review activities of this subprogram also alert industry to potential problems with new ingredients, labeling, or infant formula. Each year, CFSAN provides more than 100 consultations to assist industry. Through these consultations, CFSAN offers specific guidance to firms on how to best address safety questions relating to food ingredients and packaging. 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 maintains essential scientific and technical expertise through this subprogram. This expertise allows CFSAN to provide international leadership for developing science-based Codex 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
Base Amount: $107,199,000 (All BA)

Public Health Focus

ORA 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
- ensuring that preventative controls are in place throughout the entire food supply chain, from the point of production, to delivery into the U.S. supply chain and ultimately, consumption by the public.

Public Health Outcome

In 2010, ORA participated in more than 50 outreach events at a variety of symposiums and conferences attended by regulated industry, other government agencies and foreign regulatory bodies. ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advancement of FDA policies and initiatives to internal and external stakeholders.

In FY 2010, FDA awarded a $1.0M cooperative agreement to the International Food Protection Training Institute (IFPTI). IFPTI supports the Integrated Food Safety System (IFSS) for regulatory and public health partners through its establishment of a catalog of existing food safety/food defense courses for the Partnership for Food Protection. In FY 2010, ORA offered five of these courses at the IFPTI facility.

In FY 2011, the Institute will continue to work with ORA personnel in obtaining its goal of establishing a comparable national training curricula for federal, state, local, territory and tribal food safety inspectors. This curriculum will serve as the foundation for ensuring consistency in training across all regulatory levels.

In FY 2010, ORA awarded funds to five associations under the Small Scientific Conference Grant and to 27 state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources the associations and regulatory agencies needed to convene meetings of key stakeholders to foster communication and collaboration on a range of topics including food safety and food security/protection, intervention and prevention through the review of food supply vulnerabilities.

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 are proactive and generate efficiencies for industry, consumers and FDA because they help anticipate and prevent food safety problems. In addition to protecting public health, preventing such problems leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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 2009: 100% (Target Exceeded)	70%	90%	+20%
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 2010: 388 (Target Exceeded)	347 enrolled	423 Enrolled	+76
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	FY 2010: 5 labs (Target Met)	5 data exchange additions/conversions	5 data exchange additions/conversions	Maintain
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2008: 12.8 cases/100,000 (baseline)	12.3 cases/100,000	11.9 cases/100,000 (based on HP2020 Target)	NA*
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2008: 1.1 cases/100,000 (baseline)	1.0 cases/100,000	1.08 cases/100,000 (based on HP2020 Target)	NA*
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2008: 0.29 cases/100,000 (baseline)	0.24 cases/100,000	0.28 cases/100,000 (based on HP2020 Target)	NA*
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2008: 16.2 cases/100,000 (baseline)	6.8 cases/100,000	14.4 cases/100,000 (based on HP2020 Target)	NA*

212409: Decrease the rate of *Salmonella Enteritidis* (SE) illness in the population (cases per 100,000). (*Outcome*)	FY 2009: 2.6 cases/100,000 (Historical Actual: average rate of SE illness from 2007 to 2009)	NA	2.2 cases/100,000	NA

* The FY 2010 targets for reducing the incidence of infection caused by *Campylobacter* species, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species were set in the year 2000 as part of the **Healthy People 2010 Initiative**. The targets for FY 2010 were all calculated as 50% reductions from 1997 baseline incidence levels for these foodborne pathogens. The targets for 2010 have not yet been achieved for any of the pathogens included in this objective (though *Campylobacter* species, *E. coli* O157:H7 and *Listeria monocytogenes* are very close, with 48%, 47% and 38% reductions, respectively, as of the 2008 data). Further investigation is needed to identify sources for emerging *Salmonella* serotypes, since that rate of infection has increased in the past decade.
The FY 2011 targets start the next decade of targets as part of the **Healthy People 2020 Initiative**, and therefore the FY2012 targets are not comparable to the FY 2010 targets. In order to align the new targets for future reductions with more recent data, the baseline data for the FY 2011 targets are from FoodNet data collected from FY 2006 – FY 2008. Consequently, the FY 2011 targets show an increase over the Healthy People 2010 targets due to the new baseline. The Health and Human Services Office of Disease Prevention and Health Promotion (ODPHP) has recently given guidance to the Healthy People work groups on target setting for **Healthy People 2020**, recommending improvement targets of 10% over the 10-year period.

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

Base Amount: $114,801,090 (All BA)

Public Health Focus

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

Public Health Outcome

CFSAN base 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. Base activities also protect American consumers from harm by addressing foodborne outbreaks and cases of intentional or unintentional chemical contamination.

A significant focus of CFSAN base activities is using post-market surveillance information and scientific methods and tools to identify food products that pose a threat to public health. Funding for CFSAN base 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 example, CFSAN base resources supported the prompt interim safety/risk assessment of melamine in response to finding this adulterant in Chinese dairy products.

CFSAN base resources also support the post-market monitoring of previously authorized substances added to food to assess the need to re-evaluate safety in light of new information. For example, CFSAN base resources are currently supporting a re-

evaluation of the safety of bisphenol A (BPA), phthalates, and related chemicals in light of recent research that suggests the possibility of adverse effects at levels lower than previously indicated.

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 is one such improved early warning system, where food processors can report the possibility of food contamination. These reports trigger rapid FDA and state response to determine and stop the cause before people become sick. FDA also worked with the National Institutes of Health to develop the Safety Reporting Portal (SRP), a unified system to submit adverse events, product problems, and/or safety reports associated with regulated products. The SRP assists industry in determining what specific data need to be submitted, improving the data quality of reports, and increasing the speed and accuracy of FDA response to potential public health problems. The SRP was launched on May 24, 2010.

Protecting food from intentional contamination is also a priority of CFSAN base activities. Understanding the risks and vulnerabilities for intentional contamination in the food production, processing, and distribution system helps further strengthen the food supply against targeting for intentional contamination. In FY 2010, CFSAN re-evaluated historical vulnerability and risk assessments on regulated foods to update them for technological advances, additional select agents, and new surveillance data. Through an interagency agreement with the Department of Energy, CFSAN supported the continued development of the CARVER + Shock vulnerability assessment tool which helps agricultural producers and food processors protect their products from deliberate contamination.

Another significant focus of CFSAN base activities is developing and validating new, rapid-detection technologies capable of identifying contamination that leads to foodborne illness. Current test results require anywhere from several days to weeks to deliver, which severely limits the ability to respond to outbreaks and emergencies and to complete timely surveillance activities. In FY 2009 and FY 2010, FDA developed new tests for *E. coli* 0157:H7, *Salmonella*, *Listeria monocytogenes*, *Shigella*, and marine toxins. CFSAN continues to evaluate other promising test methods and high-throughput technologies that will dramatically shorten the time it takes inspectors to identify pathogens in the food supply chain from more than a week to less than a day.

Promoting Efficiency

Through the Strengthening Surveillance Subprogram, 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.

CFSAN research often provides essential non-proprietary data for discussions about particular test methods or product characteristics. In many cases, industry relies on CFSAN to provide uniform methods and establish standards to detect food contaminants and 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, validate, and verify 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. As a result, the Strengthening Surveillance Subprogram supports FDA's food safety and public health mission, while allowing industry to efficiently address emerging food safety concerns.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance – Field Activities
Base Amount: $273,955,000 (All BA)

Public Health Focus

To strengthen bio-security, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses including sample analysis, product testing and methods development to enable ORA to develop solutions for specific regulatory problems.

These activities serve to minimize consumers' risk of exposure to adulterated food products by preventing the marketing of 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.

ORA continues to advance regulatory science, increasing the breadth of its analytical capacity while improving laboratory efficiencies and outputs. One way ORA accomplishes these advances is through the continued development of laboratory methods. The international aquaculture industry, for example, has been concentrated in developing countries that lack regulation on drug use in food-producing animals.

Several antibiotics and other drugs are approved for use in aquaculture to improve productivity and increase yield. However, FDA continues to find a significant number of

unapproved drugs in seafood products, leading to concerns about product safety and drug withdrawal times. These conditions require FDA evaluation on a case-by-case basis.

Some of the unapproved antibiotics and drugs used in today's food products are carcinogens, some are toxic to the immune system, and some have other health impacts such as allergic reactions and adverse drug side effects. Since the products are not labeled as containing the drug, they cause unexpected health risks to the consumer. There is a growing concern that subclinical doses of antibiotics can contribute to the development of multidrug resistant pathogens.

To protect consumers from potentially harmful residues in the food that they eat, it is important that Agency oversight of food commodities include an analytical assessment for the presence of drug residues. ORA continues to develop analytical methods and expand field laboratory capabilities, both of which are imperative to meeting the ongoing issues and concerns related to food products.

Public Health Outcome

ORA continued to use the Chemistry and Microbiological Mobile Laboratories to support food defense initiatives and surveillance of import and domestic produce. The Mobile Laboratories are designed for high throughput screening of samples providing for expedited analytical timeframes and subsequent release of import shipments, which is crucial for perishable products such as produce. In 2010, supported by a total of 132 volunteers from the ORA field laboratories, the ORA Mobile Laboratories were deployed for a total of 35 weeks. A total of 8,015 samples of domestic and imported produce were analyzed. One deployment, focused on imported produce from Central and South America and Caribbean Islands, found a combined 7% violation rate for *Salmonella*, enterohemorrhagic *E. coli* (EHEC), and pesticides. The finding resulted in the addition of the firm and products to appropriate Import Alerts calling for the detention without physical examination of affected products.

In FY 2010, ORA re-invigorated the use of environmental sampling during domestic food facility inspections to assess the environmental conditions in which products are manufactured. These samples provide signals to FDA of areas of concern within a production environment and have led to numerous cases of industry electing to retain or destroy products that were manufactured in suspect conditions but have not yet been proven to be contaminated. Through surveillance efforts such as these, and joint FDA and industry action, ORA assures that potentially adulterated commodities do not enter into the U.S food supply. Additionally, ORA increased surveillance activities performed by the states on behalf of FDA by including in the Food Inspection Contract program several electives such as conducting environmental sampling during the inspection. In FY 2010, seven states chose to include this elective which called for the completion of up to 1,500 environmental sample collections within the year.

In FY 2010, ORA developed a new method to detect polycyclic aromatic hydrocarbons (PAHs) in oysters, shrimp, crabs and finfish. This method is currently being used to determine the concentration of PAHs in seafood from the Gulf of Mexico. Based on this test, FDA can confirm that the level of these chemicals in the Gulf seafood are below a level that would cause public health concern. This new method is being used for all samples collected and analyzed in support of determining whether the Gulf waters can be reopened to commercial fishing. The method was deployed to eighteen FDA and state laboratories participating in FDA's chemistry cooperative agreement with FERN.

Each laboratory can test approximately 20 samples every 24 hours using this method as compared to the existing method which is capable of testing 25 samples every 5 to 7 days.

In FY 2010, ORA purchased new equipment for field laboratories and developed new methods that allow a single test to detect specific drug residues in aquaculture and honey products, and confirm the levels of drug residues present. ORA's equipment purchase continued to expand its laboratory capacity by extending its capabilities to analyze seafood products for the presence of nitrofurans (known carcinogens) into three additional ORA field laboratories. The multi-residue analytical method ORA developed and implemented can analyze and confirm the presence of 18 different drug residues in shrimp products. The multi-residue method developed and implemented for honey allows for the detection of 17 different drug residues. Due to increased sampling stemming from joint actions with U.S Customs and Border Protection (CBP) and the ORA Office of Criminal Investigations (OCI), ORA field resources collected and analyzed 150% of the FDA target for FY 2010.

In FY 2010 ORA reevaluated and initiated changes to procedures involved in joint surveillance with facilities and products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and other organizations. The changes affect information sharing with the United States Department of Agriculture (USDA) and Occupational Safety and Health Administration (OSHA) regarding facilities such as the Wright County Egg Facility in Iowa. The Agencies are redesigning processes, including inspection, test results and oversight of proposed corrective actions by firms, to address contamination with *Salmonella* and other diseases and filth. The agencies are also evaluating information disclosure between CFSAN, the Environmental Protection Agency (EPA) and USDA on fresh produce safety at the farm and packing house. The information requested will assist CFSAN in concluding which production practice standards would best protect the public health if required by regulation, while creating minimal economic and environmental impact. ORA personnel are mediating information disclosure to OSHA regarding food facilities contained in the Food Facilities Database. These efforts will improve prevention and federal and state responses to outbreaks and contamination.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY

2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas. The joint effort called for ORA and state sampling of milled wheat products such as milled wheat flour, wheat bran and wheat germ intended for use in the human food supply to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up inspections with sampling of finished foods manufactured using the milled wheat products that exceeded FDA advisory levels. FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, which consolidated the previous process of an initial test to determine the presence of mycotoxins and a confirmation test for regulatory determination and action.

In 2010, ORA's Prior Notice Center (PNC) was able to expand its prior notice electronic targeting system capabilities, increase intelligence-related food shipment data mining, and create new targeting criteria to more effectively detect food shipments linked to high risk persons and firms. Additionally, the PNC performed more than 81,000 reviews of prior notice submissions, exceeding FDA's goal by over 1,000 reviews.

ORA is increasing efficiencies in reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources to allow for a more informed review of specific product entries. Data supporting product compliance will aid ORA in more quickly processing and releasing those entries while data more indicative of concerns or violations will result in the entries being flagged for additional scrutiny by ORA investigators. PREDICT allows 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 2010 ORA contracted with a third party to perform on site firm verifications of foreign food facilities that have registered with FDA as required by the Bioterrorism Act (BTA) of 2002. This contract allows for physical verification of a foreign firm at the location identified in the registration not only to confirm the existence of the facility but to verify the information supplied in the registration. On-site findings are then reported to FDA for appropriate follow up action, which includes for-cause inspection of the facility, addition of facilities to import alert where the manufacturing capabilities are not what was purported in the registration, and increased review of prior notice submissions to ensure accurate data is submitted.

In FY 2010, ORA evaluated handheld portable analytical tools for use in the early detection of contaminated food products. ORA qualified a variety of tools to date and started 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. The analytical screening capacity and commodity range for each tool varies. Portable tools return analytical screening results within minutes of implementing the test, providing ORA field personnel with data to assist in making appropriate regulatory determinations. These tools provide for the release of safe

shipments into U.S. commerce and detention of shipments with violative screenings for further analysis by ORA field laboratories. The first tier of tools was deployed to several ORA field offices, and they are the first in a series of portable analytical tools that will be deployed to ORA field investigators to screen a variety of products for a multitude of safety concerns.

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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214306: The average number of days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2010: 10 working days (Historical Actual)	NA	4 working days	-6
214207: The number of assessments/questionnaires completed to initiate the process of establishing comparability of foreign country food safety systems to that of the US relative to public health outcomes. (*Output)*	NA	NA	9	+9
214201: Number of prior notice import security reviews. *(Output)*	FY 2010: 81,618 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2010: 170,392 (Target	140,000	160,000	+20,000

	Exceeded)			
214203: Number of Filer Evaluations. *(Output)*	FY 2010: 1,277 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2010: 8,658 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2010: 13 labs (Target Met)	13 labs	13 labs	Maintain

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

Base Amount: $21,870,331 (All BA)

Public Health Focus

The public health focus of the Strengthening Enforcement sub-program 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.

Public Health Outcome

CFSAN base activities in this sub-program 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.

Recently, CFSAN conducted a qualitative risk assessment to identify, evaluate, and target ORA domestic field work priorities for sampling and inspecting products or processes of higher relative risk, using a three-step process to:

- estimate the likelihood of an adverse event occurring from the consumption or use of a product containing the hazards
- determine the relative severity of the health effect of that hazard
- combine data on the likelihood and severity to determine the risk category (high, medium, low).

Using this relative risk ranking approach, FDA adapted it to develop risk related priorities for imported products. This risk assessment allows CFSAN and ORA to link products and hazards of concern in a systematic and transparent manner for the first time.

CFSAN also initiated research into developing a risk-based tool to identify higher priority food firms based on the relative risk of the products that they manufacture, process, or distribute and the compliance history of those firms. In FY 2010, the risk-based model that relatively ranks domestic food manufacturers was enhanced to include the firm's compliance history and inherent factors, including foodborne outbreaks, recalls, and reports of adverse events. As a result, FDA now uses revised, risk-based strategies, such as increasing and targeting environmental sampling for *Salmonella* and/or *Listeria* during inspections of certain higher risk firms. This change has already resulted in numerous product recalls and at least two injunctions to date. The public health outcome of using this inspection and enforcement strategy when inspecting higher risk firms has and will continue to prevent illnesses resulting from contaminated foods.

In FY 2010, CFSAN base resources in this area supported improvements to the risk evaluation process and the development of quantitative or semi-quantitative tools to refine and improve the approach. CFSAN undertook additional work to refine risk evaluation methodology, obtain data to reduce uncertainty in the output of the risk models, and develop procedures to integrate the results into the joint Center/Field inspection work planning process. CFSAN used the results of these models to develop risk profiles or risk maps to assist in understanding the vulnerable steps or events where contaminants can be or are introduced into the food supply system.

For example, CFSAN developed a customizable fresh-produce risk ranking tool using data collected from the CDC and other scientific sources. The tool provides a systematic means of determining which produce/contaminant combinations are riskiest and ranks them in order of priority for interventions. The results of such tools allow FDA to implement appropriate mitigations or interventions to reduce health risks to American consumers.

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
Base Amount: $111,446,000 (All BA)

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.

Public Health Outcome

ORA investigators conduct physical inspections of regulated domestic and foreign food establishments.

In FY 2010, ORA increased the number of firms that were targeted for foreign inspection coverage by 144. Innovations included using risk factors to target firms to inspect, establishing dedicated foreign inspection cadres, and enhancing efficiencies associated with the foreign inspection program and process. The increased coverage provides a better understanding about the compliance status associated with firms that ship human food products to the U.S.

ORA started the Dedicated Foreign Food Cadre in July of 2009. The 13 cadre members bring over 160 years of experience conducting independent and complex inspections and developing compliance cases which very often resulted in regulatory actions. In FY 2010 the cadre contributed significantly by augmenting the existing foreign inspection program and exceeding the number of foreign food establishments inspected in the previous year by 144 inspections.

During FY 2010, ORA issued 668 Import Alert notices identifying modifications to human food products, food ingredients, and dietary supplements. These notices encompass various food and dietary supplement commodities and manufacturers. Some were a result of ORA import surveillance activities of regulated products at the time they were offered for import into the U.S. Others resulted from for-cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. Notable products covered under this process include shipments of tuna containing Salmonella Paratyphi implicated in illness outbreaks in 22 states and black pepper implicated in a multistate salmonelosis poisoning episode.

In FY 2010, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA personnel are working closely with other government agencies on several ongoing cases including products in the human food program.

In FY 2010, FDA received new authorities under the Prevention of *Salmonella enteritidis* in Shell Eggs during Production, Storage, and Transportation Rule. In an effort to enforce the requirements of the rule, FDA is establishing and implementing a multi-tiered internal approach to:

- identify inspection requirements, resources, and tools

- develop and implement training of ORA field staff
- initiate inspections of facilities for evaluation of egg safety for prevention of *Salmonella enteritidis* (SE).

Initial inspections of a large producer in Iowa resulted in recalls of shell eggs. Eleven firms initiated recalls associated with the Salmonella enteritidis in shell egg event. There were 156 direct accounts and 3,982 sub-accounts (customers downstream, i.e, distributors, food service establishments, institutions, manufacturers and retail outlets) of Wright County Egg and Hillandale Farms of Iowa for which audit checks were performed.

Trade submission of accurate prior notice data for imported food shipments ensures ORA can complete meaningful bio-security risk assessments. In order to ensure compliance, ORA made more than 800 informed compliance calls to the trade in 2010 to obtain accurate prior notice data and inform/remind the trade community and regulated industry of the requirements. In conjunction with CBP, ORA executed compliance enforcement actions against more than 1,300 imported food/feed shipments where the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. These compliance actions required the trade community to submit accurate prior notice data for risk assessment before the imported food/feed shipments were allowed to enter the U.S.

FDA's global efforts in China and India contributed to surveillance inspections. Investigators working in China and India conducted for-cause and surveillance inspections. This facilitates follow up on critical issues (for-cause inspection) in a timely manner. Additionally, these international offices are providing more confidence building and joint activities with foreign regulatory agencies.

In FY2010, ORA awarded food inspection contracts to 41 State Agencies and one territory. 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), and low acid canned foods/acidified foods. Additionally, these contracts allow the states the option to include additional investigative mechanisms such as environmental sampling to assist in strengthening and protecting the food supply from unintentional and deliberate contamination and prevent food safety problems before they occur.

ORA also monitors recalls of food products that have been found to present safety concerns and assures the adequacy of the firm's recall to effectively remove the defective product 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 FY 2010, FDA classified and issued recall numbers for 2,235 Class I (most serious); 564 Class II; and 139 Class III recalls of food products compared to 492 Class I, 1816 Class II, and 473 Class III recalls in 2009.

In FY 2010, FDA's MARCS-Compliance Management System indicated 19 approved injunctions, 6 seizures of food products (including dietary supplements) and 82 emergency permit controls.

ORA's Office of Enforcement (OE) and Office of Criminal Investigations (OCI) also focus on enforcement. In March 2009, the Office of Enforcement assumed the responsibility for the Agency's Debarment Program, putting Agency-wide procedures in place to ensure that more rapid, transparent and consistent debarment actions are taken. These efforts also included hiring a full-time Regulatory Counsel to initiate and process debarment proceedings and creating and maintaining a page on FDA's website where all pending and completed debarment actions are listed and publicized, enhancing public health protection by assuring that businesses and individuals who deal in FDA regulated products do not procure the services of a debarred person. It is critical to ensure that the individuals who engaged in misconduct not be trusted with patient safety and the public's health. OE initiates a comprehensive review of cases referred quarterly by OCI and other cases referred by other sources throughout FDA for potential debaree candidates. In FY2010, as a result of these referrals and reviews, OE has debarred thirteen individuals with criminal convictions from participating in certain aspects of food and drug industry. Three of these thirteen individuals debarred include FDA's first food importer debarments.
http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm194263.htm

OE managed the collaboration of information disclosure between CFSAN and the Federal Trade Commission (FTC) regarding companies marketing caffeinated alcohol beverages, a food not generally recognized as safe and an unapproved new drug.

OCI's significant case activity in FY 2010 included 39 arrests and 26 convictions with fines and restitution in excess of $68.0 million. Two cases are highlighted below:

The July 2010 sentencing of a seafood wholesaler CEO culminated in an OCI investigation into the illegal importation of $15.5 million of misbranded and adulterated Vietnamese catfish, which led to a conviction of five companies and eight individuals associated with various Vietnamese catfish processors, U.S. importers, and seafood wholesalers. The investigation tackled the long-standing practice of mislabeling seafood to avoid Customs anti-dumping duties and an FDA import alert against antibiotic-tainted Vietnamese catfish. The defendants were ordered to pay $444,000 in fines, ordered to forfeit $12,197,930, and pay $64,173,839 in restitution. Additionally, the subjects of the investigation were sentenced to a total of 97 months of incarceration, six months home confinement and 162 months of probation.

The second case led to a 44 count indictment in August 2010, charging a U.S. honey importer, 11 business executives and four affiliated companies for conspiring to import $40 million of falsely labeled and adulterated Chinese-origin honey tainted with unapproved antibiotics and avoid Customs anti-dumping duties and an FDA import alert designed to intercept honey containing unapproved antibiotics. The indictment not only seeks the forfeiture of $78 million in unpaid anti-dumping duties, but addresses the

denial of a fair market for U.S. honey producers and the deliberate violation of laws designed to protect the U.S. food supply.

In FY 2010, FDA's 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 state personnel use provide reliable support for regulatory action consistent with the agency's guidance on regulatory actions and laboratory procedures. This is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in U.S. commerce.

Promoting Efficiency

Examples of FDA efforts to promote efficiency through the Strengthening Efficiency Subprogram include the ORA Food Inspection Contract Program. The Food Inspection Contract Program – and similar contracts, grants and cooperative agreements that the Field 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 FDA and state food safety programs.

Through closer involvement with state food safety efforts, FDA gains valuable data on inspections funded with state resources. Through these grants and cooperative agreements, ORA increases the efficiency of an integrated food safety system by assuring state inspectors are better trained and more proficient, increasing the capabilities of states to respond to food incidents and outbreaks.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2011
214205: Number of high-risk food inspections. *(Output)*	FY 2010: 6,926 (Target Exceeded)	6,750	8,850	+2100

Improving Response and Recovery - Center Activities
Base Amount: $6,623,685 (All BA)

Public Health Focus

The public health focus of the Improving Response and Recovery sub-program is to protect American consumers from harm when foodborne illness outbreaks do occur. The public health focus involves responding more effectively with rapid and targeted product tracing and more accurately identifying the specific firms that are responsible for the food safety problem.

Public Health Outcome

CFSAN base program activities help 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. CFSAN uses this structure to achieve the primary public health objective of reducing the length of time between detecting and containing foodborne illness.

CFSAN base activities support the ability of FDA to respond faster, communicate more effectively to consumers and FDA food safety partners, and limit avoidable adverse economic consequences for affected industries. In FY 2010, these resources allowed the FDA, in partnership with the National Oceanic and Atmospheric Administration (NOAA) and the United States Coast Guard, to respond to issues of seafood safety stemming from the Deepwater Horizon oil spill. CFSAN assessed seafood safety through sampling and laboratory analyses and then used this information to make decisions to safely re-open harvesting areas. FDA also provided analytical and operational support to federal, state, and local agencies likewise involved in the response efforts.

As a result, FDA prevented consumers from being exposed to contaminated seafood caused by this environmental disaster. FDA was also able to help the Gulf fishing industry recover by providing assurance to consumers that seafood from re-opened fisheries was safe, helping to minimize the adverse impact of the spill on the American economy. FDA continues to monitor and evaluate on-going and long-term effects of the spill on seafood safety in FY 2011.

CFSAN base program activities 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 response and recovery activities safeguard consumers, promote economic stability, and reduce costs to industry during incidents of foodborne illness or contamination. In addition to posing clear risks to consumers, foodborne illness outbreaks 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.

Improving Response and Recovery - Field Activities
Base Amount: $49,360,000 (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. To rapidly respond to outbreaks and facilitate recovery, ORA leverages its regulatory partnerships.

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 is continuing to 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 food borne 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 continues to devote resources to the prompt and efficient response to foodborne outbreaks and events associated with FDA regulated commodities. 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 that provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide evidence for rapid trace back 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 data informs and directs inspections.

Public Health Outcome

Examples of these partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, and 50 State Meetings.

To date, ORA has developed nine RRTs through the use of cooperative agreements and will continue 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 FDA districts) to explore, develop, implement, and share best practices. This work enables federal and state partners to improve their systems to more quickly and effectively stop an outbreak and mitigate the concern. When possible and appropriate, the partners can identify sources of contamination and contributing factors for the outbreak and reach conclusions and possible interventions for the prevention of future cases. The RRTs developed tools and guidance to share and facilitate improvement on key capabilities that are essential for effective responses to emergencies.

In FY 2010, ORA held a national Rapid Response Team (RRT) conference with all state and federal partners. The conference was devoted to sharing information, discussing adaptation of best practices and identifying next steps to achieve key objectives over the next year. FDA and its partners shared concepts and national initiatives affecting response, discussed metric development, increased engagement with the Council to Improve Foodborne Outbreak Response (CIFOR), and explored way to enhance programs involving the Center for Disease Control (CDC). Conference participants identified areas of strengths in each individual program for broader implementation across all RRTs. The teams worked through various operational challenges, and defined goals aligning FDA and other national priorities with those identified by state partners.

In FY 2010, ORA implemented procedures to distribute weekly situation reports to the

states as well as each Reportable Food Registry (RFR) with the respective affected state to ensure early involvement of state counterparts in emergencies and outbreaks. During recent potential public health crises involving food products such as peanuts, cookie dough and non-fat dry milk, FDA staff worked quickly to develop specialized web pages to assist the industry and consumers by providing them with up-to-date information about the outbreak, the status of FDA's investigation, FDA's and CDC's recommendations to avoid becoming ill, FDA's response efforts, and important links to additional information. The additional information included industry guidance documents, consumer updates, recall information, FDA contact information, informational videos, social media tools, and information about how to report complaints.

Also, during large-scale, high profile, Class 1 recall situations, FDA created, posted and maintained searchable databases in real-time to ensure that the public can quickly identify recalled products. The databases allow consumers to search recalled products in a single, easily accessible location, and with understandable terms including brand name, UPC code, or product description.

FDA/FERN continues to provide training and proficiency testing to its member laboratories. Ten proficiency tests were completed in FY 2010 in all three disciplines of microbiology, chemistry, and radiology.

Training courses are also provided in the three disciplines. FERN participated in a Department of Homeland Security directed Integrated Consortium of Laboratory Networks harmonized check sample analysis as a test of the Laboratory Network concept. Menu 2010, a nationwide exercise of the radiological laboratories, involved 35 laboratories participating in the methodology-driven exercise.

FDA is continuing to enhance its IT interconnectivity with its 44 contract states. These states, which include 23 that conduct Seafood Hazard Analysis Critical Control Point (**HACCP**) inspections, report inspectional information electronically into the electronic State Access to FACTS (eSAF) system for enhanced information sharing between FDA and these states. FDA has several projects underway to further increase information sharing through eSAF, with a current focus on recall audit checks and inspection audits, as aligned with efforts towards state compliance with the Manufactured Food Regulatory Program Standards. This promotes collaboration between FDA and the states that perform this work and will allow the sharing of data in an efficient and secure manner.

In response to the Deepwater Horizon Oil Spill, ORA's Chemistry Mobile Laboratory units were deployed to Tallahassee, Florida in the summer of 2010. While located at the Florida Department of Agriculture campus, ORA field chemists collaborated with the Gulf Coast Seafood Laboratory on the development and validation of an applicable screening method for testing Volatile Organic Compounds (VOCs) in seafood. ORA laboratories analyzed more than 300 composite re-opening samples, 100 surveillance

samples and 100 baseline samples from affected Gulf State waters for presence of oil contaminants. A composite sample is a mix of several individual animals. Tens of closed state harvesting areas were re-opened based on ORA's testing of collected samples. The ORA Chemistry Mobile Laboratories as well as ORA field laboratories will continue to provide public health assistance for local seafood merchants during the recovery phase of the Deep Water Horizon Oil spill that occurred in the late spring of 2010. Both the Chemistry Mobile Laboratory and several field laboratories were equipped or are being equipped to either screen for VOCs or Polycyclic Aromatic Hydrocarbons (PAH) in seafood harvested from areas in the Gulf that were directly impacted by the Oil Spill.

In FY 2010, ORA identified and established a High Throughput Environmental testing laboratory designed to serve as a single point resource in the analyses of up to 86,000 environmental samples per year. The dedicated laboratory will serve as the primary resource for several large scale environmental sampling assignments that will be completed in FY 2011.

As a result of foodborne outbreaks and emergencies, ORA re-invigorated the use of environmental sampling in facilities that are directly or indirectly associated with an outbreak or emergency. This inspection resource provides the Agency with a comprehensive evaluation of the environment in which a food commodity is manufactured and aids in identifying sources and routes of contamination within a facility. ORA is better able to make informed regulatory determinations and work with regulated industry to contain the contamination and identify all affected products for removal or retention from introduction into the U.S. supply chain.

Promoting Efficiency

Improving the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams helps 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.

The Reportable Food Registry (RFR) is an example of how FDA uses technology to prevent food safety threats from leading to consumer illness or death. The RFR provides a reliable mechanism to track patterns of adulteration in human food products. FDA investigates reports of RFR to assure that contaminated foods are contained and recalled before illness or injury occurs.

ORA's use of grants and contracts with the states continues to leverage working relationships with state counterparts at the local level to improve surveillance activities, to enhance an integrated food safety system and to respond to public health threats in a timely and efficient manner. These programs assist FDA efforts during trace-back investigations, provide greater inspection coverage for ORA, and enhance food safety and defense through increased communication and integration of key stakeholders.

During FY 2010, FDA field laboratories implemented FDA and National Oceanic and Atmospheric Administration test methods to allow FDA to rapidly and efficiently evaluate and clear seafood products from the Gulf Coast region that may have been affected by contamination from the Deep Water Horizon oil spill. Thanks to these test methods, all Gulf Coast waters were re-opened for business by the end of FY 2010.

During FY 2011, the ORA field laboratories and the mobile chemistry laboratory will continue to evaluate and clear seafood products affected by the oil spill. Having the mobile chemistry laboratories on site in the Gulf Coast increase allows FDA to more efficiently test and clear seafood products. FDA works closely with local seafood merchants, providing analytical results in a timely manner so that merchants can quickly evaluate the safety of their seafood in the shortest time.

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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2011
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2010: 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

Base Amount: $24,010,279 (All BA)

Public Health Focus

The public health focus of the Nutrition & Labeling Strategies for Better Health sub-program 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 base resources in this sub-program support achieving this objective through the regulation of food labels and by promoting education and research programs that support good nutrition. 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.

Current nutrition initiatives include dietary guidance statements, updating the Nutrition Facts panel, sodium reduction, and regulatory activities that ensure food labels contain accurate information about the calorie and nutrient content of food that consumers can rely on. CFSAN also has new responsibilities resulting from 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. As part of implementing this new requirement, on July 7,2010, FDA published a Federal Register notice soliciting data, and other information relevant to the implementation of the new requirement, such as information about chain retail food establishments and vending machine operators, determination of calorie content of foods offered by retail food establishments, and implementation and enforcement approaches. FDA issued a second Federal Register Notice on July 23, 2010 that explained how retail food establishments and vending machine operators not otherwise subject to the provisions of the new federal menu labeling requirements may voluntarily elect to become subject to them by registering with the FDA. FDA will publish proposed regulations by March 23, 2011 that specify the manner in which restaurants and similar retail food establishments and vending machine operators are to provide nutrition information.

CFSAN base resources were used in FY 2010 to support several regulatory activities to 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 the unauthorized use of terms such as “healthy,” and others that have strict, regulatory definitions. In addition, 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 also completed the Spanish translation of the Food Labeling Guide, a comprehensive booklet that explains FDA’s food labeling requirements. Furthermore, 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.

In FY 2010, CFSAN developed and validated a five-minute method for measuring *trans* fats based on Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) spectrometry. This rapid method can measure less than 1.5% of *trans* fat in total fat, representing a significant improvement in sensitivity and accuracy from previous methods. Given that partially hydrogenated vegetable oils are the major source of *trans* fat in the American diet, this new method allows FDA to ensure a large portion of Americans are accurately informed of *trans* fat content when making their dietary selections.

CFSAN further conducts several education and outreach efforts to promote healthful choices that reduce the risk of chronic disease and obesity. First, with the Cartoon Network, CFSAN 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. 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. Second, CFSAN released a web-based program to inform consumers about using nutrition labels for "Healthy Weight Management." Third, CFSAN expanded an existing project with the National Science Teachers Association to include nutrition education for middle and high school teachers to help teach students to make healthful food choices using the Nutrition Facts Panel.

Promoting Efficiency

The Nutrition and Labeling Strategies sub-program allows American consumers to make informed decisions to improve their diet and health. According to data from the Centers for Disease Control and Prevention (CDC), chronic diseases cause seven out of 10 deaths each year.[1] 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. Treating chronic disease accounts for approximately 75 percent of the $2.0 trillion that America spends on health care each year.[2] Twelve percent of the U.S. Gross Domestic Product goes to treat diseases that are largely preventable or manageable.[3] FDA's Nutrition and Labeling subprogram helps reduce the burden on the U.S. economy associated with obesity and chronic diseases by helping consumers maintain health and reduce the risk of chronic disease and obesity.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (*Outcome)*	NA	NA	+5% over baseline	+5%

Reinventing Cosmetics Safety - Center Activities
Base Amount: $6,895,735 (All BA)

Public Health Focus

The public health focus of the Reinventing Cosmetics Safety sub-program 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 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 base resources support product surveys and laboratory investigations and allow FDA to maintain systems for voluntary cosmetic product registrations. CFSAN cosmetics program activities include the evaluation of adverse event reports and consumer complaints. Information from these sources is essential for risk-based approaches to cosmetics post-market monitoring, inspection, and other enforcement activities.

Recent issues with lead in lipstick highlight the need for resources to support both safety assessment and postmarket monitoring of cosmetics. Lead is an unintended contaminant or impurity that can be present at very low levels in some color additives and in other common ingredients, such as water, that are used to produce cosmetics. CFSAN scientists developed and validated a highly sensitive method for the analysis of total lead content in lipstick. Using this method, CFSAN tested the lead levels of specific lipsticks. The results showed that the levels of lead found in these lipstick samples were extremely low and did not present a safety concern. FDA published these findings in November 2009 and investigated a wider range of lipsticks in FY 2010. If CFSAN determines that a safety concern for lead in lipstick exists, CFSAN base funding will support advising the industry and the public and to take appropriate action to protect the health and welfare of consumers.

CFSAN base 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. CFSAN base 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 to be published in FY 2011.

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), 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
Base Amount: $3,489,000 (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 marketplace.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214208: Number of consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (*Outcome)*	NA	NA	+10% over baseline	+10%

Information Technology Investments – Foods Program Activities
(Base Amount displayed as a non-add item: $135,611,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. FDA also has a number of enterprise system projects that focus on improving the pre-

market review process for all regulated products, post-market surveillance, including adverse event detection, and future scientific computing capabilities of FDA. In addition, each center and office has program specific IT systems.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts to enhance IT as it relates to the ability FDA to advance the safety of imported and domestic food, thus enhancing public health and protecting American consumers. FDA is improving effective signal detection and rapid response by developing unified interoperable information-sharing data systems between federal, state, and local agencies. The Reportable Food Registry enables mandatory reporting of instances of adulterated and potentially harmful foods in commerce by industry and facilitates much earlier detection and removal of adulterated foods from commerce. FDA will continue improvements to processing the import data it receives through automated compliance targeting assessment algorithms using a screening tool known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). The rapid implementation of an enhanced scientific computing infrastructure will provide the backbone for the seamless integration of global and scientific data sources, improve trace back, limit the effects of adverse events, and better facilitate industry recovery. Taken together, IT projects such as these will enable FDA to adopt a more proactive response to food safety by capitalizing on pre- and post-market data, scientific research, and current events information to identify threats to the public health, ultimately reducing the incidence of food borne illness outbreaks.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	$457,104,000	$457,104,000	$0	2,569
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 Continuing Resolution	$781,449,000	$781,449,000	$0	3,387

Summary of the Budget Request

The FY 2012 budget request for the Foods Program is $1,035,080,000. This amount is an increase of $253,631,000 above the FY 2010 Enacted. The Center for Food Safety and Applied Nutrition amount is $302,750,000, supporting 1,147 FTE. The Field amount is $732,330,000 supporting 3,026 FTE.

The base funding for the Foods Program is $781,449,000, which includes $236,000,000 for Foods Program Center activities and $545,449,000 for Foods Program Field activities.

Base 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). Funding the FY 2012 request will allow CFSAN to protect public health by:

- assessing potential 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.

These efforts all help FDA achieve its public health objective of preventing illnesses resulting from contaminated foods and protecting consumers by providing better information to make well-informed food choices to improve their health and help them reduce the risk of chronic disease. CFSAN program activities help to 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 and other important emergencies pertaining to any CFSAN-regulated products.

The FDA 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.

Prioritizing Prevention

<u>Center Activities</u> (Base Amount: $61,798,880)

FY 2012 increase for Voluntary Qualified Importer Program: +$232,000; 1 FTE

FY 2012 increase for Food Export Certification User Fee: $1,185,000; 7 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 (+$5,717,000; 11 FTE)

The public health focus of this initiative is to reduce microbial contamination of fresh produce and increase public confidence in the produce supply through regulation of on-farm and postharvest handling of fresh fruits and vegetables. This investment will also support efforts by the FDA and federal, state, local, tribal, and territorial partners to improve food safety from farm to table. CFSAN will conduct the following activities with the resources in this sub-program:

- establish protective and practical performance standards for key risk factors and develop practical, risk-based preventive controls to enhance produce safety and protect the health of consumers
- provide extensive outreach, education, and technical assistance, especially for small growers, to foster compliance with food safety standards in coordination with regulatory partners, extension services, academia, and industry.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food and Feed Processing – FSMA Sections 101, 103, 104, 110, 204, 405 (+$14,295,000; 37 FTE)

The public health focus of this initiative is to better prevent foodborne illness through implementation of preventive food safety controls in food processing facilities.

Investments in effective controls for hazards in food products will also enhance public confidence in food safety. CFSAN will conduct the following activities with the resources in this sub-program:

- develop and issue regulations, performance standards, and guidance necessary for a prevention-oriented food safety system designed to protect consumers
- develop uniform hazard analysis and risk-based controls guidance to facilitate proper implementation of preventive controls regulations and standards
- develop performance standards for food hazards and evaluate food safety plans for food facilities
- engage in extensive outreach, dialogue, and other efforts with the food industry to ensure FDA standards and guidance are protective and practical.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Safe Food Transport – FSMA Section 111 (+$2,197,000; 4 FTE)

The public health focus of this initiative is to address the risks to human or animal health associated with the transportation of food. Investments in preventive controls for the safe transport of food will enhance the safety of food through improved practices concerning sanitation, packaging, isolation, and other protective measures, including information sharing between shippers and carriers, recordkeeping practices, and

limitations on the use of vehicles. CFSAN will conduct the following activities with the resources in this sub-program:

- create and fund state and U.S. Department of Transportation inspection assignments to collect data on temperature control and other food safety concerns
- conduct comprehensive research on food transportation and evaluate safety and security issues specific to food transportation, such as sanitation, pest control, employees training, and safeguards against tampering
- define cleaning protocols for transportation vehicles, establish associated performance standards, and establish test methods to demonstrate compliance
- establish a training curriculum to address safety and security issues for food transportation workers
- draft a proposed rule and guidance on industry practices and transportation-related food safety risks
- encourage the use of cooperative compliance models though outreach to industry and the scientific community during the rulemaking process.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Retail Food Safety – FSMA Section 209 (+$2,640,000; 4 FTE)

The public health focus of this initiative is to reduce contamination of foods associated with food handling practices at the point of preparation and service through improved Food Code compliance at retail and foodservice outlets. Investments in retail food safety will enhance consumer confidence regarding food safety in the retail and foodservice sectors. CFSAN will conduct the following activities with the resources in this sub-program:

- promote more widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards
- study and address obstacles that prevent adoption of the FDA Food Code
- collaborate with the retail industry to foster training and manager certification, and other industry-based initiatives to increase Food Code compliance
- revise the FDA Food Code and update the Retail HACCP Guides to keep them current with the understanding of effective risk mitigation strategies and concepts
- expand existing collaborations with institutional foodservice sectors, including school lunch programs, nursing homes, and hospitals, to promote enhanced understanding of the Food Code and foodborne illness prevention
- conduct research and provide advice on technologies and methods that prevent, mitigate or detect foodborne illness hazards in the retail environment
- develop guidance for the retail industry that describes best practices to control viral and bacterial pathogens and to reduce allergen hazards.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$7,737,000; 27 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. This initiative will allow FDA to establish a comprehensive, prevention-focused imported food safety program by shifting from an import safety approach based on reacting to problems to one that prevents such problems from occurring at appropriate points along the global food supply chain. CFSAN will conduct the following activities with the resources in this sub-program:

- Conduct initial assessments to determine countries that have comparable food safety systems or robust commodity specific export programs, followed by periodic system audits of comparable countries
- 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 begin to implement an importer accountability verification program
- Establish partnerships with other public health agencies to execute international outreach, training, technical support, and capacity building, and conduct specific workshops for Good Agricultural Practices (GAPs) training.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Critical Capacity for Implementation of FSMA (+$1,015,000; 0 FTE)

This initiative directly supports CFSAN operations and its work with other FDA units to achieve the Administration's food safety priorities. The buildings that house CFSAN are at full capacity. Without additional space to support expanding food safety workload and corresponding staffing increase, CFSAN cannot successfully implement the FDA Food Safety Modernization Act. CFSAN will conduct the following activities with the resources in this sub-program:

- renovate and outfit existing, unfinished building space to increase facility capacity
- install security devices, such as biometric readers and enhanced security surveillance tools, to comply with Select Agent Security standards
- reconfigure existing laboratory facilities at the University Station building.

Field Activities (Base Amount: $107,199,000)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($3,725,000; 13 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:

- hire 3 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 1 FTE to serve in Headquarters for program oversight and as a program auditor and 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards
- hire 2 FTE at Headquarters and 4 FTE as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire 2 FTE to develop and validate certification testing instruments.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 ($3,537,000; 6 FTE)

Investments to develop and disseminate knowledge and building capacity within and outside FDA to support the regulation of on-farm and post-harvest handling of fresh fruits and vegetables will reduce the risk of foodborne illness and enhance public confidence in the produce supply. ORA will conduct the following activities with the resources in this sub-program:

- hire 2 FTE to manage the program, provide assistance to State Regulators, and provide funding to State Regulators to attend the train-the-trainer courses and the Produce Safety Alliance training course.
- hire 4 FTE to serve as program and national Produce Safety experts
- develop a curriculum to train personnel assigned to produce safety compliance, inspection and enforcement activities. Provide training to FDA laboratory personnel regarding new training methods and detection protocols developed by the science program within FDA to use on produce directly from farms and on-farm/postharvest environmental.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food Processing – FSMA Section 110 ($8,919,000; 2 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- develop preventive controls-based inspection training or revamp existing GMP training to address preventive controls

- administer training on preventive controls to both FDA and State investigators. These resources will fund approximately 3,380 personnel – ORA Inspection personnel and State, Tribal, and Territorial regulatory partners – to attend a one-week training course utilizing a combination of face- to-face and distance learning mediums.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Retail Food Code – FSMA Section 210 ($2,955,000; 2 FTE)

Investments will allow FDA to promote widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards. ORA will conduct the following activities with the resources in this subprogram:

- establish contracts, cooperative agreements, or grants for state, local, territorial, and tribal agencies seeking to institute innovative compliance and enforcement strategies that promote improved and sustained managerial control of key operational risk factors
- Hire a contract monitor and state liaison.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

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Center Activities (Base Amount: $114,801,090)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls on Farms – FSMA Section 105 (+$1,342,000; 4 FTE)

Investments to support the regulation of on-farm and postharvest handling of fresh fruits and vegetables will reduce the risk of foodborne illness and enhance public confidence in the fresh produce supply. CFSAN will conduct the following activities with the resources in this sub-program:

- assess the value of specific preventive controls for safe produce growing and packing
- develop, evaluate, and validate rapid, specific, and sensitive microbiological test methods for various produce items and for environmental sampling on the farm and during postharvest handling
- estimate the risks associated with industry practices through field and laboratory microbiological studies.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Preventive Controls for Food and Feed Processing – FSMA Sections 101, 103, 104, 110, 204, 405 (+$2,119,000; 9 FTE)

Investments to support implementing preventing controls for food in processing facilities will result in better prevention of foodborne illness and increased public confidence through effective controls for hazards in food products and expanded inspection and compliance programs to facilitate the proper implementation of controls. CFSAN will conduct the following activities with the resources in this sub-program:

- validate the effectiveness of widely used process controls to provide industry and FDA with a better understanding of successful food safety processes
- develop and validate methods to evaluate performance standards for food hazards.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 202, 204, 205, 209, 210 (+$2,119,000; 9 FTE)

These investments support the implementation of an integrated, national food safety system that will provide greater and more efficient coverage of the food supply. The investments will reduce the incidence of foodborne illness by creating a sustainable public health infrastructure at all levels of government. CFSAN will conduct the following activities with the resources in this sub-program:

- assess the processes, data systems, and analytical capabilities needed to develop and manage a national work plan and share federal and state inventories to reconcile food establishment, inspection, and outbreak information
- develop and begin to implement standard laboratory practices, procedures, and national accreditation standards for food safety laboratories to ensure consistent and meaningful data for compliance, surveillance, and environmental samples.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$1,846,000; 2 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. Investments in science will allow FDA to improve decision-making about the admissibility of imported food and to better target products from countries that pose the greatest risk. CFSAN will conduct the following activities with the resources in this sub-program:

- Develop and/or validate new methods, rapid test kits, data sources, and analytical packages to support faster and more accurate import screening and to better target sampling at the border.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Critical Capacity for Implementation of FSMA (+$13,755,000; 18 FTE)

To support FDA's farm-to-table prevention measures, FDA will invest in risk analysis, laboratory capacity, and scientific methods. In order to enhance the capability of the

FDA to identify adulterated products through improved risk analysis, CFSAN will conduct the following activities with the resources in this sub-program:

- Develop and test modern tools to identify, evaluate, and prioritize risks
- Establish systems that use these tools to support sound risk management decisions, mitigation strategies and effective risk communications practices
- Better prioritize sampling and inspection programs
- Enhance the Safety Reporting Portal and consumer complaint reporting system.

Likewise, in order to enhance current scientific capabilities, operations, and capacity, and develop and adopt novel rapid detection methods to better protect the American food supply, CFSAN will conduct the following activities with the resources in this sub-program:

- evaluate new detection technologies and develop new and improved methods for detecting contaminants and pathogens to improve response, recovery, and overall efficiency in food testing laboratories
- procure the necessary labor, equipment, and supplies to improve and expand the capabilities of laboratory facilities and to update scientific workstations and specialized laboratory computers.

FDA Regulatory Science and Facilities: Nanotechnology (+$750,000; 2 FTE)

For the FY 2011 nanotechnology initiative, CFSAN will conduct activities that support the following FDA-wide priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: $273,955,000)

FY 2012 increase for Voluntary Qualified Importer Program: +$61,000,000; 265 FTE

FY 2012 Food Safety Training – FFSMA Section 209: +$8,000,000 / 0 FTE

FDA will spend $8.0 million on food safety training. FDA will develop and implement a national food safety training system to provide the knowledge and skills required for regulators and public health partners at all levels of government. FDA will also develop a related certification system to ensure the competency of the workforce. These resources support the authorities enacted by Congress in section 209 of the Food Safety Modernization Act. This investment will help ensure that FDA maintains a skilled national workforce to ensure that the food industry is meeting food safety standards.

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight for Food – FSMA Sections 201, 301, 302, 305, 306 and 307 ($12,444,000; 52 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 3 FTE to establish equivalence standards and assess whether other nations' food safety systems are comparable to ours and establish standards for third-party certification for imported food
- hire 14 FTE to develop, implement and conduct VQIP inspections
- hire 1 FTE to liaison with Customs and Border Protection to develop, evaluate and share voluntary programs
- hire 22 FTE to implement the Import Accountability Verification Program
- hire 5 FTE in Headquarters Operations to handle Import Alerts, Import Bulletins, assignments, guidance documents, procedures, training, bond mitigation and compliance review
- hire 2 FTE to increase security review capacity at the Prior Notice Center
- hire 5 FTE to increase enforcement expectations, Import Alerts/Import Bulletins recommendations, refusals and mitigations.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($1,868,000; 8 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:

- hire 1 FTE to serve as a National Work Plan Manager and 1 FTE to serve as National Work Plan Analyst. These FTE will assist ORA with its movements towards an integrated national workplan.
- hire 3 FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire 2 FTE to serve as Scientific Coordinators and 1 FTE as an IT Specialist. These resources will support the states as FDA moves to national standards for laboratories.

Transforming Food Safety and Nutrition: Nutrition for Better Health – Menu and Vending Machine Labeling - ($6,289,000; 2 FTE)

FDA will partner with state, local, territorial, and tribal regulatory partners to establish inspection programs to evaluate compliance with the new menu labeling standards. ORA will conduct the following activities with the resources in this subprogram:

- establish Menu Labeling contracts. Contracts will be targeted to state agencies or subdivisions of a state, county or city government with the regulatory authority to administer rules or policies that govern the inspections of restaurants and similar retail food establishments chains subject to 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).
- develop training for state inspectors to include web-based course and reference document
- hire 1 FTE to serve as Commissioning Agent and 1 FTE to serve as a Contract Monitor.

Transforming Food Safety and Nutrition: Laboratory Capacity and Capability (+$19,184,000; 80 FTE)

Using budget authority funding, ORA will build on existing capacity and capability through the hiring of an additional 80 laboratory analysts and technicians.

FDA Regulatory Science and Facilities: Nanotechnology ($277,000; 1 FTE)

ORA will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Proposed User Fee: International Courier User Fee (+690,000; 3 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities, and the number continues to grow. These shipments are often destined for individual consumers or for illegal distribution. The user fee resources for this activity allow increased import surveillance of FDA-regulated products at express courier hubs.

Current FDA staffing does not match the expected growth in import volume. Federal Express and other couriers indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

With this new user fee, FDA will:

- conduct entry reviews
- sample collections and physical exams to determine product admissibility into the U.S.
- initiate compliance actions to prevent release of unsafe products into U.S. commerce
- establish import controls to prevent future unsafe products from entering U.S. commerce.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

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Center Activities (Base Amount: $21,870,331)

FY 2012 increase for Recall User Fee: +$464,000; 2 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight – FSMA Sections 201, 211, 301-308 (+$3,026,000; 12 FTE)

The public health focus of this initiative is to increase assurance that the food imported into the U.S. is as safe as domestically produced food. The FDA Import Oversight program will shift the burden of import compliance from the limited FDA inspection force to importers and others who participate in the foreign food supply chain. This investment will allow FDA to protect American consumers and address the threat to food safety posed by dramatic growth in the volume of imported food. CFSAN will conduct the following activities with the resources in this sub-program:

- better target FDA foreign food inspections to countries and facilities deemed to not have systems comparable to the U.S. system or not having robust export programs and that do not participate in third party certification programs
- assist ORA in improving risk informed timely admissibility decisions and enforcement;
- support ongoing subject matter expertise and support for entry admissibility and enforcement activities, including PREDICT, Import Bulletins/Alerts, and inspection and enforcement strategies.

Field Activities (Base Amount: $111,446,000)

FY 2012 increase for Food Reinspection User Fee: +$6,825,000; 48 FTE

FY 2012 increase for Recall User Fee: +$9,397,000; 23 FTE

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($32,328,000; 0 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 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 twenty states grants, cooperative agreements or inter-agency agreement between federal agencies.
- 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 and Nutrition: Implementing the FDA Food Safety Modernization Act – Import Oversight for Food – FSMA Sections 201, 301, 305, 306 and 307 ($12,435,000; 44 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 2 FTE to perform periodic audits of Foreign Food Safety System Comparability Program
- hire 2 FTE to perform period audits of the Commodity Specific Export Certification Program
- hire 2 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
- hire 3 additional FTE to serve as foreign inspection trip planners
- hire 19 FTE to expand existing foreign inspection program
- hire 1 FTE to begin developing a foreign inspection Workplan.

Improving Response & Recovery

Center Activities (Base Amount: $6,623,685)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 202, 204, 205, 209, 210 (+$3,895,000; 10 FTE)

These investments support the implementation of an integrated national food safety system that will provide greater and more efficient coverage of the food supply. The investments will reduce the incidence of foodborne illness by creating a sustainable public health infrastructure at all levels of government. CFSAN will conduct the following activities with the resources in this sub-program:

- strengthen FDA preparedness, surveillance and outbreak detection, outbreak response and investigation, and post response activities under the FDA Foodborne Outbreak Team
- improve rapid response and recovery efforts by integrating and coordinating the capabilities of federal, state, and local partners to more efficiently use federal, state, and local response resources
- develop and implement traceback procedures
- align FDA operating procedures with the nationally recognized Council to Improve Foodborne Outbreak Response (CIFOR) recommendations (http://www.cifor.us/).

Field Activities (Base Amount: $49,360,000)

Initiatives

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 301, 302, 305, 306 and 307 ($467,000; 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. ORA will conduct the following activities with the resources in this subprogram

- fund 1 FTE to develop and implement traceback procedures
- fund 1 FTE to ensure consistency with Council to Improve Foodborne Outbreak Response (CIFOR) guidelines.

Nutrition & Labeling Strategies for Better Health

Center Activities (Base Amount: $24,010,279)

FY 2012 Initiatives

Transforming Food Safety and Nutrition: Nutrition for Better Health (+$2,519,000; 5 FTE)

Menu and Vending Machine Labeling

The public health focus of this initiative is to promote improved diet and nutrition for American consumers and allow them to lower their risk of obesity and chronic disease, and improve their overall health. Nutrition labeling on restaurant menus and vending machine products is a vital tool for consumers to construct healthy diets. CFSAN will conduct the following activities with the resources in this sub-program:

- review regulatory issues associated with the final rule on restaurant menu labeling
- develop and implement extensive outreach and education efforts to promote the final rules on menu and vending machine labeling to both industry and consumers
- establish inspection programs to evaluate compliance with the new menu labeling standards, in partnership with state and local governments.

Advancing Regulatory Science: Nutrition for Public Health (+$1,350,000; 2 FTE)

The public health focus of this initiative is to enhance food-labeling programs to enable American consumers to make more informed and healthful food choices, maintain health, and reduce the risk of chronic diseases such as type 2 diabetes, cardiovascular disease, and obesity. Under this initiative, CFSAN will modernize food labels to enhance the usefulness of nutrition information to the consumer. Through the regulatory actions supported by this initiative, the Agency will develop nutritional criteria for labeling on the front of food packages that consumers can rely on to make informed choices for healthy eating. This initiative will allow FDA to increase use of nutrition labeling and standardize front of package labeling to enable food choices that help consumers lower their risk of chronic disease.

Field Activities (Base Amount: $0)

Reinventing Cosmetics Safety

Center Activities (Base Amount: $6,895,735)

Field Activities (Base Amount: $3,489,000)

BA Increase for Pay Costs: +$1,795,000 (Center: $573,000; Field: $1,222,000)

Contract and Administrative Savings: (Total Program: -$6,707,000; -30 FTE)

The Center for Food Safety and Applied Nutrition (CFSAN) will achieve contract savings by:

- reducing services provided by outside contractors.
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting.

The Field will achieve administrative savings by:

- reducing administrative support FTE, both in Headquarters and in the field offices
- consolidating tasks and eliminating redundancies, the Field anticipates productivity and efficiency gains throughout the organization.

CFSAN Program Activity Data

PROGRAM WORKLOAD AND OUTPUTS	FY 2009 Actual	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FOOD AND COLOR ADDITIVE PETITIONS				
Petitions Filed	6	8 [1]	10 [1]	10 [1]
Petitions Reviewed [1]	8	13 [1]	10 [1]	10 [1]
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES				
Notifications Received	79	96 [4]	100 [4]	100 [4]
Notifications Reviewed [2]	87	73 [4]	100 [4]	100 [4]
INFANT FORMULA NOTIFICATIONS				
Notifications Received [5]	39	36	35	35
Notifications Reviewed [6]	29	39	35	35
FDA Review Time	90 Days	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [7]				
Submissions Received [8]	54	45	55	60
Submissions Reviewed [9]	50	41	50	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 reviewed includes notifications that became effective or were withdrawn.

[3] Due to a planned strategic re-deployment in FY 2007, this program was intended to be eliminated and result in the statutorily mandated safety review for food contact substances having to be submitted through the rulemaking process for food and color additives. Because the above redeployment did not take place under the FY 2007 CR or the FY 2008 CR, notifications have continued to be received. This number is greater because it includes those submissions received late in the previous fiscal year where the 120-day statutory timeframe begins in FY 2006 but ends in FY 2007.

[4] Our current estimates assume continued funding of the FCN program.

[5] A notification may include more than 1 infant formula.

[6] Number of submissions reviewed includes some submissions that were received in the previous FY.

[7] 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.

[8] Number of submissions received in current FY includes some received late in the FY that is expected to be completed in the next FY when the due date occurs.

[9] 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 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***8,745***	***10,099***	***12,099***
Domestic Food Safety Program Inspections	5,942	8,291	**To be determined**
Imported and Domestic Cheese Program Inspections	335	204	
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	479	545	
Domestic Fish & Fishery Products (HACCP) Inspections	2,082	1,361	
Import (Seafood Program Including HACCP) Inspections	339	375	
Juice HACCP Inspection Program (HACCP)	288	250	
Interstate Travel Sanitation (ITS) Inspections	998	1,057	
Domestic Field Exams/Tests	3,749	2,400	2,400
Domestic Laboratory Samples Analyzed	12,173	10,305	10,305
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***354***	***994***	***1,044***
All Foreign Inspections	354	994	*1,044* [1]
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,099***	***11,093***	***13,143***
IMPORTS			
Import Field Exams/Tests	170,392	140,200	140,200
Import Laboratory Samples Analyzed	30,374	26,549	26,549
Import Physical Exam Subtotal	**200,766**	**166,749**	166,749
Import Line Decisions	9,737,919	10,520,261	11,365,456
Percent of Import Lines Physically Examined	2.06%	1.59%	1.47%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	81,618	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,736***	***11,767***	***10,643***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***189***	***1,000***	***1000***
State Contract Food Safety (Non HACCP) Inspections	8,555	10,500	10,800
State Contract Domestic Seafood HACCP Inspections	1,098	1,200	1,250
State Contract Juice HACCP	76	100	125
State Contract LACF	84	60	75
State Partnership Inspections	189	1,000	500
State Contract and Grant Foods Funding	$16,372,900	$12,007,867	$12,968,497
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$16,705,000	$17,634	$17,730
Total State & Annual FERN Funding	**$33,077,900**	**$12,025,501**	**$12,986,227**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***19,024***	***23,860***	***24,786***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 264 foreign food inspections.

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Food and Drug Administration
FY 2012 Congressional Budget Request
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HUMAN DRUGS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$877,152**	**$883,459**	**$941,004**	**$1,151,788**	**$274,636**
Center	$741,172	$749,200	$803,747	$998,568	$257,396
FTE	3,081	3,097	3,097	3,712	631
Field	$135,980	$134,259	$137,257	$153,220	$17,240
FTE	736	738	738	791	55
Program Level FTE	**3,817**	**3,835**	**3,835**	**4,503**	**686**
Budget Authority	**$461,862**	**$462,243**	**$461,862**	**$497,534**	**$35,672**
Center	$334,188	$334,323	$334,188	$366,439	$32,251
Field	$127,674	$127,920	$127,674	$131,095	$3,421
Pay Increase (non add)				*$1,095*	*$1,095*
Protecting Patients (non-add)				*$24,796*	*$24,796*
Advancing Medical Countermeasures (non-add)				*$12,688*	*$12,688*
FDA Regulatory Science and Facilities (non-add)				*$2,752*	*$2,752*
Administrative and Contract Savings (non-add)				*-$5,659*	*-$5,659*
Budget Authority FTE	**2,085**	**1,937**	**1,937**	**2,193**	**108**
Center	1,399	1,248	1,248	1,492	93
Field	686	689	689	701	15
User Fees	**$415,290**	**$421,216**	**$479,142**	**$654,254**	**$238,964**
Center PDUFA	$406,984	$414,877	$469,559	$602,590	$195,606
FTE	1,682	1,849	1,849	2,164	482
Field PDUFA	$8,306	$6,339	$9,583	$12,298	$3,992
FTE	50	49	49	58	8
Center Generic Drugs				$29,539	$29,539
FTE				56	56
Field Generic Drugs				$6,737	$6,737
FTE				12	12
Field Medical Products Reinspection				$2,630	$2,630
FTE				18	18
Field International Courier User Fee				$460	$460
FTE				2	2
User Fees FTE	**1,732**	**1,898**	**1,898**	**2,310**	**578**

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

Human Drugs Program – Center Activities
Base Amount: $741,172,000 (BA: $334,188,000 / UF: $406,984,000)

The Human Drugs Program's mission is to promote and protect public health by ensuring that safe and effective drugs are available to Americans. The program supports FDA priorities of improving health care quality and reducing health care costs. CDER is also responsible for monitoring the safety and effectiveness of drugs once they are marketed and consumed.

Human Drugs – Field Activities
Base Amount: $135,980,000 (BA: $127,674,000 / UF: $8,306,000)

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. ORA achieve this by conducting 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.

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

*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.

(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.

New Drug Review - Center Activities
Base Amount: $411,226,000 (BA: $121,680,000 / UF: $289,546,000)

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 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.

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 draft plan for 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 analysis, 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
Base Amount: $33,310,000 (BA: $25,004,000 / UF: $8,306,000)

Public Health Focus
ORA's public health focus of New Drug Review subprogram is to assess 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:

- Have received notification from the Agency of the intent to initiate administrative proceedings to determine if the person should be disqualified from receiving investigational products;
- Persons who have been disqualified or 'totally restricted' and are no longer eligible to receive investigational drugs, biologics, or devices;
- Clinical investigators who have been recommended for disqualification;
- All clinical investigators who agreed to certain restrictions;
- Persons who agreed to restrictions which have been subsequently removed; and
- Clinical investigators who have provided FDA with adequate assurances of their future compliance with requirements applicable to the use of investigational drugs and biologics.

Additionally, 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.

Promoting Efficiency
Through its pre-approval inspection coverage, ORA prevents unsafe and ineffective drugs from being marketed to the public. 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. 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.

ORA has developed comprehensive firm history reports, reducing the amount of time an investigator spends researching a firm's history allowing for a greater focus on inspections.

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)*	FY 2009: 92% (Target Exceeded)	90%	90%	Maintain
223202: Percentage of Priority NDAs/BLAs within 6 months *(Output)*	FY 2009: 80% (Target Not Met)	90%	90%	Maintain

Generic Drug Review - Center Activities
Base Amount: $81,020,000 (BA only)

Public Health Focus
Generic drugs are widely known to be a cost-effective treatment alternative, costing consumers 20 to 70 percent less than brand-name drugs. According to the Congressional Budget Office, consumers save an estimated $8 billion to $10 billion a year by using generic drugs instead of brand-name products. 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 2009, CDER approved, or tentatively approved, 599 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 2,079 actions in FY 2010 compared to 2,006 in FY 2009.

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 such as patches that are worn on the patient's skin, injected or where there is a high variability in how they react in the human body. 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 review of generic drugs. 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 makes it imperative that CDER processes 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 New Drug Review subprogram. 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
Base Amount: $7,828,000 (BA only)

Public Health Focus
ORA's public health focus of the Generic Drug Review subprogram is to assess 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.

Performance Measures
The following table lists the performance measure associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year (Output)	FY 2010: 2079 (Target Exceeded)	1900	2000	+ 100

Drug Quality - Center Activities
Base Amount: $83,542,000 (BA: 40,160,000 / UF: $43,382,000)

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 it is used by a more 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, and monitors the quality of finished drug products in distribution through sampling and analysis.

CDER also monitors the manufacturing process for approved drug products. 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. In FY 2010, CDER exceeded its goal of inspecting 700 foreign and domestic establishments identified as high-risk human drug manufacturers by inspecting 705 high-risk firms.

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
Base Amount: $90,473,000 (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 the 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 2010, ORA entered into a 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. ORA field laboratories participated in the collaborative standards assessments of approximately 27% of the overall USP reference standards in existence prior to FY 2010.

In FY 2010, ORA worked with CDER to identify handheld portable analytical tools for use in 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. 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.

ORA continues to develop a High Throughput Drug Laboratory (HTDL) model, a highly efficient process to facilitate a high volume of sample analyses in the laboratory without requiring additional time or resources to accomplish the work. In FY 2010, ORA initiated an HTDL model targeting various cough and cold medications. The model allowed for the analysis of more than 450 products over a six week timeframe in a single ORA field laboratory assessing product potency and reviewing product labels to assure compliance with FDA regulations. The process incorporated a series of enhancements, including the utilization of technologically advanced equipment, streamlined electronic documentation, and a specialized assignments for the collection of the commodities, while maximizing existing ORA laboratory and field resources. The results of the model showed a decrease in the average time for completion of sample analysis from 37 hours per sample to 7 hours per sample while increasing the number of samples the laboratory completed in a specified timeframe (6 weeks). In addition, the laboratory was able to significantly increase the total number of samples analyzed in a single month, advancing from 25 samples per month to 360 samples per month.

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 2010, ORA worked with Customs and Border Protection (CBP) through joint operations such as Operation Safeguard 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 III, 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.

During FY 2010, ORA issued and/or updated five Import Bulletins and issued 81 notices 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 performance goal targets 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 April 2010, FDA worked with industry to notify consumers of a voluntary recall of infant and children's liquid products due to manufacturing deficiencies which may have affected the quality, purity or potency of the products. The recall encompassed several lots of products under various brand names such as Tylenol, Motrin, Zyrtec and Benedryl that were distributed within the United States and several other countries. ORA expended numerous resources towards the completion of facility inspections, sample collections/analyses and recall activities to assess the extent of the issues and assure products of concern were removed from the U.S. market while working to minimize the suspect product’s impact on the public health.

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 FY 2010, FDA classified and issued

recall numbers for 158 Class I (most serious); 389 Class II; and 321 Class III recalls of human drug products.
In FY2010, FDA's MARCS-Compliance Management System indicated seven approved injunctions and three seizures for drug products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

Some examples of recent enforcement actions include:

- **Fraudulent Chelation Products.** FDA issued warning letters to eight internet firms promoting chelation products with unproven claims to treat a range of diseases that include autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. The products were sold in a variety of dosage forms such as suppositories, capsules, liquid drops and clay baths. Three firms were also cited for promoting unapproved test kits that purported to detect the presence of heavy metals to justify the need for chelation therapy. The impact means that hundreds of thousands of consumer dollars will be saved and patients, many of them children, will be referred to available proven therapies for diseases such as autism.

- **Fraudulent H1N1 Flu Virus Products.** Since declaration by the HHS Secretary of the 2009 H1N1 Flu Virus Public Health Emergency and throughout FY 2010, FDA has taken an aggressive, proactive approach to identify, investigate, and take regulatory or criminal action against individuals or businesses that promote illegal or fraudulent H1N1 influenza products including drugs regulated by CDER. In FY 2010, FDA issued thirty warning letters, including four FDA/FTC joint letters, to offending Internet firms. As of November 2010, 95 warning letters covering 185 fraudulent H1N1 flu products have been issued resulting in a compliance rate exceeding 80 percent. The impact means that hundreds of thousands of consumer dollars will be saved and patients will be referred to available proven therapies for H1N1.

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 2010, ORA's OCI made 254 arrests, and secured 269 convictions with fines, restitutions and other monetary penalties in excess of $54 million.

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

- **Counterfeit Alli:** During the course of 2008, 2009, and 2010, the FDA issued a series of alerts on its website concerning tainted weight loss pills and counterfeit drugs. Initial alerts focused on “Superslim,” “2 Day Diet,” and Meitzitang, among other purported weight loss products believed to have been imported from China and being marketed as dietary supplements or nutritional products. The FDA stated in these initial alerts that the items posed a very serious health risk to consumers, because, based on analysis, they were found to be drugs that contained undeclared active pharmaceutical ingredients, including Sibutramine (a controlled substance), antidepressants, potent diuretics available only by prescription, and drugs not approved in the United States. In later alerts, FDA warned the public about counterfeit versions of the brand name drug 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.

  OCI initiated an investigation in January 2010 targeting the manufacturer of these products. Investigation determined that a foreign national was the individual responsible for illegally manufacturing and importing the counterfeit weight loss medication. The foreign national was arrested in March 2010. A second defendant in the U.S. was also arrested on the same date.

- **Failure to File Field Alert Reports with FDA:** An OCI investigation led to the March 2010 guilty plea by a pharmaceutical manufacturer for two felony counts of failing to file field alerts with the FDA regarding manufacturing problems related to oversized tablets of propafenone and dextroamphetamine sulfate that failed to meet product specifications. The Court sentenced the company with the maximum fine of $23,437,382, as well as ordering restitution payments to the Medicare program in the amount of $1,762,368 and the Medicaid program in the amount of $573,000 to reimburse the programs for their expenditures for drugs from the pharmaceutical manufacture that were consumed by program beneficiaries during 2008.

- **Medical Technician Sentenced to 30 Years in Prison:** An OCI investigation led to a successful prosecution in February 2010 when a surgery "scrub" technician at Rose Medical Center in Denver, Colorado was sentenced to 30 years in federal prison after pleading guilty to product tampering and obtaining a controlled substance by deceit. The defendant was a surgery “scrub” technician at Rose Medical Center in Denver and then at Audubon Surgery Center in Colorado Springs, where the defendant assisted in surgical procedures. It was discovered that the defendant had Hepatitis C while working at both facilities. The defendant was accused of stealing a powerful narcotic drug, Fentanyl, from surgical patients, injecting herself with the narcotic, and then returning the same used syringes with saline back on the surgical tray. Patients who needed the pain medication during surgery did not receive it. What they did receive, however, was exposure to the defendant's Hepatitis C. Multiple patients

at Rose Medical Center have subsequently tested positive for Hepatitis C that can be linked back to the defendant.

OCI Proactive Ongoing Initiatives:

- **Operation Pangea -** For the past three fiscal years, OCI has participated in Operation Pangea, which is an International Internet Week of Action (IIWA). For FY 2010, OCI coordinated with the ORA Office of Enforcement and CDER, to target 138 websites for illegal activity associated with prescription drugs. After months of planning**,** in less than one week CDER issued warning letters against the websites. OCI worked directly with the domain name registrars, internet service providers, and payment providers and was successful in getting 136 of the 138 websites permanently shut down. The project received positive press, and was the highlight of 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 examples of the 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 and masquerading behind the anonymity of the internet offer counterfeit and unapproved drugs to U.S. consumers, deliberately circumventing U.S. Customs and FDA regulations solely for monetary profit. Suspect websites are researched, and possible violations are identified. OCI field offices receive investigative assignments, which often include undercover buys, and other resource intensive activities, such as subpoenas and search warrants, requiring the analysis of hundreds or even thousands of emails, and voluminous financial data. OCI continues to foster strong working relationships with other law enforcement agencies in the U.S. as well as overseas to identify and prosecute violators who use the internet to sell drugs that threaten the health and safety of the American public.

- **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, but cloxacillin, an ingredient in the same class of antibiotics as penicillin (which could result in injury or death for consumers who are allergic).

Promoting Efficiency
The Government Wide Quality Assurance Program (GWQAP) has expanded access to increasing numbers of foreign regulators, providing FDA evaluations of a firm's compliance with cGMPs, which allows foreign governments to make purchase decisions based upon a firm's compliance status.

The ORA/US Pharmacopoeia (USP) collaboration assures that methods used by regulated industry are robust, comprehensive and use the most current technology. In addition, it allows for the maintenance of a high level of expertise in ORA field laboratories and increased vigilance as more complex pharmaceuticals are received for evaluation. These efforts also enhance ORA drug product surveillance by promoting the manufacturing of safe, unadulterated and effective pharmaceutical products.

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 continue 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.

ORA collaborates with other government agencies, resulting in more efficient inter-agency information sharing. For example, during FY 2010, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to leverage information sharing and analysis across numerous government agencies i to identify safety risks in imported products. Once FDA identifies risks through this collaboration, the appropriate agencies work together to minimize the risk.

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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2010: 705 (Target Exceeded)	700	750	+ 50

Post Market Safety Oversight - Center Activities
Base Amount: $144,208,000 (BA: $72,673,000 / UF: $71,535,000)

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 inform the public of such risks, in order to ensure that a drug is used properly or remove 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. 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.

The FDAAA contains important new authorities to require post market studies and clinical trials, safety labeling changes, and risk evaluation and mitigation strategies (REMS). The new safety authorities enabled FDA to transition away from mostly voluntary risk minimization action plans (RiskMAPs) to the required post market assessments and REMS. During FY 2009, FDA approved 74 drugs with required post market safety studies or clinical trials. FDA has also required REMS in place of voluntary RiskMAPs to ensure that the benefits of a drug outweigh its risks. As of January 14, 2011, FDA has approved 163 REMS, 161 of which include a medication guide. Of the REMS approved, 55 also include one or more of the following elements: communication plan, Elements to Assure Safe Use, and implementation systems.

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 protected and greatly 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 in an efficient manner.

Post Market Safety Oversight - Field Activities
Base Amount: $4,369,000 (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.

Promoting Efficiency

Congress has required that adverse drug experience information relating to all prescription drugs be made available to FDA. To meet this requirement, FDA operates an inspection program is to confirm that regulated industry is submitting all adverse drug experience reports to FDA in accordance within required time frames. The secondary focus of this program is to provide greater emphasis on verifying 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 when necessary.

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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
222303: Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA.	FY 2010: 94% (Historical Actual)	80%	80%	Maintain
222203: The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry. *(Outcome)*	FY 2009: 83% (Historical Actual)	80%	85%	+5%
222201: The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. *(Efficiency)*	FY 2010: $7.35 (Target Exceeded)	$10 / report	$10 / report	Maintain
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)*	FY 2010: 60 million	55 million	70 million	+ 15 million
292203: Number of safety	FY 2010: 15	13	13	

analyses that are conducted using Medicare and Medicaid SafeRx* pilot. *(Output)*				Maintain

<u>Oversight of Drug Promotion-</u> Center Activities
Base Amount: $21,176,000 (BA: $18,655,000 / UF: $2,521,000)

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
Standardized data will enhance the review of drug advertisements directed to healthcare professionals and/or 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)*	N/A	Issue guidance and establish baseline	30%	N/A

Information Technology Investments – Human Drugs Program
(Base Amount displayed as a non-add item: $ 96,894,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts to enhance and improve the human drug review process. CDER's Computational Science Center is a business-driven initiative to identify and implement tools, trainings, technologies, methodologies and standards to support and continually improve CDER's regulatory decision making in a quantitative fashion by advancing the science of safety, efficacy, and product quality assessment over the drug life cycle. Implementation of the Regulated Product Submission message will allow FDA to meet CDER IV IT performance goals such as cross-referencing previously submitted regulatory information. Document Archiving Reporting and Regulatory Tracking System (DARRTS) currently supports many of the regulatory applications; with the migration of biologics license applications (BLA) to DARRTS, it will provide CDER a single integrated tracking, archiving and review system for PDUFA marketing applications.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2007 Actual	$543,565,000	$315,138,000	$228,427,000	2,915
2008 Actual	$680,926,000	$353,909,000	$327,017,000	2,996
2009 Actual	$802,492,000	$437,385,000	$365,107,000	3,630
2010 Actual	$883,459,000	$462,243,000	$421,216,000	3,835
2011 Continuing Resolution	$941,004,000	$461,862,000	$479,142,000	3,835

Summary of the Budget Request

The FY 2012 budget request for the Human Drugs Program is $1,151,788,000. This represents an increase of $274,636,000 above the FY 2010 Enacted Level. The Center for Drug Evaluation and Research amount is $998,568,000, supporting 3,712 FTE. The Field amount is $153,220,000, supporting 791 FTE.

The base funding for the Human Drugs Program is $877,152,000, which includes $741,172,000 for the Human Drugs Program Center activities and $135,980,000 for the Human Drugs Program Field activities.

The mission of the Human Drugs Program is to ensure that the drugs 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 still 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.

New Drug Review

Center Activities (Base Amount: $411,226,000)

FY 2012 increase for current law user fees (PDUFA): +$132,983,000; +319 FTE

FY 2012 Initiatives

Advancing Regulatory Science Initiative: Nanotechnology (+$475,000; +1 FTE)

Developments in the science of nanotechnology present opportunities for new drug development that challenge existing drug review approaches. CDER is assessing characterization methodologies to better evaluate the physico-chemical properties of products containing nanomaterials, and investigating models and approaches to better predict human responses to such nanomaterials. This work will allow CDER to understand how best to assess the safety and efficacy of drugs based on nanotechnology.

Advancing Regulatory Sciences Initiative: Updating Drug Review Standards for New Technologies (+$2,000,000; 4 FTE)

Drug development is rapidly expanding into highly specialized and fast-evolving areas such as systems biology, genomics, proteomics, nanotechnology, and combination products. It is crucial that FDA develop capacity and capabilities in these areas and articulate clear regulatory standards for products utilizing these advanced technologies. This will help sponsors streamline their research and development activities and improve post-market risk management. By taking the guess work out of the drug development process and reducing industry risk, this will translate to more advanced therapeutic options for the American public.

In order to develop regulatory standards for cutting-edge technologies, FDA must conduct research and provide input to external groups that seek to develop, for example, new biomarkers or biosimilar products, also known as follow-on proteins or follow-on biologics.

- Once validated, new biomarkers–objectively measured biologic characteristics–will help provide clear standards against which to measure the effects of therapies utilizing these advanced technologies and will inform the development of regulatory standards.
- Biosimilars provide alternatives to brand-name protein products produced through biotechnology or derived from natural sources.

Protecting Patients Initiative: Human Subject Protection in Clinical Trials
($500,000; +1 FTE)

FDA will implement a quantitative risk-based program to target clinical site inspections. This will be paired with a separate initiative to increase inspections. These resources will allow FDA to implement a quantitative risk-based program to target inspection resources at high-risk clinical and laboratory sites where bioequivalence studies are conducted. This initiative will assist FDA in ensuring the quality of data on which bioequivalence assessments are made in the generics program.

Medical Countermeasures Initiative (+$6,153,000; +22 FTE)

Under MCM Pillar 1, CDER will actively participate in the Public Health & Security Action Teams (PHSATs) to ensure that the highest priority MCM products and technologies receive the necessary support throughout the product lifecycle. CDER will hire additional personnel who will serve as valuable reviewers and liaisons among FDA, PHSATs, and sponsors throughout the review process.

Under MCM Pillar 2, CDER will engage with industry and federal partners to address challenges with the development of animal models needed for the regulatory assessment of MCMs. CDER will begin to establish external partnerships to advance regulatory science for MCM.

Under MCM Pillar 3, CDER will work with the Office of the Commissioner to analyze gaps and optimize the legal and policy framework needed for an effective emergency public health response

Biosimilars Initiative: (+$8,522,000; +19 FTE)

The requested funds will enable FDA to hire additional scientific, analytical, regulatory, and legal staff with the expertise needed to address the broad regulatory issues associated with biosimilars. FDA will also provide essential product-specific advice through pre-IND and pre-application meetings, and review submissions. These funds will also support the acquisition of additional laboratory capacity to develop physical reference standards needed for biosimilar review and manufacturing quality assurance.

With the requested funds, FDA will accomplish the following activities:

• Develop a work plan for implementing the new provisions, including proposed regulations, draft guidance documents, and a user fee program that must be established for biosimilar biological products.
• Establish a process for addressing urgent inquiries from sponsors, including requests for meetings to clarify the potential impact of the Section 351 of the Public Health Service Act (42 U.S.C. 262) provisions on existing and new development programs.
• Develop draft guidance as they relate to the implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

• Conduct meetings with stakeholders, experts, regulated industry, and the public regarding key scientific and regulatory issues and provide input related to the implementation of the BPCI Act.
• Develop recommendations and options for a Biosimilars User Fee Program.

This initiative directly supports the HHS priority of transforming health care through improved coverage, cost control and quality outcomes, focusing on reducing health care costs while promoting high value and effective care.

Field Activities (Base Amount: $33,310,000)

FY 2012 increase for current law user fees (PDUFA): +$ 3,992,000; +8 FTE

FY 2012 Initiatives

Advancing Regulatory Science Initiative: Nanotechnology
(+$277,000; +1 FTE)

For the nanotechnology initiative, ORA's Arkansas Regional Laboratory will conduct activities that support the following FDA-wide priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Biosimilars Initiative: (+$420,000 / +2 FTE)

FDA will hire the scientific, analytical, regulatory, and legal staff to address the broad regulatory issues relating to biosimilars. FDA will also provide essential advice in pre-IND and pre-application meetings, and review submissions. These funds will also support the acquisition of additional laboratory capacity to develop physical reference standards needed for biosimilar review and assuring manufacturing quality.

ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance ORA will be able to conduct eight domestic pre-approval NDA inspections by FY 2014 and five foreign pre-approval NDA inspections by FY 2015.

Medical Countermeasures Initiative: (+$655,000 / +3 FTE)

Under Pillar 1, ORA Field operations will conduct enhanced inspection and compliance activities, identify as early and efficiently as possible problems that impede MCM product development, and provide technical assistance to minimize risk during MCM product manufacturing. With these resources, ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance, ORA will

be able to conduct ten MCM inspections by FY 2014 and an additional 13 foreign MCM inspections by FY 2015.

Generic Drug Review

Center Activities (Base Amount: $81,020,000)

FY 2012 increase for proposed user fees (GDUFA): +$19,200,000; +36 FTE

Protecting Patients Initiative: Generic Drug Review (+$2,000,000; +4 FTE)

FDA will augment the resources devoted to reviewing generic drug applications to ensure that safe and effective generic drug products are made available to the public. The initiative augments the generic drug review program by expanding FDA's capacity to protect public health, promote public confidence in generic drugs, and thus sustain the availability of the generic industry. These additional funds will enhance FDA's ability to conduct timely, complete reviews of generic drug applications with quality standards equivalent to the brand industry, and support development of regulatory scientific standards for equivalence needed to encourage development of new generic drug alternatives for more complex dosage forms.

The FY 2012 budget request proposes a user fee structure for the review of generic drug applications (known as abbreviated new drug applications). These resources will ensure that the generics review staff can hire additional reviewers to speed up the process of getting new generic drugs to market. Given that approximately 70 percent of prescriptions are now written for generic products, and that generic products can be significantly less expensive than brand name drugs, this initiative stands to have a material impact on Americans' pocketbooks. The user fee dollars will be used not only to hire additional staff but to also support the development of industry guidance and scientific standards to further expand the availability of generic alternatives in a wide range of dosage forms and product lines.

Field Activities (Base Amount: $7,828,000)

FY 2012 increase for proposed user fee (GDUFA): +$6,737,000; +12 FTE

FY 2012 Initiatives

Protecting Patients Initiative: Increasing Medical Product Inspections (+$621,263; +3 FTE)

FDA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2014 due

to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This initiative is the inspectional effort that ties to other initiatives, including the Improving Human Subject Protection initiative.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete hiring of 3 additional employees and will have begun training these employees. By September 30, 2015, once the new employees are fully trained, ORA will conduct an additional 15 foreign generic drug bioequivalence laboratory inspections.

Drug Quality

Center Activities (Base Amount: $83,542,000)

FY 2012 increase for current law user fees (PDUFA): +$28,313,000; +70 FTE

FY 2012 Initiatives

Protecting Patients Initiative: Launching Electronic Drug Registration and Listing System to Stop Illegal Imports (+$3,300,000; +6 FTE)

FDA will complete and validate a new electronic drug registration and listing system. This system will enable FDA access to information regarding drug products, ingredients, firms, and facilities around the world, thereby improving FDA's ability to efficiently and effectively screen imports of drugs at the border.

Protecting Patients Initiative: Partnering with Foreign Authorities to Leverage Capabilities (+$730,000; +3 FTE)

FDA will increase its capacity to work with other countries' regulatory authorities that perform high-quality inspections, and to establish strong incentives for meeting international manufacturing quality standards. This funding is necessary for FDA to be able to better ensure the safety of the U.S. drug supply by inspecting high-risk establishments in every corner of the globe and to allow the agency to enhance its relationships with foreign regulatory agencies. Enhanced collaboration among FDA and

foreign regulatory agencies will help prevent unsafe products from being exported to the U.S. This will also increase FDA's capacity to exchange information with foreign regulatory agencies.

Protecting Patients Initiative: Improve Oversight of Drug Quality through Inspections of Foreign Drug Manufacturing Facilities (+$500,000; +2 FTE)

CDER will target the highest risk manufacturing facilities and provide expert staff to participate in inspections of overseas drug manufacturing facilities. Funding will enable the hiring of two expert pharmaceutical inspectors. New personnel will augment FDA's ability to inspect an increasing percentage of high-risk manufacturing establishments, particularly those in foreign countries. An increase in FDA field drug inspection resources will also support this initiative.

Medical Countermeasures Initiative: (+$2,520,000; +9 FTE)

Under MCM Pillar 2, CDER will conduct collaborative research to assess the utility of mass spectrometry, in vitro biological assays, and other technologies to analyze the effects of radiation on stockpiled therapeutic proteins. CDER will also examine and prepare for the development of animal models to predict the safety and efficacy of new products in humans when testing such products on humans is unethical or not feasible. MCM products also have to work as expected in large-scale events such as terrorist attacks, pandemics, or large-volume, rapid scale-ups of manufacturing. This will require development of supporting quality analytics and productive technologies. CDER will conduct research to improve assessment of the shelf-life of MCM products in the Strategic National Stockpile.

Under MCM Pillar 3, CDER will work with the Office of the Commissioner to analyze gaps and optimize the legal and policy framework needed for an effective emergency public health response.

Field Activities (Base Amount: $90,473,000)

FY 2012 increase for proposed user fees (Reinspection): + $2,630,000; +18 FTE

FY 2012 Initiatives

Protecting Patients Initiative: Increasing Medical Product Inspections (+$2,702,737; +13 FTE)

FDA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2015 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This initiative is the inspectional effort that ties to other initiatives, including the initiative to Improve Oversight of Drug Quality through Inspections of Foreign Drug Manufacturing Facilities.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete hiring of 13 additional employees and will have begun training these employees. By September 30, 2015, once the new employees are fully trained, ORA will conduct an additional 46 foreign GMP surveillance drug process inspections.

FY 2012 Proposed User Fee: International Courier (+460,000; +2 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. Current FDA staffing does not match the growth in import volume. Couriers expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee. The user fee resources will support increased import surveillance of FDA-regulated products at express courier hubs

FDA will conduct entry reviews, sample collections and physical exams to determine product admissibility into the U.S., initiate compliance actions to prevent release of unsafe products into U.S. commerce and establish import controls to prevent future unsafe products from entering U.S. commerce.

This user fee supports patient safety and reduces health care costs by keeping unapproved and counterfeit products out of U.S. commerce.

Post Market Safety Oversight

Center Activities (Base Amount: $144,208,000)

FY 2012 increase for current law user fees (PDUFA): +$32,942,000; +90 FTE

FY 2012 increase for proposed user fees (GDUFA): +$10,339,000; +20 FTE

FY 2012 Initiatives

Protecting Patients Initiative: Improving Post Market Safety Activities (Sentinel Initiative) (+$5,000,000; +9 FTE)

FDA will improve its ability to transition from a series of pilot projects and research activities into a fully functional National Sentinel System Network - a national electronic system for monitoring medical product safety contained in various private and public sector and large health care databases. The Sentinel Initiative is a collaborative effort, as mandated in Section 905 of FDAAA.

Because of its technical and scientific complexity, the Initiative depends on leveraging the resources and expertise of those within the FDA and other public- and private-sector organizations. Multiple contracts - eight in 2008 and three in 2009 - have been competed and let to evaluate a variety of key foundational issues that will inform the development of the Sentinel System. It is expected that most of the pilot projects described here will be accomplished using a variety of mechanisms such as contracts, cooperative agreements, and interagency agreements.

Protecting Patients Initiative: Promoting the Safe Use of Drugs (+$500,000; +1 FTE)

These funds will enable the hiring of one FTE to help manage the Safe Use Initiative, with responsibilities including outreach to stakeholders and the public, research, project management, and other duties as required. These funds will also cover related operating expenses including training, travel, contracts, and overhead expenses. Specific projects may target certain populations at greater risk of injury from preventable adverse drug events such as children or elderly patients taking multiple medications. Other examples include certain medication errors (drug mix-ups), incorrect prescriptions, inadvertent overdosing, and avoidable drug interactions, while providing opportunities for skilled graduate students or researchers to examine data they would otherwise not be able to access.

Medical Countermeasures Initiative: (+$3,360,000; +12 FTE)

Under MCM Pillar 2, CDER will support targeted communication research related to medical countermeasures. The goals of the research will be to improve understanding of how best to communicate critical information to public health authorities, health care providers, and recipients of MCMs in emergency circumstances. This initiative will improve FDA’s understanding of how people most effectively receive, process, and understand communication about products used in emergencies, thereby improving the ability of the public health community to effectively act during a public health emergency.

CDER will improve methods and access to data sources to monitor safety and use of MCM products to obtain vital information about how these products perform in an emergency. This will also improve its ability to conduct post market influenza surveillance. Medical products administered in response to influenza are particularly complex to monitor due to the compressed timeframe in which they are administered, the diverse target populations, and the non-traditional health care settings in which these products are utilized. Improved surveillance will increase FDA's capacity to monitor the safety and effectiveness of influenza products, and mitigate risks associated with improper or unsafe use of MCM products.

Under MCM Pillar 3, CDER will work with the Office of the Commissioner to analyze gaps and optimize the legal and policy framework needed for an effective emergency public health response.

Field Activities (Base Amount: $4,369,000)

Oversight of Drug Promotion

Center Activities (Base Amount: $21,176,000)
FY 2012 increase for current law user fees (PDUFA): +$1,368,000; +3 FTE

BA Increase for Pay Costs

+$1,095,000 (Center: $779,000; Field: $316,000)

Contract and Administrative Savings

Total Program: -$5,659,000

The request for $497,534,000 in total budget authority for the Human Drugs Program also reflects a contract and administrative savings reduction of -$5,659,000 for FY 2012. The Center's portion of the these savings is -$4,088,000 and the Field's portion is -$1,571,000 and 7 FTE.

Center Activities

2012 Initiatives

Contract and Administrative Savings (-$4,088,000; -0 FTE)

The Center for Drug Evaluation and Research (CDER) will achieve contract savings by:

- performing certain research into epidemiological or adverse event issues in partnership with academic institutions rather than through research contracts;

- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting;

- reducing the amount spent on training activities by reducing training and identifying lower-cost training options; and

- evaluating CDER contracts and administrative spending to identifying and eliminating under-used resources.

Field Activities

2012 Initiatives

Contract and Administrative Savings (-$1,571,000; -7 FTE)

The Field will achieve contract savings by:

- Obtaining the best value for the American Public through blanket purchase agreements and agency-wide approaches to contracting.

- Reducing administrative support by 7 FTE, both in Headquarters and in the field offices, and by consolidating tasks and eliminating redundancies, ORA anticipates productivity and efficiency gains throughout the organization.

Center Drugs Program Activity Data (PAD)

CDER Workload and Outputs			
New Drug Review	**FY 2010 Actual**	**FY 2011 Estimate**	**FY 2012 Estimate**
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	103	141	141
Efficacy Supplements	108	123	123
Manufacturing Supplements	1,789	1,850	1,903
Commercial INDs (Drugs and Biologics) with Activity	5,784	5,500	5,500
Sponsor Requests: IND-Phase Formal Meetings	1,729	1,729	1,800
Sponsor Requests: Review of Special Study Protocols	323	323	323
Submissions of Promotional Materials	79,596	80,000	80,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	24	24	24
Reviews: Standard NDA/BLA	144	140	150
Approvals: Priority NDA/BLA	15	15	15
Approvals: Standard NDA/BLA	76	72	72
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	11.8	11	11
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	17.7	17	16
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	9	9	9
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10	10	10
Reviews: NDA Supplementals	2,838	2,900	3,000
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	5,348	5,722	6,540
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	82	82	90
Receipts: IND/IDE Amendments (Biologics Only)	16,677	16,700	16,700
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	9	9	9
Approvals: PLA/BLA	8	8	8
Reviews: License Supplement (PLA/ELA/BLA)	219	220	220
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	813	820	820
Outputs – Reviews/Approvals			
Actions – ANDA	2,079	2,000	2,000
Approval Actions - ANDA (both Tentative and Full Approvals)*	565	565	700*
Median Review Time from ANDA Receipt to Approval (months)	26.7	26.7	17.5*
Actions - ANDA Supplementals (Labeling and Manufacturing)	3,681	3,700	5,000
***Assumes additional generic drug user fee resources.			
Over-the-Counter Drug Review			
OTC Monographs Under Development**	28	28	28
OTC Monographs Published**	6	5	5
**Category includes Proposed Rules and Final Rules			
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	6	5	5
New Written Requests Issued	16	16	16
Pediatric Exclusivity Determinations made	3	5	5
Post Exclusivity Safety Report	9	9	9
Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	717,061	720,000	720,000
Electronic Submissions: % of Total Adverse Drug Reaction Reports	73%	80%	85%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	87%	90%	90%
Submissions: Drug Quality Reports	7,827	11,000	12,000
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	1,972	1,900	1,900
Number of drugs with Risk Communications	100	100	100
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	50	45	50
Number of FOI Requests	2,455	2,500	2,500
Number of FOI Requests Processed	2,733	2,700	2,700
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	72	100	100
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	237	289	295
Number of Citizen Petitions Completed [1] (excluding suitability petitions and OTC monograph-related petitions)	79	80	80

[1] Citizen Petitions completed may include petitions filed in prior years.

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,159***	***2,236***	***2,236***
Pre-Approval Inspections (NDA)	154	197	197 [1]
Pre-Approval Inspections (ANDA)	63	91	91
Bioresearch Monitoring Program Inspections	548	558	558
Drug Processing (GMP) Program Inspections	1,174	915	915
Compressed Medical Gas Manufacturers Inspections	231	285	285
Adverse Drug Events Project Inspections	79	147	147
OTC Monograph Project and Health Fraud Project Inspections	31	221	221
Domestic Laboratory Samples Analyzed	1,908	888	888
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***639***	***587***	***587***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	201	117	117 [2]
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	106	62	62
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	214	231	231 [3]
Foreign Drug Processing (GMP) Program Inspections	380	490	490 [4]
Foreign Adverse Drug Events Project Inspections	5	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,798***	***2,823***	***2,823***
IMPORTS			
Import Field Exams/Tests	7,696	6,200	6,200
Import Laboratory Samples Analyzed	253	405	405
Import Physical Exam Subtotal	**7,949**	**6,605**	**6,605**
Import Line Decisions	409,728	473,758	547,794
Percent of Import Lines Physically Examined	1.94%	1.39%	1.21%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***146***	***146***	***146***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	124	124	124
State Partnership Inspections: GMP Inspections	22	22	22
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,944***	***2,969***	***2,969***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014 for medical countermeasure (MCM) and biosimilar domestic inspections. During the full performance year (FY 2014), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 10 MCM and 8 biosimilar domestic pre-approval NDA inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015 for medical countermeasure (MCM) and biosimilar foreign inspections. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 13 MCM and 5 biosimilar foreign pre-approval NDA inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015 for foreign generic drug bioequivalence laboratory inspections. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 15 foreign bioresearch monitoring inspections.

[4] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 46 foreign GMP surveillance inspections.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT[1]

The following table displays funding levels for FY 2010 through FY 2012.

	FY 2010 Enacted	FY2010 Actual	FY2011 CR	FY 2012 Request	+/- FY 2010 Ennacted
Program Level [1]	**22,109,801**	**22,785,290**	**22,183,385**	**22,260,610**	**$150,809**
Orphan Product Grants [2]	14,035,060	14,035,060	14,035,060	14,035,060	-
Pediatric Consortia Grants [3]	3,000,000	3,000,000	3,000,000	3,000,000	-
Program Administration [4]	5,074,741	5,750,230	5,148,325	5,225,550	150,809

[1]Orphan Product Grants are part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.

[2]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.

[3]Program Administration is part of the aggregate amount of budget authority contained in the Other Activities budget line item of the All Purpose Tables.

[4] FY 2010 includes a $1,200,000 increase to implement FDAAA and will support 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 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: The ODA has been very successful – as of September 30, 2010, 353 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 device programs under the Food Drug and Cosmetic Act – 50 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. Furthermore, the discovery and innovation of medical products for smaller populations has potentially positive public health implications for personalized health care in the future.

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.

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, 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. Grants ensure that product development occurs in a timely manner with a very modest investment. 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 45 to 60 ongoing grant-funded projects. A major portion of the appropriated funds for a given fiscal year go towards continued funding of previously approved grants.

Public Health Outcome: There have been 45 products approved by FDA for marketing which received development support from the orphan grants program. Highlights of these include treatments for Fabry Disease (approved in 2003), Mucopolysaccharidosis Type II, also known as Hunter Syndrome (approved 2006), Cystic Fibrosis patients with Pseudomonas Aurginosa (approved 1997), infant botulism (approved 2003), and a titanium expandable rib prosthesis for Thoracic insufficiency syndrome (approved 2004). A more recent example of the success of the orphan grants program was the approval in 2008 of the Diaphragm Electrical Stimulator for ventilator dependent tetraplegic patients. This new device increases patient mobility and reduces the noise and social stigma patients must endure.

In FY 2010, OOPD funded 18 new grants (out of 80 applications) and provided funding for approximately 28 other ongoing clinical study projects. Research projects that recently were awarded new grants include studies for the treatment coral snake venom, pediatric Graves disease, advanced melanoma, cystic fibrosis, pediatric brain tumor imaging, and corneal epithelial defects.

Promoting Efficiency: Funding clinical trials for promising orphan products continues to reap significant public health benefits to society. [2] Not only have 45 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.

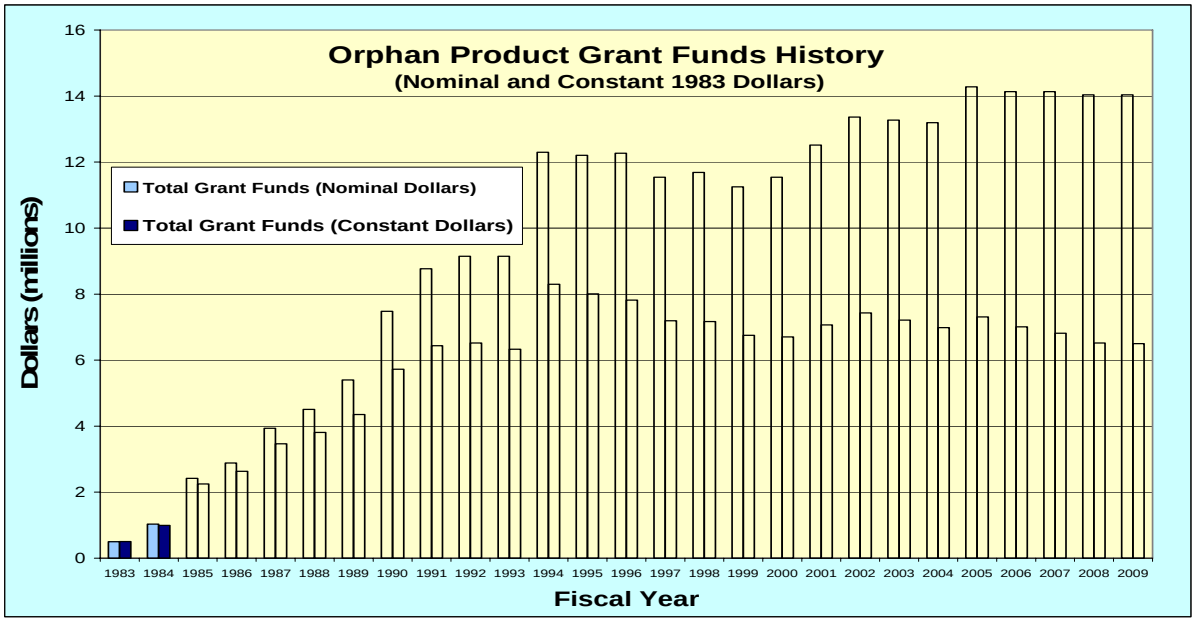
FDA grant funds are covering less and less of the cost for conducting clinical trials. The cost of clinical trials continues to increase far faster than the rate of inflation. For example, pediatric study costs increased eight-fold between 2000 and 2006 as a result of more complexity.[3] In addition, 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

[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)

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]

Because of the increased costs of clinical trials noted above, FDA recently increased the maximum grant award amount and maximum number of grant years. Going into FY 2011 there is a large portfolio of existing clinical studies awarded multi-year grants in prior fiscal years. These approved ongoing studies receive their annual grant award first, and with the remaining appropriated funds, the FDA awards new orphan product grants. With increased award amounts and increased number of award years, and if there are no increases in the amount of grant funds appropriated in FY 2011, the FDA expects that it can only fund up to eight new orphan product grants in FY 2011.



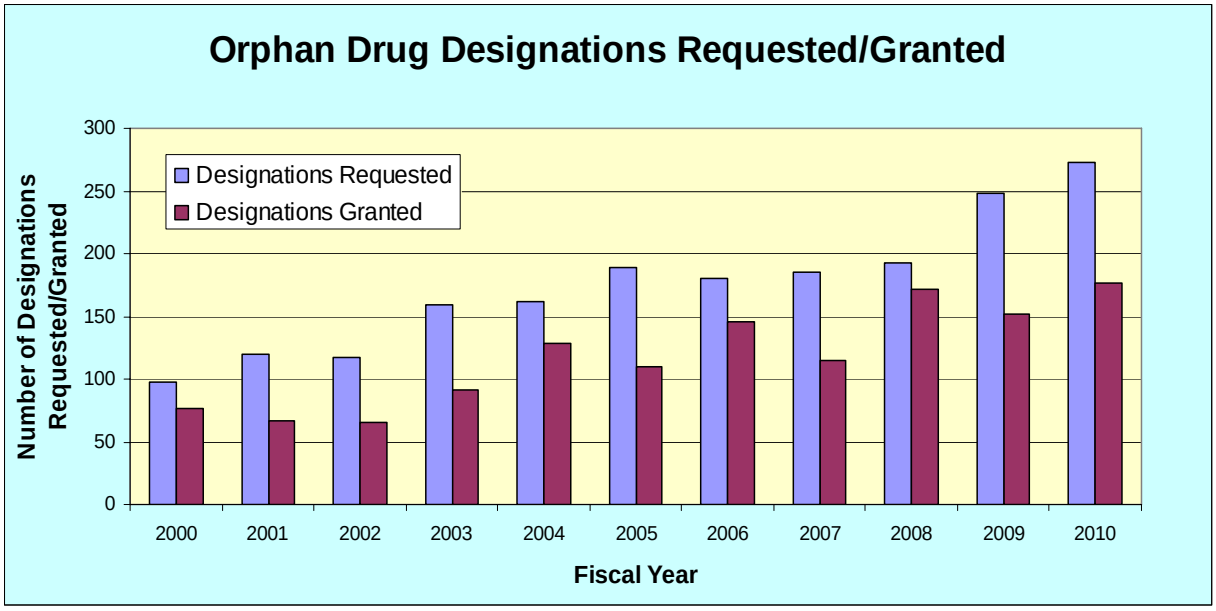
Orphan Drug Designation Activity

Public Health Focus: There are an estimated 7,000 rare diseases, with a public health impact directly affecting more than 25 million people (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

[4] Field, M.J. and T.F. Boat, editors. Rare Diseases and Orphan Products: Accelerating Research and Development. *Institute of Medicine.* 2010.

that affect fewer than 200,000 persons in the U.S. Medical products for diseases or disorders that affect more than 200,000 persons 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 market exclusivity for a specific indication following the approval of the product by FDA.

Pubic Health Outcome: Of the 2,278 orphan designations issued by OOPD, 353 have resulted in marketing approval with orphan exclusivity. During FY 2010, OOPD reviewed 273 applications for orphan designation, the most ever in a single year.. These include potential treatments for many kinds of cancers, multiple myeloma, sickle cell disease, and pediatric ulcerative colitis. OOPD designated 177 orphan drugs in FY 2010.



The number of requests for orphan designation has more than doubled in the last ten years (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 2010, 38.5 percent of all the new molecular entities (NME) approved by the FDA were orphan designated drugs and biologics.

FDA approved 11 prior orphan designated drugs for marketing in FY 2010. One recent example is the marketing approval in March 2010 of Viread (tenofavir) for the treatment of HIV infection in combination with other antiretroviral agents in children from 12 to less than 18 years old. This disease affects approximately 50,000 to 100,000 people in the

United States. This drug, which was given orphan status in March 2009, was approved in one year.

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).

Public Health Outcome: 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. In FY 2010, OOPD received 28 HUD applications and designate 14 of these.

An HDE approved in January 2010 is a transcatheter pulmonary valve for the treatment of pediatric and adult patients with congenital malformation of the pulmonary heart valve. The heart valve is implanted through a catheter, which can prevent or delay the need for open heart surgery. This option is thus a much less invasive procedure to treat heart conditions.

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				FY 2012 +/- FY 2011
Increase the total number of decisions on applications for promising orphan drug and humanitarian use device designations. Baseline period is FY 2008 Target period is FY 2009 - 2013	FY 2009: 269 FY 2010:301	312	335	+23

Pediatric Consortia Grants Activity

Public Health Focus: 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. There currently exists a great public health need for medical devices designed specifically with children in mind. 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, four Pediatric Device Consortia have been established under this program; collectively they have helped facilitate the early development of over 80 potential medical devices for children." The four 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/).

Promoting Efficiency: The goal of FDA's Pediatric 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.

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

Measure				FY 2012 +/- FY 2011
Increase the number of medical devices facilitated in development by the new Pediatric Device Initiative (program funded through 2011)	FY 2009: N/A FY 2101: 80	90 under development	100 under development	+10

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; 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 assisting patients and advocacy groups on issues of concern related to rare diseases and orphan products, such as drug shortages.

Public Health Outcome: OOPD participated in various public health outreach activities during FY 2010. Some of these activities include participation in international governmental conferences, patient support meetings, and meetings addressing rare medical conditions. In FY 2010**,** OOPD received more than 75 invitations/requests to speak/participate at orphan-drug stakeholders' meetings. OOPD made presentations at nearly 50 of these meetings. The presentations ranged in scope from explaining to a

small patient advocacy group with less than 250 patients in this country how orphan drugs and humanitarian devices could be developed with ODA incentives and HDE provisions 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 prominently explained and displayed, and the questions and concerns from stakeholders were satisfactorily addressed. Examples of public health related OOPD outreach activities in FY 2010 include:

- Co-sponsored an extramural training course in Maryland on the important aspects of designing and analyzing clinical trials in small populations
- Co-sponsored 2 workshops (California and Minnesota) for drug sponsors on preparing an application for requesting an orphan drug designation,
- Presented at the 6th International Conference on Rare Disease and Orphan Drugs in Buenos Aires,
- Presented at the Neglected Disease Forum in Washington, D.C., sponsored by the Tufts Center for the Study of Drug Development
- Presented at the 11th Annual Rett Syndrome Symposium in Leesburg, Virginia.

Promoting Efficiency: OOPD continues its public health outreach activities to increase the feasibility and level of sponsor interest in orphan products development through the orphan grants program, orphan designations programs, and HUD program. Companies and others interested in commercializing new products for rare diseases and conditions often seek the advice of OOPD staff. 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 and potentially useful to patients with rare diseases. 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. OOPD provides valuable expertise in regulatory concerns and facilitation with the FDA review divisions.

Five Year Funding Table

The following table displays funding levels from FY 2007 through FY 2011 for the Office of Orphan Products.

Fiscal Year	Program Level
2007 Actual	$17,167,256
2008 Actual	$17,691,161
2009 Actual	$19,840,060
2010 Actual	$22,785,290
2011 CR	$22,183,385

Budget Overview and Supported Activities

Summary of the Budget Request

The FY 2012 President's Budget request for the Office of Orphan Products Development is $22,183,385. The request represents an increase of $ 150,809 above the FY 2010 enacted. This change represents the total FY 2012 inflation increase

Office of Orphan Product Development
Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2009 Actual	FY 2010 Actual	FY 2011* Estimate	FY 2012 Estimate
GRANTS PROGRAMS				
New Orphan Product Grants Awarded	22	18	8	8
Total Pediatric Consortia Grants (new and continuations)	3	4	4	4
ORPHAN DRUG REQUESTS, DESIGNATIONS, AND MARKET APPROVALS				
Designation Requests	248	273	290	310
Designations	153	177	218	230
Market Approvals	19	11	22	24
HUD REQUESTS AND DESIGNATIONS				
Designation Requests	18	28	22	25
Designations	11	14	11	12

*preliminary estimates based on recent year

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Food and Drug Administration
FY 2012 Congressional Budget Request
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BIOLOGICS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table

(Dollars in thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$304,374**	**$291,430**	**$317,787**	**$368,260**	**$63,886**
Center	$260,305	$249,416	$273,182	$320,803	$60,498
FTE	1,003	1,023	1,023	1,131	128
Field	$44,069	$42,014	$44,605	$47,457	$3,388
FTE	230	227	227	239	9
Program Level FTE	**1,233**	**1,250**	**1,250**	**1,370**	**137**
Budget Authority	**$205,563**	**$205,542**	**$205,563**	**$224,933**	**$19,370**
Center	$165,490	$165,596	$165,490	$183,775	$18,285
Field	$40,073	$39,946	$40,073	$41,158	$1,085
Pay Increase (non add)				*$481*	*$481*
Protecting Patients (non-add)				*$8,192*	*$8,192*
Advancing Medical Countermeasures (non-add)				*$11,790*	*$11,790*
FDA Regulatory Science and Facilities (non-add)				*$1,425*	*$1,425*
Administrative and Contract Savings (non-add)				*-$2,518*	*-$2,518*
Budget Authority FTE	**858**	**874**	**874**	**926**	**68**
Center	637	652	652	700	63
Field	221	222	222	226	5
User Fees	**$98,811**	**$85,888**	**$112,224**	**$143,327**	**$44,516**
Center PDUFA	$83,747	$76,781	$96,624	$123,998	$40,251
FTE	335	341	341	399	64
Field PDUFA	$3,489	$1,685	$4,025	$5,165	$1,676
FTE	5	5	5	6	1
Center MDUFMA	$11,068	$7,039	$11,068	$13,030	$1,962
FTE	31	30	30	32	1
Field MDUFMA	$507	$383	$507	$597	$90
FTE	4	0	0	4	0
Field Reinspection				$537	$537
FTE				3	3
User Fees FTE	**375**	**376**	**376**	**444**	**69**

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*
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's responsibility is to help ensure the safety, purity, potency, and effectiveness of biological products, including vaccines and allergenics, 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. The Biologics Program also helps to defend the public against the threats of emerging infectious diseases and potential acts of bioterrorism through preparedness planning and the development, licensing, and ensuring the availability of safe and effective medical countermeasures. These countermeasures are used to diagnose, treat, or prevent disease from pathogen exposure.

The 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. In 1988, this Bureau became the Center for Biologics Evaluation and Research (CBER), a Center within FDA. The FDA Biologics Program consists of CBER and the Office of Regulatory Affairs' Field Biologics Program.

The Field Biologics component in the Office of Regulatory Affairs (ORA) supports Biologics Program activities by being the "boots on the ground," assessing industry compliance with the applicable regulations to protect the public health. ORA achieves this by conducting domestic and foreign inspections, performing entry review and import field exams on imported products, investigating adverse events and consumer complaints, and monitoring and evaluating compliance with recalls of violative products. In the instance of unsatisfactory inspectional outcomes, ORA seeks to further defend the public health by taking corrective actions.

The Biologics Program is funded by budget authority and is also supported by user fees (UF), for example, user fees for prescription drug and medical device review 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.

Regulatory responsibilities are executed in three subprograms: 1) Vaccines Premarket Review and Postmarket Safety (including allergenics); 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 base funding in these subprograms are as follows:

Vaccines Premarket Review and Postmarket Safety – Center Activities
Base Amount: $125,556,170 (BA: $74,470,500 / UF: $51,085,670)

Public Health Focus

The public health focus of the Vaccine Premarket Review and Postmarket Safety subprogram is to ensure that Americans have access to safe and effective vaccines and allogenic products. Vaccines touch American lives on a daily basis, and have reduced preventable infectious diseases with fewer people experiencing the devastating effects of measles, pertussis and other illnesses such as influenza. CBER plays a critical role in fostering the development and increasing the availability of safe and effective biological products that preserve public health by helping to control emerging infectious diseases.

Public Health Outcome

CBER has an important role in the development and regulation of vaccine products, starting early in the premarket process and continuing while the product is on the market. To encourage and expedite development of new vaccines to protect the public health, CBER continues to optimize the vaccine development, review, and licensing processes. CBER develops animal models that potentially predict vaccine effectiveness and, in the case of influenza vaccines, develops new potency assays, and prepares anti-sera for use in potency testing of these vaccines. CBER also studies the genetic makeup of reference influenza viruses to determine their potential to grow easily in eggs or cell cultures, a characteristic important in increasing manufacturing yield for influenza vaccines.

FDA's investments have improved the infrastructure for increasing manufacturing diversity and capacity for pandemic influenza vaccine production. CBER has advanced the science and regulatory capacity necessary for ensuring timely licensure of vaccine products, created reference materials for manufacturers to make the vaccine, and fostered international cooperation among foreign governments and international organizations, including the World Health Organization (WHO).

Monitoring the safety of vaccines after licensure ensures they are safe under conditions of use in the general population, identifies rare adverse effects that might alter the risk-benefit profile, and provides evidence that using vaccinations to prevent death and disease is safe and effective. As part of post-marketing commitments or requirements, CBER continues to monitor the safety and/or effectiveness of vaccines. CBER monitors the Vaccine Adverse Event Reporting System which collects information about adverse

events that may occur after the administration of licensed vaccines. In addition, the Centers for Disease Control and Prevention (CDC) and CBER perform studies and rapid-cycle analysis through the Vaccine Safety Datalink, an active surveillance system with eight health-maintenance organizations. CBER also conducts final lot release testing to ensure a product is safe and effective prior to industry releasing the product on the market. CBER is working with other Department of Health and Human Services (HHS) counterparts to actively monitor adverse events associated with immunization.

To further enhance the safety of vaccines, CBER established an interdisciplinary Vaccine Safety Team that increased collaboration, coordination, evaluation and communication and is poised to respond to complex and emerging vaccine safety issues. For example, CBER developed tests to assess the tumor-forming potential of cell cultures that Industry may use in the manufacturing of vaccines and screening for contaminating infectious agents.

Under the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization of Prescription Drug User Fee Act (PDUFA), the Sentinel project, and Risk Evaluation and Mitigation Strategies, FDA has received increased regulatory authority and responsibility to improve vaccine safety surveillance. PDUFA enables the Biologics Program[1] to ensure the timeliness and predictability of FDA review of new Biologics License Applications (BLAs) for vaccine products. Under the PDUFA program, FDA agreed to pursue a comprehensive set of application review performance goals. During FY 2009, the latest completed performance period, the Biologics Program met two of its three user-fee performance goals for the Vaccines Premarket Review and Postmarket Safety subprogram. CBER completed review and action on 75 percent of four priority applications within six months of receipt. The goal was missed because critical new data were submitted by the sponsor near the PDUFA review deadline for one application. CBER decided to continue the review and not to issue a Complete Response letter needed to meet the PDUFA review deadline because of the public health importance of the vaccine.

In response to the outbreak of the 2009 novel influenza A (H1N1) virus, CBER collaborated with the CDC, HHS and other partners to provide a coordinated public health emergency response. CBER, working extensively with U.S. licensed manufacturers of seasonal influenza vaccines, approved five manufacturers to produce vaccine against the 2009 H1N1 virus. In addition, CBER approved eleven manufacturing supplements for seasonal influenza vaccine manufacturers to expand vaccine-manufacturing capacity. Internationally, CBER coordinated with other countries to achieve a common understanding of the regulatory approaches and to harmonize advice to manufacturers, where possible, for the production of H1N1 vaccine. CBER

[1] CBER is showing its performance measures goal table by subprogram but several of the program measures are Prescription Drug User Fee (PDUFA) that span several subprograms. Performance results for PDUFA measures contained in the subprogram performance tables will be stated in the subprogram narratives. PDUFA measures cover CBER's Cells, Tissue and Gene Therapy Premarket Review and Postmarket Safety and Vaccine Premarket Review and Postmarket Safety subprograms.

also worked with the WHO Essential Regulatory Laboratories to generate pandemic influenza reference strains and reagents needed for pandemic H1N1 vaccine development and helped select and grow a reference virus for the H1N1 vaccine. For the 2010-2011 influenza season, CBER approved seven vaccines that protect against seasonal influenza and the 2009 H1N1 influenza viruses.

CBER met the FY 2010 performance target of completing and evaluating a pilot vaccine adverse effects program and participating in one international workshop or conference. Other specific accomplishments include finalizing guidance for industry to facilitate vaccine production, and the approval of the BLA supplement for Gardasil which prevents genital warts in males nine to 26 years of age. CBER also approved Menveo, a Meningococcal ACWY Conjugate Vaccine for active immunization of persons 11 to 55 years of age to prevent invasive meningococcal disease caused by Neisseria meningitis serogroups and Prevnar 13, a Pneumococcal 13-valent Conjugate Vaccine for the active immunization to prevent invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes for infants and toddlers.

Promoting Efficiency

CBER plays a critical role in fostering the development and increasing the availability of safe and effective biological products that help control emerging infectious diseases, save lives, and reduce the health and economic consequences of disease. The October 2010 issue of the *Journal of Emergency Medicine*, described the annual health and economic burden – through increased mortality, hospitalization, and employee absenteeism – linked to seasonal influenza. In the United States alone, influenza complications annually lead to approximately 50,000 deaths and 300,000 hospitalizations. Also, when adjusted for inflation to reflect current 2010 dollars, each year influenza complications lead to an estimated $12.3 billion in direct health care costs, $19.3 billion in projected lost earnings, and $102.9 billion in total economic loss during epidemics.

Vaccines Premarket Review and Postmarket Safety – Field Biologics
Base Amount: $5,582,000 (BA: $4,372,000 / UF: $1,210,000)

Public Health Focus

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness of vaccines and allergenics 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 in foreign countries and by performing entry review and import field exams on imported products.

Public Health Outcome

Inspections are conducted at manufacturing and processing facilities and clinical study sites, including clinical investigators and institutional review boards. 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
- Laboratories are competent and adhere to contractual agreements with the licensed establishments.
- Compliance of good manufacturing practices for vaccines and allergenic products.

Biologics and vaccines are typically not shipped through normal trade channels but are more frequently entered through mail and courier facilities. ORA monitors these shipments through targeted blitz operations at various mail and courier facilities to detect counterfeit and unapproved versions of approved medications. ORA also works with Customs and Border Protection (CBP) to monitor mail shipments under Operation Safeguard and has been involved in the global initiative, Operation Pangea, a collaborative effort amongst agencies in 43 countries to target counterfeit medicines being sold via the Internet.

Operation Pangea III is intended to raise public awareness of the risks associated with purchasing counterfeit medicines over the Internet through the use of international enforcement actions. Increased consumer awareness is one of many strides FDA is making to increase public health protection through increased information and communications.

ORA has been very active in surveillance and enforcement on vaccines. Since declaration by the Secretary of the 2009 H1N1 Flu Virus Public Health, FDA has taken an aggressive, proactive approach to identify, investigate, and take regulatory or criminal action against individuals or businesses that promote illegal fraudulent H1N1 influenza products. In FY 2010, FDA issued thirty warning letters, including four FDA/Federal Trade Commission (FTC) joint letters, to offending internet firms. As of November 2010, 95 warning letters covering 185 fraudulent H1N1 flu products have been issued resulting in a compliance rate exceeding 80 percent.

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 these

manufacturers and application of the regulations while ensuring experienced investigatory staff are performing timely, comprehensive and efficient investigations.

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 U.S. consumers.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2009: 100% (Target Exceeded)	90%	90%	Maintain
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2009: 75% (Target Not Met)	90%	90%	Maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2009: 100% (Target Exceeded)	90%	90%	Maintain
234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production. *(Output)*	FY 2010: Pilot completed and evaluated; participated in one workshop. (Target Met)	Complete and evaluate the pilot vaccine adverse-effects program and participate in at least one international workshop of conference.	Evaluate and compare new methods to determine the potency of influenza vaccines	N/A

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety – Center Activities
Base Amount: $48,192,500 (BA: $31,443,100 / UF: $16,749,400)

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 (which are used to treat or cure a disease or abnormal medical condition by introducing genetic material into the

body to replace faulty or missing material), tumor vaccines, xenotransplantation, stem cells (therapies intended to repair, replace, restore, or regenerate cells, tissues or organs), and combination products, such as bioengineered tissues.

With the aging U.S. population and advances in medicine, tissue transplantation, gene therapies and the use of stem cells are rapidly growing industries that have the potential to affect significant gains in the Nation's health. The number of musculoskeletal tissue transplants increased from approximately 350,000 in 1990 to currently more than one million per year. In 2009, President Obama issued Executive Order 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,* which, among other things, allowed FDA to grant clearance to begin the first human clinical trial of cells derived from human embryonic stem cells.

Public Health Outcome

Cellular and gene therapy products, as well as therapeutic cancer vaccines, immunotherapy, and combination products including a cellular component, hold the promise to fight disease, restore normal function, repair injuries, replace lost cells, replace missing or faulty genes, or regenerate failing organs.

Gene therapy products are a novel and rapidly evolving product class that require early scientific and regulatory interaction and guidance. Patient safety is the focus of FDA review in early phase studies. Promoting the development of safe and effective products is the goal in all stages of product development. 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. Within FDA, CBER and the Center for Devices and Radiological Health (CDRH) have 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 tissue-engineered products.

While gene therapy products have the potential to correct problems and cure disease, they also have the potential to result in serious adverse events. Many of the developmental pathways for cell and gene therapy products are in their infancy with no precedence 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 gene therapies include 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. CBER is 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.

CBER also regulates xenotransplantation products, which is the transplantation of nonhuman tissues or organs into human recipients. CBER works with international scientific societies, national health authorities, and the WHO to help the global community develop xenotransplantation guidelines. CBER has also implemented a

transparent approach to ensure the safety of products used in clinical trials and is studying mechanisms that underlie xenotransplantation adverse events.

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 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 2009, the latest completed performance period, the Biologics Program met two of the three of user-fee performance goals for the Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety subprogram. CBER completed review and took action on 75 percent of four priority applications within six months of receipt. This goal was missed because critical new data were submitted by the sponsor near the PDUFA review deadline for one application. CBER decided to continue the review and not to issue a Complete Response letter needed to meet the PDUFA review deadline because of the public health importance of the vaccine.

Specific subprogram accomplishments include the issuance of guidance documents for Industry to support the development of novel therapies. The draft guidance documents included: addressing the potency tests for cellular and gene therapy products, somatic cell therapy for cardiac disease, and clinical considerations for investigational studies of therapeutic cancer vaccines. CBER issued a final guidance for allogenic pancreatic islet cell products used for the treatment of Type 1 diabetes mellitus. CBER also approved PROVENGE, an autologous cellular immunotherapy designed to stimulate a patient's own immune system against prostate cancer.

CBER also helps to ensure the safety of many types of human tissues and cells, transplanted during various medical procedures to restore proper function to patients. Some examples of tissues used for transplantation include: skin replacement following severe burns, tendons and ligaments used to repair injuries, bone replacement and corneas used to restore eyesight. CBER's role in the human tissue-industry oversight began in 1993 with interim regulations, including limited donor-screening requirements. In 1997, CBER implemented interim regulations and they were made effective in 2004 (Registration and Listing and Good Tissue Practices) and 2005 (Donor Suitability) to enhance tissue safety.

CBER continues to implement a risk-based comprehensive approach for assuring the safety of HCT/Ps and to prevent the transmission of infectious disease from HCT/Ps. Recently, CBER developed a program in tissue microbiological safety to help detect emerging infectious diseases and enhance efforts in regulating human tissues. CBER continues to monitor tissue safety and meets regularly to address tissue safety and policy issues through the interdisciplinary CBER Tissue Safety Team.

[2] CBER is showing its performance measures goal table by subprogram, but several of the program measures are Prescription Drug User Fee (PDUFA) that span several subprograms. Performance results for PDUFA measures contained in the subprogram performance tables will be stated in the subprogram narratives. PDUFA measures cover CBER's Cells, Tissue and Gene Therapy Premarket Review and Postmarket Safety and Vaccine Premarket Review and Postmarket Safety subprograms.

Accomplishments for FY 2010 include the issuance of draft guidance documents for current good tissue practices to help prevent the introduction, transmission, or spread of communicable disease during the manufacturing process and to assist in the submission of an Investigational New Drug Application (IND) for minimally manipulated, unrelated allogenic placental/umbilical cord blood for specified indications. CBER also issued a final guidance to industry on obtaining a biologics license for minimally manipulated, unrelated allogenic placental/umbilical cord blood, for specified indications. Additionally, in collaboration with American Association of Blood Banks (AABB), CBER presented “Cord Blood Licensure: The Workshop.”

Promoting Efficiency

Gene-related 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 that will ensure the safety and effectiveness of gene therapies. Because regulatory pathways for approving these important new therapies are not yet fully developed, 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 such as stem cells. These interactions also allow CBER to identify and address research needed to evaluate scientific concerns in advance of receiving applications for new therapies.

As previously mentioned, the number of musculoskeletal tissue transplants increased from approximately 350,000 in 1990 to currently more than one million per year. To further enhance the safety and the availability of human tissues intended for transplantation, CBER established a tissue microbiology program to develop techniques to detect and characterize infectious agents that could threaten the safety of human tissues that are processed as grafts. The CBER lab also assists in validating studies of FDA-approved tests using cadaver samples to determine tissue donor eligibility. The added expertise also provides a more robust scientific infrastructure, improves regulatory practices, and enhances the office's performance of regulatory reviews. Maintaining this expertise allows 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 Biologics
Base Amount: $10,882,000 (BA: $9,902,000 / UF: $980,000)

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 enforcement cases. Inspections are focused on an establishment's ability to procure and process 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 the protocol, 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.

A number of enforcement tools are utilized to bring about compliance with the law in these industries. Injunctions are used to stop or prevent future violations of the law. Orders of Retention, Recall, or Destruction of HCT/Ps are used when conditions do not provide adequate protections against the risk of communicable disease transmission.

Public Health Outcome

Inspections are conducted at manufacturing and processing 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 good manufacturing practices.
- Laboratories are competent and adhere to contractual agreements with the licensed establishments.

ORA monitors recalls of human biological products that have been found to present safety concerns and ORA assures the adequacy of the firm's recall to effectively remove defective product from commerce. Through the classification process, the Center determines the level of public health risk that the product presents. In FY 2010, FDA classified and issued 2,724 recalls; 2 were class I (reasonable probability of causing serious adverse health consequences or death); 2,088 class II (temporary or

medically reversible adverse health consequence), and 634 class III (not likely to cause adverse health consequences) recalls of biological products.

In some circumstances, the findings of ORA necessitate further inquiries and action. During FY 2010, ORA's Office of Criminal Investigations (OCI) made 5 arrests, and secured 3 convictions with fines, restitutions and other monetary penalties in excess of $1.1 million.

In July 2010, an OCI investigation led to the indictment of an individual for conducting a clinical trial on more than a dozen multiple sclerosis patients without an approved Investigational New Drug Application (IND) or Institutional Review Board (IRB) oversight. The clinical trial was referred to as "amniotic stem cell implants," and involved surgically implanting placental tissue in the abdomens of patients. An FDA issued warning letter did not deter the actions of the individual; in fact the individual raised the price of the implants from $5,000 to $10,000. After being indicted and arrested, pretrial conditions for release called for the individual to shut down two websites and to perform no work in the medical field. Trial is pending.

In another example, an OCI investigation led to the successful prosecution in February, 2010, of a biotech company for violation of Title 42 USC §§ 264, 271, regulations to control communicable diseases and Title 21 CFR §§ 1271(a) and (c), registration of human cells, tissues, and cellular and tissue-based products. The owner of the company was selling expired product and not adhering to manufacturing procedures. The Court ordered the defendant to pay a $100,000 fine and associated costs for destroying the tissue seized by the OCI in connection with the investigation.

Promoting Efficiency

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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	FY 2009: 100% (Target Exceeded)	90%	90%	Maintain
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	FY 2009: 75% (Target Not Met)	90%	90%	Maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	FY 2009: 100% (Target Exceeded)	90%	90%	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2010: 564 (Target Exceeded)	518	533	+15

Blood and Blood Products Premarket Review and Postmarket Safety – Center Activities
Base Amount: $86,556,330 (BA: $59,576,400 / UF: $26,979,930)

Public Health Focus

According to the most recent National Blood Collection and Utilization Survey Report (2007), over 30 million blood components were transfused in 2006. Additionally, CBER currently regulates almost 2,700 active registered blood establishments. The public health focus of the Blood and Blood Products Premarket Review and Postmarket Safety subprogram is to ensure the safety and availability of blood and blood components used for transfusion and for the safety and effectiveness of pharmaceutical products made from blood.

Public Health Outcome

CBER has progressively strengthened the overlapping safeguards that protect patients from known diseases (HIV, Hepatitis B and Hepatitis C) and emerging diseases, such as Chagas disease, that could contaminate the Nation's blood supply. CBER has worked actively with the blood community to streamline, standardize, and cognitively assess the donor questionnaires used for 15 million blood donations each year. These questionnaires help to identify and prevent donations from donors who are at increased-risk for transmissible infections. The outcome of this effort substantially reduces transmissible agents, such as HIV, in the blood donor population, thereby reducing transmission of infections to recipients. Enhancements to the effectiveness of the donor

questionnaire are ongoing. This is achieved by including questions to protect the blood supply from emerging infectious agents for which no laboratory test exists, improving donor understanding of screening questions, improving accuracy of donor self-deferral, and helping to ensure the efficiency of the donor questionnaire process.

CBER requires blood establishments to use FDA licensed tests to ensure the safety of the blood supply. These efforts have reduced the risk of transfusion transmission of HIV and hepatitis C virus (HCV) to approximately one in every two million donations. The following tests are approved for the regulation of blood: HIV-type 1 and 2, hepatitis B virus, HCV, human T-lymphotropic virus types I and II, cytomegalovirus, T. pallidum, the agent of syphilis, West Nile Virus, and *Trypanosoma cruzi* (*T-Cruzi)*, a blood-borne parasite that causes Chagas disease. Since variants of a disease, such as HIV, may emerge at any time and escape detection by current screening tests, CBER also maintains an active surveillance program to detect and intervene if viral variants emerge. The ongoing effort to enhance the sensitivity, specificity and operational efficiency of donor screening tests minimizes the risk that blood transfusion recipients will acquire serious and life-threatening infections.

CBER regulates over 400 facilities that collect 19 million donations of source plasma used to manufacture plasma derivatives. Licensed plasma derivatives, including clotting factors such as Factor VIII and Factor IX for the treatment of hemophilia and immune globulins, are used to treat infections or immunodeficiency. In addition, CBER regulates recombinant versions of clotting factors and establishes product standards to perform lot release testing for products to ensure that the products reaching patients are safe, pure, and potent. Assuring the safety, purity and potency of plasma derivatives impacts the health of nearly one-half million acute and chronic product recipients.

CBER is currently working closely with both Federal and private sector partners to establish effective hemovigilance systems to provide both surveillance data for trending of blood-related outcomes and sentinel data to detect any unforeseen new problems. 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. 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.

The Biologics Program exceeded its FY 2009 target for review and action on blood bank and source plasma BLA submissions within 12 months of receipt by reviewing and acting on 99 percent of 346 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 variant Creutzfeldt-Jakob Disease (vCJD). CBER also approved a second test to screen blood, tissue and organ donors for antibodies to the blood-borne parasite, *T. cruzi*, which causes Chagas disease, a serious and

potentially fatal parasitic infection. FDA also participated in the HHS Advisory Committee on Blood Safety and Availability to discuss FDA's policy on blood donor deferral for men who have sex with men.

Promoting Efficiency

CBER works closely with others in the Public Health Service (PHS) to identify and respond to potential threats to blood safety, to develop safety and technical standards, to monitor blood supplies and to help industry promote an adequate supply of blood and blood products. The transfusion risks of HIV, hepatitis B virus (HBV) and HCV have decreased significantly from the 1980s due to changes stimulated by safety interventions. For example, the residual risk per blood component for HCV is 1 in 1,149,000 while in 1983 it was 1 in 200.

In FY 2009, CBER approved nucleic acid tests (NAT) that more accurately tests blood and blood components for HIV, HBV and HCV. After these approvals, CBER issued guidance for reentry of previously deferred blood donors in FY 2010. In the case of HBV, an estimated 21,500 potentially eligible donors were deferred in the late 1980s and 1990s due to false positive blood tests. Due to the availability of the HBV NAT and improved specificity of blood testing, FDA issued guidance to recommend an algorithm for donors that were deferred due to false tests for establishments that collect whole blood or blood components intended for transfusion. As a result, over 200,000 donors could be eligible for reentry into the blood donor pool. This will increase the supply of safe blood, and reduce the risk of blood-borne disease transmission, leading to the reduction of costly premature deaths and unnecessary hospitalizations.

Blood and Blood Products Premarket Review and Postmarket Safety – Field Biologics
Base Amount: $27,605,000 (BA: $25,799,000 / UF: $1,806,000)

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 and processing 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 contractual agreements with the licensed establishments.

In October 2009, as a result of ORA's continued oversight of the American Red Cross (ARC) Amended Consent Decree of Permanent Injunction, FDA issued two Adverse Determination Letters to the ARC and assessed $16.166 million in fines in June of 2010. The violations included failure to properly implement and consistently follow a problem management standard operating procedure and for failure to control suspect blood products.

In some circumstances, the findings of ORA necessitate further inquiries and action. For example, in September 2010 an individual was sentenced to five years probation and fined $75,000 after he was identified as being involved in the diversion of blood derivatives. The OCI investigation revealed the individual illegally obtained blood derivatives through his business even though he did not have the patient population to support the purchase of those derivatives. Once he obtained the derivatives, he diverted them to other individuals/pharmacies and personally profited from the sales.

Promoting Efficiency

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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	FY 2009: 100% (Target Exceeded)	90%	90%%	Maintain

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)*	FY 2009: 99% (Target Exceeded)	90%	90%	Maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2010: 1,073 (Target Exceeded)	1,000	1,000	Maintain

Information Technology Investments – Biologics Program Activities
(Base Amount displayed as a non-add item: $ 56,348,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to the IT infrastructure, FDA-wide enterprise investments and the existing center specific IT systems, automation of the Managed Review Process is planned. A key component is the development and implementation of the Common Communications Module (CCM). This module will facilitate workload and work flow assessment within the Center as well as provide review templates and ready access to support guidance documents and analytical tools for data evaluation. The CCM will allow CBER reviewers to concentrate on scientific and public health issues. Enhanced IT systems 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. Enhanced capability is of extreme importance 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 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	$202,162,000	$146,328,000	$55,834,000	1,045
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 Continuing Resolution	$317,787,000	$205,563,000	$112,224,000	1,250

Summary of the Budget Request

The FY 2012 budget request for the Biologics Program is $368,260,000. This amount is an increase of $63,886,000 above the FY 2010 enacted level. The CBER amount is $320,803,000, supporting 1,131 FTE. The Field Biologics amount is $47,457,000, supporting 239 FTE.

Base funding for the Biologics Program is $304,374,000, which includes $260,305,000 for CBER activities and $44,069,000 for the Field Biologics activities.

The Biologics Program is committed to advancing public health through innovative regulation that facilitates the safety, effectiveness, and timely delivery of biological products to patients. With the base funding, CBER will facilitate the safety of the Nation's blood supply and the products derived from blood, the production and approval of safe and effective adult and childhood vaccines, 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.

Vaccines Premarket Review and Postmarket Safety

Center Activities (Base Amount: $125,556,170)

FY 2012 increase for current law user fees (PDUFA): +$24,553,110, 39 FTE

FY 2012 Initiatives

Advancing Medical Countermeasures Initiative: (+$5,676,500 / 22 FTE)

Under MCM Pillar 1, CBER will provide expertise on the newly established Public Health & Security Action Teams (PHSATs) to ensure that Medical Countermeasures (MCM) products and technologies receive the necessary support throughout the product lifecycle. Additionally, CBER will enhance regulatory review by automation of the receipt processing and management of regulatory submissions and improve monitoring of influenza vaccines post-licensure for safety and adverse events.

Under MCM Pillar 2, CBER will also establish external partnerships to advance regulatory science for MCM and enhance risk communication strategies for use in public health emergencies. This pillar also includes MCM regulatory science projects in animal model biomarkers, ensuring MCM product quality and development of diagnostic platforms for CBRN/Flu.

Under MCM Pillar 3, CBER will work with FDA's Office of the Commissioner to analyze gaps in regulation and optimize the legal and policy framework needed to support the activities described above, and others, to assure an effective emergency public health response.

Protecting Patients - Vaccine Safety (+$1,000,000 / 2 FTE)

CBER will ensure the safety of vaccines through regulatory guidance, scientific knowledge, and new technologies. CBER will develop biological markers and other approaches to evaluate the safety of vaccines and vaccine components. CBER will also explore the mechanisms of vaccine-related adverse events and explore ways to mitigate these mechanisms and biomarkers of predisposition. These new biomarkers and approaches will take advantage of state-of-the art scientific and technical developments, support the evaluation of vaccine formulations and manufacturing processes proposed by product developers, and enhance the regulatory review of novel vaccine products required to protect both U.S. and global public health.

Protecting Patients - Section 351 of the Public Health Service Act (42 U.S.C. 262) (+$403,200 / 1 FTE)

FDA will begin development of scientific and regulatory policies to build a biosimilars review program to facilitate the review and availability of follow-on biologics.

Regulatory Science - Nanotechnology Initiative (+$213,750 / 0 FTE)

CBER will work to evaluate the use of nanoparticles in analytic tests for detection of infectious agents of concern in cell substrates used to produce biologics. In addition, the funds will be used to understand the mechanism of action between nanomaterials and the human body by assessing the vascular and blood cell compatibility of carbon fullerenes.

Field Activities (Base Amount: $5,582,000)

FY 2012 increase for current law user fees (PDUFA): +$581,000

FY 2012 increase for proposed user fees (Reinspection): +$58,000

2012 Initiatives:

Advancing Medical Countermeasures Initiative: (+$437,000 / 2 FTE)

Under Pillar 1, ORA Field operations will conduct enhanced inspection and compliance activities, identify as early and efficiently as possible problems that impede MCM product development, and provide technical assistance to minimize risk during MCM product manufacturing. With these resources, ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance, ORA will be able to conduct 9 domestic MCM inspections by FY 2014.

Cells, Tissues and Gene Therapy Premarket Review and Postmarket Safety

Center Activities (Base Amount: $48,192,500)

FY 2012 increase for current law user fees (PDUFA): +$8,050,200; 13 FTE

FY 2012 Initiatives

Advancing Medical Countermeasures Initiative (+$2,724,720 / 11 FTE)

Under MCM Pillar 1, CBER will provide expertise on the newly established PHSATs to ensure that MCM products and technologies receive the necessary support throughout the product lifecycle.

Under MCM Pillar 2, CBER will also establish external partnerships to advance regulatory science for MCM and enhance risk communication strategies for use in public health emergencies. This pillar also includes regulatory science projects in animal model biomarkers, ensuring MCM product quality and development of diagnostic platforms for CBRN/Flu.

Under MCM Pillar 3, CBER will work with FDA's Office of the Commissioner to analyze gaps in regulation and optimize the legal and policy framework needed to support the activities described above, and others, to assure an effective emergency public health response.

Protecting Patients - Section 351 of the Public Health Service Act (42 U.S.C. 262) (+$172,800 / 1 FTE)

FDA will begin developing scientific and regulatory policies to build a biosimilars review program to facilitate the review and availability of follow-on biologic products.

Protecting Patients - **Improving Safety of Human Tissues and Cord Blood (+$2,500,000 / 6 FTE)**

CBER will continue to improve the safety of human tissue and cord blood by increasing outreach efforts to improve industry practices and performance. Additionally, CBER will continue to build a capacity to identify and respond to adverse events, reducing the risk of disease transmission caused by infected tissues.

Regulatory Science – Nanotechnology Initiative (+$90,250 / 0 FTE)

CBER will work to evaluate the use of nanoparticles in analytic tests to detect infectious agents of concern in cell substrates used in producing biological products. In addition, the funds will be used to understand the mechanism of actions between nanomaterials and the human body by assessing the vascular and blood cell compatibility of carbon fullerenes.

Regulatory Science - Stem Cell Initiative (+$950,000 / 2 FTE)

CBER will work with investigators and the scientific community to develop analytic tests for characterization of stem cell products, and conduct outreach activities to ensure the scientific community is aware of regulatory requirements for stem cells that may be used to facilitate clinical translation of these therapies.

Field Activities (Base Amount: $10,882,000)

FY 2012 increase for current law user fees (PDUFA): +$471,000

FY 2012 increase for proposed user fees (Reinspection): +$133,000; 1 FTE

FY 2012 Initiative

Protecting Patients Initiative: Increasing Medical Product Inspections (+$830,000; 4 FTE)

Field Biologics will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2015 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This initiative will permit Field Biologics to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity,
- safer tissues,
- improved data collection and risk analysis for medical products, and
- enhanced postmarket safety assessment.

By September 30, 2012, Field Biologics will complete hiring of 4 additional employees and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 68 domestic human tissue inspections.

By September 30, 2015, Field Biologics will conduct an additional 2 foreign human tissues inspections.

Blood and Blood Products Premarket Review and Postmarket Safety

Center Activities (Base Amount: $86,556,330)

FY 2012 increase for current law user fees (PDUFA): +$7,647,690; 12 FTE

FY 2012 increase for current law user fees (MDUFMA): +$1,962,000; 1 FTE

FY 2012 Initiatives

Advancing Medical Countermeasures Initiative: (+$ 2,951,780 / 12 FTE)

Under MCM Pillar 1, CBER will provide expertise on the newly established PHSATs to ensure that MCM products and technologies receive the necessary support throughout the product lifecycle.

Under MCM Pillar 2, CBER will also establish external partnerships to advance regulatory science for MCM and enhance risk communication strategies for use in public health emergencies. This pillar also includes regulatory science projects in animal model biomarkers, ensuring MCM product quality and development of diagnostic platforms for CBRN/Flu.

Under MCM Pillar 3, CBER will work with FDA's Office of the Commissioner to analyze gaps in regulation and optimize the legal and policy framework needed to support the activities described above, and others, to assure an effective emergency public health response.

Protecting Patients - Section 351 of the Public Health Service Act (42 U.S.C. 262) (+$576,000 / 2 FTE)

FDA will begin development of scientific and regulatory policies to build a biosimilars review program to facilitate the review and availability of follow-on biologics.

Protecting Patients - Blood Safety Initiative (+$2,500,000 / 3 FTE)

CBER will continue to protect the U.S. blood supply from infectious diseases. Specifically, CBER will improve the prevention, detection, monitoring, analysis and response to manufacturing deviations, as well as observed and potential adverse events and adverse reactions. CBER will strive to maximize product quality and safety through the review of quality standards such as reference materials and guidance documents.

Regulatory Science – Nanotechnology Initiative (+$171,000 / 1 FTE)

CBER will work to evaluate the use of nanoparticles in analytic tests for detection of infectious agents of concern in blood and blood products as well as in cell substrates used to produce biologics. In addition, the funds will be used to understand the mechanism of action between nanomaterials and the human body by assessing the vascular and blood cell compatibility of carbon fullerenes.

Field Activities (Base Amount: $27,605,000)

FY 2012 increase for current law user fees (PDUFA): +$624,000; 1 FTE

FY 2012 increase for current law user fees (MDUFMA): +$90,000

FY 2012 increase for proposed user fees (Reinspection): +$346,000; 2 FTE

2012 Initiatives:

Protecting Patients and Section 351 of the Public Health Service Act (42 U.S.C. 262) (+$210,000 / 1 FTE)

FDA will begin development of scientific and regulatory policies to build a strong biosimilars review program to facilitate the review and availability of follow-on biologics.

BA Increase for Pay Costs: +$481,000 (Center: $382,000; Field: $99,000)

Contract and Administrative Savings (Total Program: -$2,518,000)

The request for $224,933,000 in total budget authority for the Biologics Program also reflects contract and administrative savings reduction of -$2,518,000 for FY 2012. The Center's portion of these savings is -$2,027,000 and the Field's portion is -$491,000.

Center Activities

2012 Initiatives

Contract and Administrative Savings (-$2,027,000)

CBER will achieve contract savings by:

- conducting training to improve the skills of the acquisition workforce and program offices
- using technology to improve contract management and to manage contract costs
- increasing competition by expanding the use of blanket purchase agreements and other agency-wide approaches to contracting to achieve savings for information technology, copiers, scanners and temporary services.
- using FDA-wide contracts to combine resources and reduce cost, such as CBER joining with other FDA centers in contracts to support is activities on the NIH campus.
- using more cost-effective contract types or ending contracts that do not fully meet program needs.

Field Activities

2012 Initiatives

Contract and Administrative Savings (-$491,000; -2 FTE)

ORA will achieve contract savings by:

- reducing administrative support FTE, both in Headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA.

BIOLOGICS PROGRAM ACTIVITY DATA

Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
NDA/BLA Submissions			
Applications received Standard: Priority:	 11 1	 12 2	 12 2
Applications completed [1/] Standard: Priority:	 20 1	 22 2	 22 2
Applications approved [2/] Standard: Priority:	 26 3	 28 4	 28 4
Applications pending [3/] Standard: Priority:	 27 5	 29 6	 29 6
Efficacy Supplements			
Applications received Standard: Priority:	 26 0	 28 1	 28 1
Applications completed [1/] Standard: Priority:	 8 2	 9 3	 9 3
Application approved [2/] Standard: Priority:	 15 0	 16 1	 16 1
Applications pending [3/] Standard: Priority:	 29 1	 31 2	 31 2
Original Manufacturing Supplement			
Applications received	1,397	1,513	1,513
Applications completed [1/]	336	364	364
Applications approved [2/]	1,275	1,381	1,381
Applications pending [3/]	780	845	845

Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Device Premarket Applications - PMAs			
Applications received Supplements received	0 32	1 35	1 35
Applications completed [1/] Supplements completed [1/]	5 7	6 8	6 8
Applications approved [2/] Supplements approved [2/]	0 22	1 24	1 24
Applications pending [3/] Supplements pending [3/]	1 13	2 14	2 14
Device 510(k)s			
Applications received	55	60	60
Applications completed [1/]	57	62	62
Applications approved [2/]	44	48	48
Applications pending [3/]	25	27	27
Investigational Applications			
Commercial IND/IDE Receipts [4/]	156	169	169
IND/IDE Amendment Receipts [4/]	13,372	14,000	14,000
Active INDs/IDEs [4/]	2,817	3,100	3,100
Other Activities			
Patient Safety			
Adverse Event Report Received [5/]	46,405	51,046	56,151
Biological Product Deviation Report Received	51,012	52,000	52,000
Sponsor Assistance/Outreach			
Meetings	385	350	375
Final Guidance Documents [6/]	23	24	24
Admin/Management Support			
Advisory Committee meetings held	15	15	16
FOI requests processed	394	405	405

1/ Completed means complete action letter was sent to sponsor. Includes withdrawn, denied, NSE, and exempts.

2/ Approved includes all applications approved during the fiscal year, regardless of year of receipt.

3/ Pending 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.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	
FDA WORK				
DOMESTIC INSPECTIONS				
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,902***	***2,091***	***2,116***	
Bioresearch Monitoring Program Inspections	106	180	180	
Blood Bank Inspections	1,061	1,100	1,100	
Source Plasma Inspections	158	225	225	
Pre-License, Pre-Market) Inspections	18	30	30	
GMP Inspections	29	25	25	[1]
GMP (Device) Inspections	5	10	10	
Human Tissue Inspections	552	545	570	[2]
FOREIGN INSPECTIONS				
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***57***	***73***	***73***	
Bioresearch Monitoring Program Inspections	10	5	5	
Foreign Human Tissue Inspections	13	15	15	[3]
Blood Bank Inspections	7	10	10	
Pre-License Inspections	4	10	10	[4]
GMP Inspections	22	30	30	
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,959***	***2,164***	***2,189***	
IMPORTS				
Import Field Exams/Tests	90	100	100	
Import Line Decisions	51,307	65,159	65,790	
Percent of Import Lines Physically Examined	0.18%	0.15%	0.15%	
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,959***	***2,164***	***2,189***	

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 9 domestic MCM vaccine inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 68 domestic human tissue inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 2 foreign human tissue inspections

[4] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 8 foreign vaccine biosimilars manufacturer inspections

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ANIMAL DRUGS AND FEEDS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$154,863**	**$153,919**	**$154,863**	**$176,458**	**$21,595**
Center	$101,652	$100,787	$101,652	$117,009	$15,357
FTE	447	488	488	487	40
Field	$53,211	$53,132	$53,211	$59,449	$6,238
FTE	278	279	279	307	29
Program Level FTE	**725**	**767**	**767**	**794**	**69**
Budget Authority	**$134,798**	**$134,360**	**$134,798**	**$147,898**	**$13,100**
Center	$81,980	$81,918	$81,980	$92,247	$10,267
Field	$52,818	$52,442	$52,818	$55,651	$2,833
Pay Increase (non add)				*$309*	*$309*
Transforming Food Safety and Nutrition (non-add)				*$11,214*	*$11,214*
Protecting Patients (non-add)				*$684*	*$684*
FDA Regulatory Science and Facilities (non-add)				*$2,150*	*$2,150*
Administrative and Contract Savings (non-add)				*-$1,257*	*-$1,257*
Budget Authority FTE	**636**	**677**	**677**	**682**	**46**
Center	361	401	401	399	38
Field	275	276	276	283	8
User Fees	**$20,065**	**$19,559**	**$20,065**	**$28,560**	**$8,495**
Center ADUFA	$15,290	$14,644	$15,290	$19,261	$3,971
FTE	66	65	65	66	0
Field ADUFA	$250	$546	$250	$315	$65
FTE	2	2	2	2	0
Center AGDUFA	$4,382	$4,225	$4,382	$4,898	$516
FTE	20	22	22	20	0
Field AGDUFA	$143	$144	$143	$160	$17
FTE	1	1	1	1	0
Field Food Reinspection				$2,550	$2,550
FTE				18	18
Field Medical Products Reinspection				$134	$134
FTE				1	1
Center Export Certification				$82	$82
FTE				0	0
Recall User Fee				$1,160	$1,160
Center				$521	$521
FTE				2	2
Field				$639	$639
FTE				2	2
User Fees FTE	**89**	**90**	**90**	**112**	**23**

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. CVM fosters public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other authorities. CVM is responsible for regulating drugs, devices and food additives used in animals — approximately 8.5 billion chickens and turkeys, 160 million cattle and pigs, 11 million sheep and goats, 65 million dogs, 75 million cats, 9.5 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. 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 accomplishes its responsibilities through premarket review of animal drug submissions. The Program also conducts surveillance and compliance activities to prevent marketing of unsafe products, and coordinates enforcement actions against unsafe products.

The authority to regulate animal drugs and medicated feeds derives from the FD&C Act, which Congress amended in 1968 to include new authorities for animal drugs. In December 2010, the President signed The Food Safety Modernization Act into law. The law gives FDA the power to directly issue a food recall. Previously, FDA had to arrange a voluntary recall with the company in question. Food and feed production facilities must also alert the FDA, through writing, of all identified hazardous practices currently in place and their plans to implement preventive measures going forward. The Animal Drugs and Feeds Program is funded through appropriations and user fees. The Animal Drug User Fee Act (ADUFA) was enacted in FY 2003 (FY 2004 – FY 2008) and

* 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.

reauthorized in FY 2008 (FY 2009 – FY 2013). The new Animal Generic Drug User Fee Act (AGDUFA) was enacted in FY 2008. With the new Minor Use and Minor Species Grant Program initiated in FY 2009, CVM provides funding for the development of new animal drugs intended for minor species or minor uses in major species to defray 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 of biosecurity of the feeds supply
- compliance with recalls of violative products.

In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) 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 and AGDUFA.

The Animal Drugs and Feeds Program executes its public health responsibilities in two major areas: food safety and medical product safety. Foods safety focuses on four strategic areas to ensure the safety of the human and animal food supply (pre and post market):

- prioritizing prevention
- strengthening surveillance
- strengthening enforcement
- improving response and recovery

Medical product safety focuses on pre- and post-market safety and compliance for companion animals and exotic animals that can transmit disease from animals to humans.

<u>Prioritizing Prevention</u> - Center Activities
Base Amount: $35,503,000 (BA: $23,700,000 / UF: $11,803,000)

Public Health Focus

Prevention is the cornerstone of an effective, proactive food safety strategy. Prevention allows FDA 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.

Public Health Outcome

CVM reviews animal drug applications, establishes standards for feed contaminants, approves safe food additives, and manages FDA's medicated feed and pet food programs. CVM works with all stakeholders to promote corporate responsibility through the identification and implementation of new regulations to further support the production of safe feed for all animals.

CVM reviews new and generic animal drug applications not only for the effect on the targeted animal users, but also the human users who may consume food produced from the animal. CVM works to bring animal drugs to market more quickly, including products developed using new technologies such as biotechnology — genetically engineered animals and cloning. Bringing animal drugs to the market quickly helps to ensure that the public has access to safe and effective drugs on a timely basis. This access to safe and effective drugs protects public health by reducing the use of unapproved — illegally compounded animal drugs — and improperly labeled drugs used to treat animal diseases and for growth promotion.

In March 2010, CVM approved the generic new animal drug, FLUNAZINE -S, for the control of fever associated with swine respiratory disease. In addition, in November 2009, CVM approved the new animal drug, Resflor Gold, for the treatment of bovine respiratory disease (BRD) and control of BRD-associated fever in beef and non-lactating dairy cattle. In October 2009, CVM approved the new animal drug, EAZI-BREED CIDR Sheep and Goat Insert. This progesterone Controlled Intravaginal Drug Release (CIDR) is a steroid hormone that allows out-of-season breeding in sheep.

In January 2010, CVM issued a revised Animal Feed Safety System (AFSS) Framework Document comprised of components that cover the processes FDA used to ensure that ingredients used in animal feeds are safe, the methods used in making feeds result in safe products, and regulatory oversight is present at levels commensurate with risk to human and animal health. AFSS is a comprehensive, risk-based, preventive system that minimizes or eliminates the risks to animal and human health that can arise from animal feed. The AFSS covers regulation of the labeling, production and distribution 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 in animal feed.

One of the developments addressed in the revised AFSS Framework Document is the policy announcement about a pilot program concerning Generally Recognized As Safe (GRAS) notifications for feed ingredients. CVM implemented this voluntary pilot program to accept submission of notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the individual’s determination that such use is GRAS. The pilot program facilitates industry submissions of high quality GRAS food additive petitions and reduces the time to approval for new ingredients thereby increasing the number of ingredients that are

approved for use in animal food. The new AFSS Framework Document also discusses the Reportable Food Registry rule, which states industry must, and public health officials may, report when there is a reasonable probability that an article of human food or animal food/feed will cause serious adverse health consequences or death to humans or animals.

In an effort to improve the public awareness of animal and human health issues, CVM developed the Animal Health Literacy Campaign. The campaign is geared towards using social media to connect with consumers, veterinarians, and industry to share important animal health and safety tips, public health updates, and product recalls. Information is disseminated to consumers through a variety of methods, such as articles, brochures, and posters. As a compliment to the Animal Health Literacy Campaign, CVM launched its Pet Health and Safety Widget and Animal Health Twitter account to provide real time updates on important public health issues. The Pet Health and Safety Widget went live in December 2009, displaying content featured on CVM's Web site for consumers and other stakeholders to place on their own Internet sites or blogs. As a result, visitors to these sites have instant access to CVM Updates, and animal health and safety tips. Shortly after the widget launch, the first tweet further opened the doors of communication between FDA and the public in February 2010. Twitter is a free social media marketing tool that allows CVM to connect and keep in touch with our user base through the exchange of quick, frequent answers to one simple question: What's happening in the world of CVM and animal health?

Promoting Efficiency

CVM continues to exceed all user fee performance goals under ADUFA. Sustaining this performance not only protects the American public as they consume products from food-producing animals, it also gives manufacturers a reliable review process and timeline for animal drug applications and reduces the cost of product development. The following enhancements to the review process are efficiencies that CVM will sustain with the resources in this subprogram:

- An electronic tool for submitting industry applications that transforms the receipt and review of applications through a modern web-friendly environment. The electronic tool increases efficiency and decreases administrative costs to industry and government.
- 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.
- A process to address End-Review Amendments (ERA). This process allows CVM to achieve a complete review decision sooner on applications and reduce the number of review cycles. CVM used the ERA process to request additional information on 153 applications and other animal drug submissions during FY 2009 and FY 2010. Manufacturers used the ERA process for 93 percent of these submissions. CVM completed reviews for 88 percent of these applications and submissions in only one review cycle.

CVM implemented the first generic drug user fee program and established performance goals for review of generic drugs, allowing the faster approval of lower cost generic drugs. CVM instituted business reengineering procedures for generic animal drug review that eliminated a backlog of more than 150 generic new animal drug submissions. This efficiency supports the review of current generic applications bringing safe and effective products to the market more efficiently and allows CVM to successfully meet performance goals.

CVM established a pilot program to find an effective mechanism to further strengthen the animal biotechnology program in an efficient and proactive manner. The objective of this program is to maximize available resources and expertise across CVM by engaging professionals of the appropriate expertise – regardless of their organizational unit. This pilot matrix program enhances the continuity of pre- and postmarket animal drug activities and provides internal peer-review of CVM's assessments and actions. In summary, the pilot is a program grounded in risk-based, full lifecycle regulatory oversight and a team-based review process to further strengthen the animal biotechnology program. CVM is conducting quarterly assessments to affirm the progress and benefits of the pilot program.

Prioritizing Prevention - Field Activities
Base Amount: $12,372,000 (All BA)

Public Health Focus

To advance public health and protect consumers, ORA focus 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.

Public Health Outcome

ORA views state-based grant programs such as the Small Scientific Conference (SSC) and Food Protection Task Force grants (FPTF) as an important mechanism for providing feed safety and feed defense program coordination. SSC and FPTP grants foster communication, cooperation, and collaboration within the states and among State, local, and tribal food protection, public health, agriculture, and regulatory agencies, enabling states to strengthen food protection systems.

ORA's focus on prevention includes non-research international harmonization activities. ORA's work with FDA's Office of International Programs (OIP) Beyond our Borders offices in China, India and Latin American 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.

In FY 2010, ORA awarded five associations with SSC grants and 27 state/local groups FPTF grants. These grants supported 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 FDA initiatives to internal and external stakeholders. ORA participated in more than 50 outreach events at a variety of symposiums and conferences attended by regulated industry, other government agencies and foreign regulatory bodies.

ORA awarded contracts to 36 states under the Feed Safety BSE Contract program in FY 2010. 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.

Promoting Efficiency

The use of grant and contract programs allows ORA to increase its focus on prevention. Through these efforts, ORA is enhancing the evaluation of feed supply vulnerabilities, risk-based inspections, sampling, and surveillance and bolster an integrated feed safety system and U.S. feed defense efforts.

ORA was recently accepted into the Pharmaceutical Inspection Co-operation Scheme. This will promote a more efficient use of inspection resources through the sharing of Good Manufacturing Practices (GMP) inspection reports with 37 participating global authorities, as well as the development and promotion of harmonized GMP standards and guidance documents and training of competent authorities.

ORA continues to provide state partners with training on the latest risks facing feed safety and BSE prevention to support ORA’s efforts of protecting public health through public and industry education.

ORA outreach provides FDA with the opportunity to ensure transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. Through this outreach, ORA is able to identify areas where regulated industry can work as partners to more efficiently protect the public health. 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2009: 100% of 5 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)*	N/A	90% w/in 680 days	90% w/in 380 days	-300 days

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities
Base Amount: $13,286,000 (All BA)

Public Health Focus

New animal drug products are carefully tested before they are marketed. However, wider use of the drug products may disclose 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; therefore, post-marketing surveillance is critical to ensuring the safety of our food supply. If the public health warrants, FDA may recommend withdrawal of an approved drug if it is found to be unsafe or ineffective.

Public Health Outcome

FDA reviews and analyzes information from adverse event 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 unsafe drug residues in meat and poultry products and to conduct educational and enforcement activities. CVM also conducts surveillance to protect animal feed from contamination by toxic materials such as mycotoxins, pesticides, heavy metals, and industrial chemicals.

CVM utilizes an existing early warning surveillance system as a mechanism for notifying the public of recalls involving contaminated animal feed. With this system, CVM can

analyze and administer the data to identify adulterated food and feed products and outbreaks of illness that will be collected and provide notice to veterinarians and stakeholders during recalls. The early warning surveillance system continues to be refined and will be used in addition to MedWatch Plus. As a component of the early warning surveillance system, the Pet Event Tracking Network (PETNet) is an additional surveillance tool that provides secure reporting/ notification, only accessible by state/federal government officials, for the exchange of early information on outbreaks of illnesses associated with adulterated food and feed. These systems improve detection of food system "signals" that enable FDA and regulatory partners to respond rapidly to either prevent or quickly limit the adverse events caused by adulterated food and feed.

In regulatory research, 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 and the United States Department of Agriculture, 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. In May 2010, CVM reported on *Salmonella*, *Campylobacter and Escherichia coli* in the NARMS 2007 Executive Report . This report summarizes data on isolates recovered from food animals at federally inspected plants, retail meats, chickens, and humans. In addition, in December 2010, CVM reported on identifying and analyzing trends in antimicrobial resistance in the 2008 NARMS Retail Meat Annual Report .

In June 2010, CVM issued a draft guidance document on the judicious use of medically important antimicrobials in food-producing animals. The intent of the draft guidance is to provide information on how to reduce the development of resistance to medically important antimicrobial drugs used in food-producing animals. FDA acknowledged the efforts to date by various veterinary and animal producer organizations to institute guidelines for the judicious use of antimicrobial drugs, but FDA believes additional steps are needed.

In December 2010, as mandated by ADUFA II, CVM published its first annual report summarizing sales and distribution data of antimicrobial drugs approved for food-producing animals. The collection of data on antimicrobial drugs, such as sales and distribution information, 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, such as cattle, swine, and poultry.

CVM is working closely with the World Health Organization (WHO) Advisory Group for Integrated Surveillance of Antimicrobial Resistance (AGISAR) to help outline FDA priorities, identify regional pilot projects and special research studies, and prioritize regions for laboratory capacity building exercises in 2010. As a result, FDA will be

supplied with the vital data necessary to inform and prioritize science based approaches to assuring food safety and to minimize public health concerns with regards to antimicrobial use in food producing animals.

Promoting Efficiency

In this subprogram, the introduction of the field of social science helps CVM provide better, more targeted communications to various stakeholders. CVM has recently integrated the use of social science into some of its key program areas. For example, CVM is conducting a “mental modeling” study designed to identify factors that influence dairy farmers' ability to avoid tissue residues. Dairy cattle represent approximately seven percent of the U.S. beef sold, yet they contribute to approximately 80 percent of the drug tissue residues identified by the USDA.

CVM conducted an expert workshop with key players in the dairy industry such as producers, veterinarians, packers, and regulators. The experts provided input on the dairy farmers’ experiences, where they obtain information, who they trust, and what influences their decisions. This input will be used to create a "mental model" map which can help CVM better understand how to best communicate the need to protect consumers and public health by avoiding tissue residues associated with animal drugs.

CVM conducts studies with food-producing animals in a production-like environment to provide other regulatory scientists, reviewers, and regulators with the tools to address drug residue and withdrawal-time issues for animal drugs. Developing new methods through these studies has generated efficiencies for industry through the availability of additional tools that industry uses in surveillance of their 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 of more rapidly responding and assessing specific food-related hazards.

The information generated through the National Antimicrobial Resistance Monitoring System (NARMS) that supports the judicious use of antimicrobials by industry reduces governmental oversight and regulatory costs. 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. The process of collecting data from NARMS partners at CDC and USDA has been simplified and sped up by creating a new process known as extract, transform, and load. CVM is analyzing improvements such as this in the workflow and dataflow 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
Base Amount: $13,843,000 (All BA)

Public Health Focus

To strengthen bio-security, 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 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.

Public Health Outcome

ORA uses 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.

During FY 2010, ORA issued several notices identifying modifications to animal feed and drug related Import Alerts encompassing various animal feed and drug commodities and manufacturers. These actions were a result of ORA import surveillance activities 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.

In FY 2010, ORA began staffing the Commercial Targeting and Analysis Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA

personnel are working closely with other government agencies on several ongoing cases including products in the animal feed and animal drug program.

ORA continues to conduct routine surveillance examinations, sampling, and analysis to ensure the compliance, safety and security of animal feeds. In January 2010, FDA issued a press release warning consumers not to use a packaged dog treat product due

to concerns that the product had been contaminated with Salmonella. FDA became aware of the issue when routine surveillance sample collection and analyses found the product to be contaminated.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of the mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY 2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas.

The joint effort called for ORA and state sampling of grain by-products intended for use in animal feed to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up with sampling of finished feeds manufactured using the milled wheat products, grains or grain by-products that exceeded FDA advisory levels.

FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, consolidating into a single test the previous testing process comprised of an initial test to determine the presence of mycotoxins and the confirmation test for regulatory determination and action. These efforts increased ORA analytical efficiencies.

ORA continues to award contracts and grants to the states to increase collaborative efforts, leverage existing resources and continue to bolster an integrated feed safety system. In FY 2010, ORA-awarded contracts included:

- 19 Tissue Residue program contracts to states to provide for completion of 260 tissue residue inspections by state inspectors
- 27 FPTF grants to state and local groups
- SSC grants to five associations allowing for increased interactions at operational levels to assure uniformity and consistency in enforcement activities.
- contracts awarded to 36 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.

In FY 2010, ORA initiated a nationwide investigation to collect and analyze samples of import and domestic distiller grain samples for the presence of antibiotic residues. ORA also developed a new analytical method to allow for the confirmation of residues and determination of residue levels using a single method to screen for 21 drugs. Additionally, ORA purchased and outfitted two ORA field laboratories with new equipment to complete this testing, expanding the available ORA laboratory resource network.

Promoting Efficiency

ORA is increasing efficiencies by reviewing import entries through the implementation of PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting). PREDICT gathers intelligence from various sources to allow for a more informed review of specific product entries. With data that supports ORA's ability to confirm that an imported product complies with import standards, ORA will more quickly process and release those entries; data indicative of concerns or violations will result in entries being flagged for additional scrutiny by ORA investigators. 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 to assess tools for the investigator toolbox. This initiative 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. This initiative also supports the evaluation of additional instruments for laboratory use that will enhance laboratory capacity and capability.

ORA continues to evaluate violations identified during inspections of foreign facilities to establish pre-emptive import controls. ORA increases exams and sampling of products manufactured where violations are likely to ensure a high level of scrutiny when those products are offered for import into the United States.

ORA oversight of grants and cooperative agreements with the states has enhanced and developed programs to safeguard products intended for animal use and furthered the development of an integrated feed safety system. Using these grants and cooperative agreement funds, ORA has increased integrated feed safety system by assuring better trained state inspectors, increasing state capabilities to respond to feed incidents and outbreaks.

ORA achieves efficiencies by leveraging resources with our state Tissue Residue Inspection partners by identifying the causes of illegal drug residues and obtaining compliance through voluntary or regulatory actions. Additionally, ORA strengthens surveillance and risk analysis activities by using experienced state-employed veterinarians to investigate animal producers that the USDA Food Safety and Inspection Service identifies as firms with tissue residue violations. ORA identifies the causes of the residues and pursues appropriate enforcement actions.

ORA's expansion of prior notice bio-security targeting capabilities and intelligence data mining have allowed ORA to provide an increased focus on import 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2010: 22% (Target Not Met)	50%	55%	+5%

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities
Base Amount: $8,858,000 (All BA)

Public Health Focus

Appropriate enforcement strategies and regulatory decisions need to be in place to ensure the compliance of marketed products. Inspections serve as a foundation to ensure products are manufactured according to good manufacturing practices. Working with our state counterparts, the Animal Drugs and Feeds Program conducts high-quality targeted, risk-based interventions with emphasis on the points of manufacture and distribution to prevent contaminated food/feed from entering the food supply.

Public Health Outcome

CVM developed 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 toxic materials such as mycotoxins, pesticides, heavy metals, and industrial chemicals, and to prevent the establishment and amplification of BSE through feed.

In addition, CVM developed the Polymerase Chain Reaction (PCR)-based method for testing animal feed for prohibited materials. As the new PCR-based method is routinely used, it will enhance FDA's ability to make sure animal feed is safe and free of prohibited materials that may spread the agent thought to cause BSE. In less than 2.5 hours, the new real-time PCR-based method can detect processed materials from cattle, sheep, and goats, as well as a select set of processed materials from chickens, turkeys, and geese. This method not only detects animal materials that have been processed in North America, but also animal materials processed in the European Union, which are more difficult to detect due to a different processing method.

CVM conducts the activities of the Animal Drugs and Feeds program with assistance from ORA. ORA provides FDA leadership on enforcement, foreign and domestic inspections, and laboratory analysis.

Promoting Efficiency

To promote efficiency and improve public health in the Strengthening Enforcement subprogram, CVM has written a draft Compliance Policy Guide to focus the regulatory response to the classes of feeds and Salmonella serotypes that have shown the highest risk of causing human or animal illness. Previously, without a policy to prioritize Salmonella serotypes of greatest significance, all Salmonella events were treated equally. This efficient, risk-based decision tool allows FDA and others to focus resources on Salmonella serotypes of human and animal health concern for the prevention of and response to Salmonella events.

CVM is also promoting efficiency by continuously working with 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 affected. Additionally, CVM has established safeguards to identify the conditions for the safe use of products such as sugarcane, which was contaminated by an oil well blowout.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
Base Amount: $12,087,000 (All BA)

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.

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 on potentially high-risk areas.

ORA and experts from the Center for Veterinary Medicine (CVM) review risk-based scenarios of bioterrorism and develop criteria that targets animal feed and feed ingredients that pose an increased risk for intentional contamination. ORA implemented this science and risk-based screening criteria, thereby strengthening FDA's defense of the animal feed industry.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. To continue to ensure compliance, ORA made more than 800 informed compliance calls to the import trade community and regulated industry in FY 2010 to obtain accurate prior

notice data and inform the trade community of the existing requirements. In conjunction with CBP, ORA executed compliance enforcement actions against more than 1,300 imported food and feed shipments where the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful bio-security risk assessments. The actions required resubmission of accurate prior notice data before the imported food and feed shipments were allowed to enter the U.S.

ORA's Ruminant Feed Ban cooperative agreements with the states enhance an integrated feed safety system. The agreements support the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs, and they assure a broader regulatory framework for the U.S. feed supply.

In FY2010, FDA classified and issued recall numbers for 40 Class I (most serious); 126 Class II; and 31 Class III recalls of animal products. In FY2010, FDA's MARCS-Compliance Management System indicated 3 approved CVM injunctions.

An OCI investigation led to a guilty plea from the owner of a veal feed business for misbranding violations under the Food, Drug and Cosmetic Act. The company owner was directing the contract farmers to use feeding protocols that included the routine addition of formaldehyde and potassium permanganate to the veal calves' feed. These are "drugs" within the meaning of the FDCA, and they are not approved for use in veal calf meat intended for human consumption. In October 2009, the company owner signed a guilty plea agreement on behalf of its company that resulted in criminal fine of $550,000. The owner and the company were also ordered to pay special assessments.

Promoting Efficiency

OLRA revised its Regulatory Procedures Manual (RPM) 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.

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 and feed import trade community and FDA, while continuing to ensure the U.S. animal feed supply does not experience an act of bio-terrorism.

Ruminant Feed Ban contract programs enhance FDA efforts to build an integrated feed safety system by increasing ORA and state ability to locate and visit companies

involved in the manufacture, distribution, and transportation of animal feed as well as animal feed operations and to verify their compliance with the BSE/ruminant feed ban.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2010: 279 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2010: 567 (Target Exceeded)	490	490	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 2010: 25% w/in 15 working days (Target Not Met)	80% w/in 15 working days	50% w/in 15 working days	-30%

Improving Response and Recovery - Center Activities

Base Amount: $2,235,000 (All BA)

Public Health Focus

Early detection of illnesses associated with food, tracing the source of the outbreak, and removing the contaminated product from the market is critical to containing potential risks to the public.

Public Health Outcome

CVM is improving on how to communicate with consumers about food-related emergencies and ensuring that communications related 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, in collaboration with the Center for Food Safety and Applied Nutrition (CFSAN) and other FDA Offices, participated in the development and launching of the Reportable Food Registry to provide a reliable mechanism to track patterns of adulteration in food in order to support FDA's efforts to target limited inspection resources to protect the public health.

In advance of foodborne illness events, CVM reviews and improves the protocol and roles and responsibilities for emergency coordination. CVM now 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. CVM has participated in review and updating of the FDA Emergency Operations Plan (EOP) to include a strategic plan for rapid response to import-safety incidents and to reflect changes to the National Response Framework.

Promoting Efficiency

CVM is developing the Veterinary Laboratory Response Network (Vet-LRN), a system that is "proactive" in a "reactive" situation. This network will provide the means for rapid response to report animal injury and will establish protocols to facilitate veterinary diagnostic reporting to FDA. Working with the Food Emergency Response Network (FERN) partners, CVM established a network of state and federal laboratories that integrate resources and expertise for timely and accurate reporting, identification, and analysis of animal feed chemical and microbiological contamination events. Upon completion, Vet-LRN will reduce duplication by coordinating resources and expertise between diagnostic laboratories thereby saving costs to both consumers and government investigators.

Coordinating intra-Agency efforts between NCTR, CFSAN and CVM has saved government resources by not duplicating, but complementing, each center's efforts by leveraging equipment and manpower. As a recent 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 needed 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.

Improving Response and Recovery - Field Activities
Base Amount: $9,832,000 (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. ORA continues to 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 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.

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 developed 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.

Currently ORA has 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 work enables Federal and state partners to improve their systems to more 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 responded to numerous pet foods and animal feed RFRs in FY 2010. Significant resources were expended into nationwide investigations, sample collections and analyses of a variety of products for various contamination concerns including animal feed contamination leading to animal death and Salmonella contamination of pet treats,

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.

ORA's continued use of grants and contracts with the states leverages working relationships with state counterparts at the local level to improve surveillance activities, enhance an integrated feed safety system and respond to public health threats in a timely and efficient manner. These programs assist FDA efforts during trace-back investigations, allowing for greater inspectional coverage for ORA and enhance feed safety and defense through increased communication and integration of key stakeholders.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. *(Outcome)*	FY 2010: 9 (Historical Actual)	2	11	+9 (Total of 11 labs)

Animal Drug Review - Center Activities

Base Amount: $24,310,000 (BA: $16,441,000 / UF: $7,869,000)

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. To meet this need, CVM serves public interest 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, indexing 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. CVM administers a grant program to support the development of new animal drugs intended for minor species or minor uses in major species. In March 2010, CVM issued Guidance for Industry on "Anesthetics for Companion Animals". This guidance document makes recommendations to assist developers of general anesthetic drugs, injectable or inhalational, for use in companion animals — dogs, cats, and horses. The guidance discusses the contents of the target animal safety, effectiveness, and labeling technical sections of a new animal drug application for general anesthetics.

The support of the reauthorized Animal Drug User Fee Act (ADUFA) of 2008 and the Animal Generic Drug User Fee Act (AGDUFA) of 2008 has 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 prevent drug makers from making 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.

In November 2009, CVM approved a generic new animal drug, Sevoflurane, for the induction and maintenance of general anesthesia in dogs. In December 2010, CVM approved the first drug, Equidone Gel (domperidone), for the prevention of fescue

toxicosis, a life threatening disease that can cause serious reproductive problems in horses. Fescue, a type of grass, carries the endophytic fungus, which produces toxins that interfere with the hormones involved in pregnancy and milk production.

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 utilizes the broad expertise across the CVM and FDA in a matrix review environment.

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 thus reducing the likelihood of unapproved drug use. When a

drug is designated for a particular intended use, the sponsor of the drug obtains seven years of exclusive marketing rights upon approval (or conditional approval) of the drug for that intended use. This program assists drug approval through grants to support safety and effectiveness testing and through exclusive marketing rights. In addition, this program supports the pharmaceutical industry in this effort through grants that pay for 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 provides an additional incentive to the industry to seek approval.

The MUMS Indexing program benefits the regulated industry by providing a reasonable and less expensive path to legal marketing of minor species drug products. Indexing takes much less time than drug approval which allows companies to begin to recoup their investment 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 recently 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. This research includes:

- drug safety and efficacy studies
- standard methods development
- aquatic species model development
- therapeutics evaluation
- support of minor species initiatives.

Research in these areas establishes models and standards that can be used in guidances for regulated industry resulting in lower resource allocation during preapproval interactions and the formal approval process.

Animal Drug Review - Field Activities
Base Amount: $2,544,000 (BA: $2,151,000 / UF: $393,000)

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 (NADA) and Abbreviated New Animal Drug Applications (ANADA). The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA performs 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 in the conduct of 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2009: 100% of 5 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)*	N/A	90% w/in 680 days	90% w/in 380 days	-300 days

Post-market Safety and Compliance - Center Activities
Base Amount: $17,460,000 (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 discloses problems not evident during the pre-market review stage. Nonetheless, our 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 similar public health objective to ensure the safety of companion animal related products throughout the life cycle. CVM utilizes and maintains an Adverse Drug Experience (ADE) database to provide a surveillance system to identify drug safety signals and effectiveness issues of concern that were not detected during pre-market testing of FDA-approved animal drugs. Though there is not mandatory ADE reporting for the manufacturers of drugs not FDA approved for animals, CVM monitors the reports that it receives for these products to identify safety and effectiveness issues of concern. CVM scientists use the ADE database to make decisions about product safety, which may include changes to the label or other regulatory action.

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 US and worldwide. Animals are the major source of the pathogens involved in zoonoses. CVM has the ability to address regulatory issues designed to prevent and control zoonotic diseases in both animal and human populations. The most current 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.
In the area of regulatory research, CVM initiated a multi-phase study on herding dogs that are predisposed to have a genetic defect which increases their sensitivity to certain classes of drugs such as the avermectin class heart worm medication. Dogs that have this genetic defect are at risk of developing toxic reactions to what normally are therapeutic doses of the drug. These reactions can even cause the animals to die. The results of these studies will influence how veterinary clinical data are generated and evaluated, the type of preclinical data requested to support drug approval, and ultimately the product label. CVM will improve the ability to predict therapeutic effects and adverse reactions for drugs used in veterinary practice, providing better information for practitioners and their client-owners.

Promoting Efficiency

CVM developed and implemented a pharmacovigilance program that accepts reports electronically and pre-populates an adverse drug events database. The program provides significant administrative savings to industry and allows CVM to provide more real-time surveillance of adverse drug event reports so that safety signals can be identified and communicated to veterinarians and animal and pet owners. Electronic submission of adverse event information was made possible through CVM's Electronic Submissions System (ESS), which integrates with the FDA Electronic Submissions

Gateway (FDA ESG) to allow adverse drug event reports to be transmitted directly from industry to CVM – gateway-to-gateway submission. ESG allows thousands of adverse event reports to immediately enter the database for processing and analysis. The Safety Reporting Portal (SRP), implemented separately, allows individual mandatory adverse event reports for animal drugs. SRP is intended primarily to provide the electronic submission option for sponsors without sophisticated electronic pharmacovigilance programs or for those with few adverse drug event reports. This provides financial savings to those companies and ensures they provide the appropriate adverse event safety information needed to protect animals and humans.

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. Paralleling with CDER's efforts, in 2008, CVM began a similar patient safety initiative to prevent medication errors in animals. While early in the process, CVM has identified reports of preventable medication errors in animals that are similar to the medication errors in people, which may cause unnecessary harm and injury to animals.

Post-market Safety and Compliance (medical) - Field Activities
Base Amount: $2,533,000 (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 monitor and sample imports to ensure the safety of the animal drug supply. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) and the Forensic Chemistry Center complement the regular Field force activities.

ORA support 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.

Promoting Efficiency

ORA evaluates adverse event reports in consultation with CVM and uses this information to perform targeted inspections to determine potential root causes of adverse events.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
242201: Review adverse experience reports to detect animal product hazards early. *(Output)*	FY 2010: 22% (Target Not Met)	50%	55%	+5%

Information Technology Investments – **Animal Drugs and Feeds Program Activities** (Base Amount displayed as a non-add item: $23,885,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

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 feed. FDA is committed to moving to an all electronic work environment to support the center's business process. CVM's Electronic Document Submission and Review (EDSR) project created an electronic system to receive, process, review, and respond to pre-market submissions and reviews, and will leverage these processes for post-market, product quality, administrative, drug index files, and scientific computing submissions and reviews. In addition, CVM is committed to convert its paper records into an electronic archive. CVM is also committed to expanding and to enhancing the National Antimicrobial Resistance Monitoring System (NARMS) with its external stakeholders including CDC, USDA, and state agencies to support the FDA Food Safety Initiative.

CVM will 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. The electronic processing capability

will be expanded to include the reporting of voluntary animal drug events, the reporting for medicated feeds, and the reporting of reportable foods, which would better allow FDA to use the information to promote and protect the public health.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	$105,718,000	$94,749,000	$10,969,000	588
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 Continuing Resolution	$154,863,000	$134,798,000	$20,065,000	767

Summary of the Budget Request

The FY 2012 budget request for the Animal Drugs and Feeds Program is $176,458,000. This amount is an increase of $21,595,000 above the FY 2010 Enacted Budget. The Center for Veterinary Medicine amount in this request is $117,009,000 supporting 487 FTE. The Field amount is $59,449,000, supporting 307 FTE.

The base funding for the Animal Drugs and Feeds Program is $154,863,000, which includes $101,652,000 for the Center activities and $53,211,000 for the Field activities.

The Animal Drugs and Feeds Program is committed to meeting its mission of protecting human and animal health. With the base funding, CVM will achieve its responsibilities for the evaluation, approval and surveillance of

- animal drugs,
- food additives,
- feed ingredients
- animal devices.

CVM mission activities 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 public health.

Base funding also allows the Animal Drugs and Feeds Program to meet the trigger requirements for user fee collections under ADUFA and AGDUFA. These user fees supplement the appropriated portion of the new animal drug review program while enabling the Program to retain user fee supported FTE. With these user fees, the Program will continue to improve the quality and timeliness of the new animal drug and animal generic drug review process.

Prioritizing Prevention

Center Activities (Base Amount: $35,503,000)

FY 2012 increase for current law user fees: +$2,775,000 (+$2,383,000 ADUFA, +$310,000 AGDUFA and +$82,000 Food Export Certification)

Initiatives

Transforming Food Safety and Nutrition Initiative: Preventive Controls for Food and Feed Processing (+$3,000,000; 10 FTE)

CVM will implement a preventive, risk-based system to fully address all aspects associated with the manufacturing, packing, and storage of animal feed. Currently, only medicated feeds are required to be made under GMP regulations in 21 CFR 225. CVM will develop regulations to help the animal feed industry design a systems approach to preventing, eliminating, or reducing to acceptable levels potential risks to human and

animal health. This system will ensure that hazards are properly identified and controls are in place and will help 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.

FDA Regulatory Science and Facilities Initiative: Building Expertise to Regulate New Animal Biotechnology Products (+$1,850,000; 10 FTE)

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 around biotechnology, genetically engineered animals that produce new or improved products. Genetically engineered animal provide the potential for new or improved versions of human and animal drugs that treat human and animal diseases (with biopharm products).

FDA will increase its ability to regulate this complex new technology by hiring and training staff with core scientific capacities to improve the knowledge base and expertise in facilitating the review and potential approval of animal biotechnology products. This initiative is necessary for FDA to fulfill its mission to the public by supporting the creation of a world-class science workforce that will bring much-needed core scientific capacities in animal biotechnology to FDA. Funding this initiative will increase the accuracy and efficiency of FDA review process and reduce adverse health events and the time-to-market period for new animal biotechnology products. In addition, this investment will create a regulatory pathway for animal biotechnology, provide a stimulus to innovations key to public health, increase our stakeholders' understanding of animal biotechnology, and increase public confidence in FDA's ability to regulate this new technology.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$210,000; 0 FTE)

Animal Drugs and Feeds will conduct activities that support the following FDA-wide nanotechnology priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: $12,372,000)

Initiatives

Transforming Food Safety and Nutrition: Preventive Controls for Food and Feed Processing - FSMA Section 110 (+$674,000; 0 FTE)

Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources in this subprogram

- administer training on preventive controls to both FDA and State investigators. These resources will fund approximately 270 people – ORA investigators and State, Tribal, and Territorial inspectors – to attend a one-week training course utilizing a combination of face-to-face and distance learning mediums.

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+$467,000; 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 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 1 FTE to develop and validate certification testing instruments
- fund 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Center Activities (Base Amount: $13,286,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Integrated Food Safety System (+$1,274,000; 5 FTE)

CVM will work with our partners, federal and state, to:

- develop standard lab methods to detect animal feed contamination
- develop and conduct training for food safety officials related to animal feed safety standards
- integrate the scientific and inspection capabilities of both federal and state regulatory agencies.

This standardization will assure all regulatory partners are applying the same requirements in analyzing the safety of the feed supply. This will improve oversight and accountability of our animal feed programs. In addition, CVM will work with our partners to develop a network to share data enabling the regulatory partners to close gaps in our oversight of the feed industry. In particular, the development and enhancement of surveillance networks aimed at coordinating infrastructure - facilities, equipment, and professional expertise of state and federal laboratories. It is critical for FDA to prevent and respond to high priority microbial and chemical contamination events and form the

science basis for feed safety standards,including the development of guidances and regulations.

Transforming Food Safety and Nutrition Initiative: Import Oversight (+$2,621,000; 8 FTE)

With the increasing amount of animal feed products being imported into the country, FDA will establish new systems to prevent the importation of unsafe feeds rather than rely on detention of a product at the border. This will include assessments of feed safety systems in exporting countries for comparability to the US feed safety systems and establishing an accreditation system for third party certifiers that will review and assess the feed safety systems in other countries. FDA will conduct outreach with international public health agencies to help establish international cooperation and ensure a safe feed supply.

Transforming Food Safety and Nutrition Initiative: NARMS (+$1,100,000; 1 FTE)

With this increase, FDA will expand the current National Antimicrobial Resistance Monitoring System (NARMS) surveillance and monitoring infrastructure to expand the number of retail meat testing sites, and to test additional high-priority commodities such as seafood and animal feeds. This expansion of NARMS will allow FDA to make more informed science based decisions related to the use of safe and effective antimicrobial drugs for animals, while promoting prudent and judicious use of antimicrobial drugs in animal and human medicine. NARMS is the only National Surveillance program for monitoring changes in antimicrobial resistance in foodborne pathogens.

Field Activities (Base Amount: $13,843,000)

Initiatives

Transforming Food Safety and Nutrition: Import Oversight – FSMA Sections 201, 301, 302, 305, 306 and 307 (+$233,000; 1 FTE)

This investment supports a comprehensive prevention-focused import feed and pet food safety program that will rely on the food supply chain such as:

- feed and animal food manufacturers
- processors
- packers
- distributors
- importers.

This program provides assurances that the feed and pet food imported to the United States are safe and meet regulatory requirements. ORA will conduct the following activities with the resources in this subprogram:

- hire 1 FTE to assist in the development, implementation and conduct of Voluntary Qualified Importer Program (VQIP) inspections

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($700,000; 3 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:

- hire 1 FTE to serve as a National Work Plan Analyst. This FTE will assist ORA with its movements towards an integrated national workplan
- hire 1 FTE to serve as an Official Establishment Inventory (OEI) Coordinator for the field
- hire 1 FTE to serve as a Scientific Coordinator. This resource will support the states as FDA moves to national standards for laboratories

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Center Activities (Base Amount: $8,858,000)

FY 2012 increase for current law user fees: +$521,000; 2 FTE (Recall)

Field Activities (Base Amount: $12,087,000)

FY 2012 increase for current law user fees: +$3,189,000; 20 FTE (+$2,550,000; 18 FTE Food Reinspection and +$639,000; 2 FTE Recall)

Initiatives

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+$685,000; 3 FTE)

This initiative incorporates CFSAN, CVM, ORA, and Headquarters and Office of the Commissioner (HQ/OC) activities to achieve an integrated food safety system. Budget authority funds for this initiative will enable FDA to support an increase of 33 tissue residue inspections.

Transforming Food Safety and Nutrition: Import Oversight – FSMA Sections 201, 301, 302, 305, 306 and 307 (+$234,000; 1 FTE)

This investment supports a comprehensive prevention-focused import food and feed safety program that will rely more heavily on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. ORA will conduct the following activities with the resources in this subprogram

- hire 1 FTE to expand existing foreign inspection program

Improving Response and Recovery

Center Activities (Base Amount: $2,235,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Integrated Food Safety System (+$226,000; 1 FTE)

CVM will work with our partners to develop a network of share data. Share data will enable regulatory partners to close gaps in our oversight of the feed industry. In particular, the development and enhancement of surveillance networks aimed at coordinating infrastructure - facilities, equipment and professional expertise of state and federal laboratories. It is critical for FDA to prevent and respond to high priority microbial and chemical contamination events and form the science basis for feed safety standards, including the development of guidances and regulations.

Field Activities (Base Amount: $9,832,000)

Animal Drug Review

Center Activities (Base Amount: $24,310,000)

FY 2012 increase for current law user fees: +$1,794,000 (+$1,588,000 ADUFA and +$206,000 AGDUFA)

Initiatives

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$90,000; 0 FTE)

Animal Drugs and Feeds will conduct activities that support the following FDA-wide nanotechnology priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: $2,544,000)

FY 2012 increase for current law user fees: +$82,000 (+$65,000 ADUFA and +$17,000 AGDUFA)

Post-market Safety and Compliance

Center Activities (Base Amount: $17,460,000)

Initiatives

Protecting Patients: Improving Postmarketing Safety in Animal Drugs (+$500,000; 3 FTE)

FDA relies on information from adverse event reporting (ADE) to ensure safety of drugs throughout the drug life cycle. With this funding, FDA will acquire scientific and technological resources and expertise necessary to analyze data to improve the safety of animal drugs through a more comprehensive, proactive, and efficient analysis of reported ADE data. Early identification of unsafe and ineffective drugs through a more robust surveillance system will help foster public assurance that FDA is working for their benefit by promoting confidence in the nation's foods and drugs.

Real time surveillance is necessary to prevent injuries and death assuring public confidence that ineffective drugs are detected early on and that public health are not at risk due to a lag in review time. These resources will help provide a real time active surveillance system in detecting animal safety, human use hazards, and product ineffectiveness issues proactively before a crisis arises.

Field Activities (Base Amount: $2,533,000)

Proposed Medical Products Reinspection User Fee: (+$134,000; 1 FTE)

Initiatives

Protecting Patients: Increasing Medical Product Inspections (+$184,000; 1 FTE)

FDA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2014 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This component will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete its hiring of additional employees and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 17 domestic Animal Drug Manufacturing /Type A Medicated Articles Inspections.

BA Increase for Pay Costs: +$309,000 (Center: $191,000; Field: $118,000)

Contract and Administrative Savings (Total Program: -$1,257,000)

The request for $147,899,000 in total budget authority for the Animal Drugs and Feeds Program also reflects a contract savings reduction of -$1,257,000. The Center's portion of the savings reduction is -$795,000 and the Field's portion is -$462,000.

Center Activities

Contract and Administrative Savings (-$795,000; 0 FTE)

The Center for Veterinary Medicine (CVM) will achieve contract savings by:

- reducing costs by using existing FDA and center contracts and by identifying other measures to award contracts that can reduce costs
- determining where services can be accomplished in-house rather than by procuring services from outside sources
- using in-house expertise to teach training courses instead of paying contractor services
- streamlining activity time reporting processes to improve efficiency and productivity, which will reduce the need for contract support for this system
- using telework to increase productivity, improve efficiency, and reduce overhead costs for rental space.

Field Activities

Contract and Administrative Savings (-$462,000; -3 FTE)

The Office of Regulatory Affairs (ORA) will achieve contract savings by:

- reducing administrative support FTE, both in Headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA.

Animal Drugs & Feeds Program Activity Data (PAD)			
Animal Drugs & Feeds Workload and Outputs	**FY 2010 Actuals**	**FY 2011 Estimate**	**FY 2012 Estimate**
New Animal Drug Applications (NADAs) [1]			
Received	12	12	13
Completed	13	13	14
Approved	11	11	11
Pending [2]	3	2	1
New Animal Drug Application Supplements [1, 3]			
Received	552	552	552
Completed	493	523	552
Approved	344	344	344
Pending [2]	212	241	241
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	21	21	21
Completed	32	32	32
Approved	10	10	12
Pending [2]	25	14	3
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	187	187	187
Completed	196	196	196
Approved	112	112	112
Pending [2]	166	157	148
Investigational New Animal Drug (INAD) Files [4]			
Received	3,377	3,377	3,377
Completed	3,088	3,377	3,379
Pending [2]	702	702	700
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	271	271	271
Completed	269	271	271
Pending [2]	67	67	67
Food (Animal) Additive Petitions	39	39	39
Investigational Food Additive Petitions	89	89	89
Adverse Experience Reports (AERs) [5]			
Received	52,926	55,000	58,000
Reviewed	11,562	12,100	31,900

[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	2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,181***	***1,938***	***1,750***
Pre-Approval /BIMO Inspections	53	79	79
Drug Process and New ADF Program Inspections	229	205	205 [1]
BSE Inspections	1,721	1,486	1,205
Feed Contaminant Inspections	42	25	25
Illegal Residue Program Inspections	362	400	454 [2]
Feed Manufacturing Program Inspections	222	141	141
Domestic Laboratory Samples Analyzed	2,250	2,458	2,458
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***52***	***66***	***66***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	29	45	45
Foreign Drug Processing and New ADF Program Inspections	37	33	33
Foreign Feed Inspections	3	10	10 [3]
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,233***	***2,004***	***1,816***
IMPORTS			
Import Field Exams/Tests	5,202	3,600	4,550
Import Laboratory Samples Analyzed	755	740	740
Import Physical Exam Subtotal	**5,957**	**4,340**	**5,290**
Import Line Decisions	237,039	237,162	237,285
Percent of Import Lines Physically Examined	2.51%	1.83%	2.23%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,401***	***6,054***	***5,670***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***124***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,385	5,800	5,200
State Contract Inspections: Feed Manufacturers	416	350	425
State Contract Inspections: Illegal Tissue Residue	176	550	650
State Partnership Inspections: BSE and Other	124	300	300
State Contract Animal Drugs/Feeds Funding	$2,532,300	$2,950,000	$2,937,853
BSE Cooperative Agreement Funding	$2,893,500	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$408,700	$401,000	$429,395
Total State Funding	**$5,834,500**	**$6,351,000**	**$6,367,248**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,758***	***8,358***	***7,786***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 17 animal drug inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 33 tissue residue inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 12 foreign animal feed inspections.

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DEVICES AND RADIOLOGICAL HEALTH

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table

(Dollars in thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$366,900**	**$369,971**	**$366,900**	**$394,946**	**$28,046**
Center	$272,771	$279,151	$272,771	$292,384	$19,613
FTE	1,294	1,332	1,332	1,373	79
Field	$94,129	$90,820	$94,129	$102,562	$8,433
FTE	461	469	469	511	50
Program Level FTE	**1,755**	**1,801**	**1,801**	**1,884**	**129**
Budget Authority	**$313,935**	**$313,452**	**$313,935**	**$329,102**	**$15,167**
Center	$233,932	$233,584	$233,932	$247,726	$13,794
Field	$80,003	$79,868	$80,003	$81,376	$1,373
Pay Increase (non add)				*$753*	*$753*
Protecting Patients (non-add)				*$5,829*	*$5,829*
Advancing Medical Countermeasures (non-add)				*$8,428*	*$8,428*
FDA Regulatory Science and Facilities (non-add)				*$4,009*	*$4,009*
Administrative and Contract Savings (non-add)				*-$3,852*	*-$3,852*
Budget Authority FTE	**1,494**	**1,525**	**1,525**	**1,553**	**59**
Center	1,048	1,077	1,077	1,103	55
Field	446	448	448	450	4
User Fees	**$52,965**	**$56,519**	**$52,965**	**$65,844**	**$12,879**
Center MDUFMA	$32,836	$41,283	$32,836	$38,655	$5,819
FTE	220	232	232	244	24
Field MDUFMA	$1,049	$1,442	$1,049	$1,235	$186
FTE	7	13	13	14	7
Center MQSA	$6,003	$4,284	$6,003	$6,003	$0
FTE	26	23	23	26	0
Field MQSA	$13,077	$9,510	$13,077	$13,077	$0
FTE	8	8	8	8	0
Field Medical Product Reinspection				$3,424	$3,424
FTE				24	24
International Courier User Fee				3,450	3,450
FTE				15	15
User Fees FTE	**261**	**276**	**276**	**331**	**70**

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. In keeping with its mission, the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by:

- assuring the safety, effectiveness, and quality of medical devices
- assuring the safety of radiation-emitting products
- fostering innovation
- providing the public with accurate, science-based information about the products it oversees throughout the total product life cycle.

CDRH regulates medical devices that range in complexity from eye glasses and medical gloves to sophisticated implantable devices and diagnostic tests that utilize the latest in molecular biology. In addition to medical devices, the Devices Program regulates radiation-emitting electronic products — medical and non-medical — such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

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 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 Office of Regulatory Affairs (ORA) Field offices nationwide support Devices Program activities by assessing industry compliance with applicable regulations. ORA does the following:

- conducts premarket and postmarket inspections of domestic and foreign manufacturers

[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.

- 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.

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
Base Amount: $131,595,148 (BA: $108,933,498 / UF: $22,661,650)

Public Health Focus

The Premarket Device Review program focuses on increased access to innovative, safe and effective products and technologies to improve public health. 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. These innovative medical devices advance patient clinical care, treatment, and rehabilitation as well as provide tools for health maintenance and disease prevention.

Through CDRH's Premarket Device Review activities, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- transforming health care
- promoting high-value effective care.

Public Health Outcome

In the past fiscal year, CDRH’s Premarket Device Review program received over 8,000 premarket submissions resulting in innovative devices and radiological products that improve public health. Recent examples of devices approvals include:

- the first heart valve approved for sale in the United States that can be implanted through a catheter in a leg vein and guided to the heart without open-heart surgery
- an artificial cervical disc that allows motion at the operated spinal level, unlike a fusion procedure

- an implantable miniature telescope used to magnify objects to improve vision in patients with end-stage, age-related macular degeneration
- the first rapid blood test for antibodies to the hepatitis C virus (HCV)
- the first test for the 2009 H1N1 Influenza Virus.

In recent years, CDRH experienced significant growth in the number and the complexity of medical device applications due to an acceleration of scientific discovery. These trends offer not only the promise of exciting, new diagnostic tools and devices to improve patient care, but pose significant public health challenges. Americans rely on an assurance from FDA that medical devices marketed for public use will be safe and effective. This assurance must be backed by rigorous and independent scientific analyses and matched with resources for CDRH scientists and engineers to keep pace with rapid growth in application volume and complexity.

CDRH is responding to the challenge by working smarter. CDRH fosters medical device innovation and enhancing device safety by improving the transparency, consistency and quality of its premarket review process. CDRH leadership directed staff to assess and provide recommendations for improvements to the premarket notification (510(k)) program. The 510(k) process is used to review most medical devices prior to marketing in the United States. The recommendations are designed to provide industry with better guidance and predictability on FDA policies, leverage outside scientific expertise, and support informed decision making. CDRH reviewed and analyzed public comments from a variety of stakeholders and announced in January 2011 plans to implement the recommendations that have widespread support. These recommendations include creating new guidance and improving staff training.

The Premarket Device Review program provides rapid response to national emergencies. CDRH worked with industry and government partners to rapidly review *in vitro* diagnostic tests for detection of the H1N1 flu virus and created a submission template and guidance to help manufacturers develop and validate diagnostic tests. CDRH approved 18 Emergency Use Authorizations for H1N1 tests. In preparation for the 2010-2011 influenza season, FDA cleared three additional tests for market release, one developed by the Centers for Disease Control and Prevention (CDC) for public health laboratory surveillance and two by commercial companies for the diagnosis of influenza infection.

CDRH also supports activities to meet the unique needs of children and youth. These activities include funding the Pediatric Device Consortia Program, which promotes development of devices for pediatric populations, and premarket device review guidance to improve the quality of marketing submissions. To date, four Pediatric Device Consortia have been established, collectively facilitating the early development of over eighty potential medical devices for children.

CDRH strives to prevent unnecessary harm to human research subjects and to assure the integrity of data collected through the Bioresearch Monitoring (BIMO) Program. In the past fiscal year, CDRH issued over 300 clinical and non-clinical inspections at medical device research sites and conducted significant outreach to Institutional Review Boards (IRB) to ensure clinical study data integrity and adherence to required human patient safety protocols. Investigations of for-profit IRBs identified more than 10 research studies that were incorrectly identified in the exempt or non-significant risk categories. Once CDRH determined that these studies involved significant risk, FDA terminated the studies to protect the research subjects. The research cannot resume until CDRH determines that the sponsors corrected the studies' problems.

Promoting Efficiency

Through its Premarket Device Review program, CDRH has been a leader in encouraging the use of innovative clinical trial designs and analyses to support regulatory approval of medical devices. CDRH has developed several improved methods that can result in smaller clinical trials and can leverage data from previous trials to support more streamlined and efficient device development.

For example, Bayesian clinical trial designs can use data from previous studies so that fewer new clinical trial subjects are required to achieve the same level of evidence to support device approvals. Adaptive clinical trials can be used to increase or decrease the number of clinical trial subjects to achieve the optimum number necessary to demonstrate a clinical trial result.

In some situations, "propensity score" methods can be used to appropriately compare outcomes between patients in a current study or establish a control group of patients from a previous study. The CDRH web page also provides data on the type and design of pivotal clinical trials necessary to support high quality premarket approval applications for devices. FDA can review high quality applications more efficiently and in less time. FDA's efforts allow industry to deploy their financial resources more efficiently and improve their competitiveness in the global market place.

CDRH also works with industry and other stakeholders to develop best practices, policies, and guidance that improve efficiency by making premarket applications more consistent and complete. These efforts result in fewer cycles of FDA review and faster results for industry. For example, CDRH provides technical assistance to manufacturers who need support for new product development.

To train researchers on FDA expectations for medical device research, CDRH implemented Academic Centers for Excellence, an educational outreach program located in public and private universities. In FY 2009 and FY 2010 CDRH conducted town-hall meetings to solicit input from industry and other stakeholders about the medical device program and released a total of 69

guidance documents to communicate up-to-date information regarding FDA's current thinking on medical devices and radiological products. The medical device industry uses the information in these guidances to innovate and stimulate economic opportunity within the medical device sector.

Premarket Device Review – Field Activities
Base Amount: $8,448,743 (BA: $7,451,743 / UF $997,000)-

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 works to ensure that firms 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, once manufactured, become a viable supply of safe commodities for U.S. consumers.

Promoting Efficiency

Through the Field activities of the Premarket Device Review subprogram, ORA collaborates with CDRH on the most efficient way to conduct bioresearch monitoring inspections. 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. Through this subprogram, FDA helps ensure that sponsors collect data that can support a device application rather than conducting clinical trials that yield data that sponsors cannot rely upon to support device approval.

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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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] 86% of 28 in 180 days and 93% of 28 in 295 days (Target Exceeded)	60% in 180 days and 90% in 295 days	50% in 180 days and 60% in 295 days	-10% in 180 days and -30% in 295 days
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. *(Outcome)*	FY 2009: 93% of 153 in 180 days and 97% of 153 in 210 days (Target Exceeded)	85% in 180 days and 95% in 210 days	75% in 180 days and 85% in 210 days	-10% in 180 days and -10% in 210 days
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. *(Outcome)*	FY 2009: 91% of 3,324 in 90 days and 98% of 3,324 in 150 days (Target Exceeded)	90% in 90 days and 98% in 150 days	75% in 90 days and 80% in 150 days	-15% in 90 days and -18% in 150 days
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2010: 392 (Target Exceeded)	300	300	Maintain

[1/] FY 2009 cohort is not fully complete for PMAs and 510(k)s.

Postmarket Safety – Center Activities

Base Amount: $51,900,834 (BA: $46,194,962 / UF: $5,705,872)-

Public Health Focus

CDRH postmarket safety activities focus on monitoring medical devices performance, including adverse events, to ensure that devices and radiological products remain safe and effective for patients and consumers. CDRH analyzes safety signals with potential clinical impact and when an issue surfaces, it responds to quickly identify and limit potential problems with medical devices and radiological products. Additionally, CDRH's postmarket safety activities are focused on improving techniques for detecting signals of potential medical device problems and applying risk-based decision making in evaluating the need for intervention.

Through CDRH's Postmarket Safety activities, FDA is able to achieve important HHS and Administration priorities including:

- improving health care quality and patient safety
- promoting high-value effective care.

Public Health Outcome

CDRH's recent postmarket safety outcomes include advances in the Medical Product Safety Network (MedSun). MedSun is a national network of 350 hospitals designed to prevent unnecessary device-related injuries and deaths by partnering with FDA to report device-related adverse events and near misses. The number of recalls resulting directly from MedSun reporting more than doubled from 11 to 24 over the 2008 – 2009 calendar years (CY) while manufacturers' actions increased from 66 to 78. For CY 2010, MedSun-based recalls and manufacturers' actions have surpassed the previous two years with a total of 32 recalls and 101 manufacturers' actions resulting from MedSun reporting.

The Sentinel Initiative is a national electronic system that will transform FDA's ability to monitor medical products. CDRH's lead role in the initiative enables emerging medical device safety concerns to be identified sooner and appropriate responses to be provided earlier. In FY 2010, Sentinel activities included exploring capabilities for active surveillance of registries through a pilot study that addressed a statewide cardiovascular registry and a network of institutions implanting cardiovascular devices. Under the SafeRx project for safety evaluation, CDRH examined the use of Medicare data to understand device performance, initially focusing on surgical mesh and gastric banding devices.

Rapid communication to the public, clinical community and manufacturers about device problems posing a significant public health risk is essential for consumer safety. As part of its risk communication strategy, CDRH launched CDRH Learn, an online educational training tool to improve training of U.S. and international limited resources by empowering more foreign and domestic safety regulators. The medical device and radiological health regulation modules are available in multiple languages and were viewed over 180,000 times since the launch of the tool. CDRH also streamlined its risk communication processes to provide quicker communication to the public, clinical community, and manufacturers about device problems.

CDRH continues to prepare world class data systems for state-of-the-art product surveillance. Its Unique Device Identifier (UDI) initiative will enable CDRH to enhance and improve its postmarket surveillance and recall processes. UDI implementation will improve CDRH's and industry's understanding of medical devices throughout the entire product life cycle and provide valuable data to compare the performance of marketed devices. Following extensive public outreach, CDRH developed a proposed rule to require medical device manufacturers to place a UDI on a label, or on the device itself, and supply critical identifying information in a UDI database. CDRH will publish the rule in the first half of CY 2011. The Initiative will provide significant cost savings to industry including supply chain efficiency savings and reduced costs to distribute products globally by using a common UDI framework.

Other important postmarket safety activities include developing scientifically sound post approval studies to assure the safety of newly marketed devices. CDRH's staff of highly trained epidemiologists works with industry and other stakeholders to design, track, oversee, and review results for studies when they are mandated as a condition of premarket approvals.

CDRH is committed to advancing the delivery of safe and effective devices for use in the pediatric population and expanding its efforts to better understand the performance of pediatric medical devices in the postmarket surveillance period. CDRH is engaging in a number of initiatives to address pediatric device needs. For example, CDRH is collaborating with healthcare systems and hospitals to track adverse events related to pediatric patients, providing outreach to industry, and developing sophisticated systems to enhance the tracking and flagging of pediatric data.

Promoting Efficiency

CDRH strategically designs Postmarket Safety activities to operate most efficiency. For example, a program known as CDRH Learn provides on-line training on key regulatory issues. This web tool reduces the need to send CDRH experts to foreign and domestic locations.

The CDRH unique device identifier (UDI) initiative allows FDA, device manufacturers and the medical community to identify devices by batch numbers and locations, allowing FDA and industry to conduct more targeted recalls. This improvement has obvious benefits for FDA and patients but also benefits industry by preventing blanket recalls that may reduce consumer confidence in products from multiple manufacturers.

CDRH is also finalizing a rule to require electronic medical device reporting, known as eMDR. eMDR is expected to provide significant cost savings to industry and FDA related to data entry, storage, handling and reporting. This electronic submission system will replace a far less efficient manual reporting system. eMDR is designed to meet the needs of large volume reporters -- who can submit reports in batch -- and small volume reporters who can submit reports one-at-a-time. Manufacturers have electronically submitted more than 150,000 reports using the eMDR system, at great savings to FDA and manufacturers.

Likewise, CDRH increased industry's awareness of existing clinical trial data helping eliminate costly trials and duplicative data gathering and allowing manufactures to conduct more efficient post-approval studies. For example, the Interagency Registry for Mechanically Assisted Circulatory Support is a national registry that captures short- and longer-term clinical-trial quality data on patients receiving heart pump assistance devices. Device manufacturers can avoid the significant cost of developing and conducting new clinical studies by using this

registry to support applications for “de novo” classification. De novo classification is available for devices that have never been marketed in the United States but whose safety profile and technology are now reasonably well understood.

Postmarket Safety – Field Activities
Base Amount: $819,164 (BA: $767,164 / 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 that monitor the postmarket safety of products already available to the public for use.

Public Health Outcome

ORA conducts inspections of both domestic and foreign medical device firms where issues or concerns have been identified. In January 2010, FDA announced a Class I recall of Huber needles and Huber Infusion sets following the receipt of MDRs and inspections of numerous Exelint International Co. manufacturing facilities. Huber needles are used to access ports implanted under the skin of chronically ill patients for repeated access to veins for withdrawing blood and infusing medication, blood products, and solutions. These needles should be designed to penetrate the port without cutting and dislodging any silicone cores (or slivers) from the ports into which they are inserted.

Investigations found that the needles cored in 60 to 72 percent of tests. These cores could cause the ports to leak and could lead to a silicone sliver entering the patient’s body, risking serious adverse events such as stroke, heart attack, organ damage and death. ORA’s inspections, investigations, sample collections and analyses into safety concerns related to Huber needles and Huber infusion sets led to the recall of more than 2 million units distributed nationwide.

In 2010, ORA investigations followed up on complaints regarding products labeled as Bard polypropylene surgical mesh. ORA worked with Bard to identify the counterfeit products and ORA laboratory analysis showed that the counterfeit mesh was not sterile, differed in weave pattern and in the size of the weave openings, and differed in the finish of the edge of the mesh, perhaps allowing it to unravel. In June 2010, FDA issued a Class I recall of the counterfeit polypropylene surgical mesh products, resulting in the recall of 15 lots of product.

Promoting Efficiency

FDA issued-press releases, guidance to industry, and alerts provide 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 provide industry with guidance on the FDA's current initiatives and provide up-to-date information to consumers and medical professionals about device safety concerns. These FDA communications ensured efficient and timely public health response and industry and consumer awareness.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
252201: The minimum number of reports per year that 80 percent of MedSun hospitals, enrolled for at least 11 months in the program will submit. *(Outcome)*	FY 2010: 3 Reports (Target Met)	3	3	Maintain
252202: By 2013, enroll 80% of the top 15 MDR reporters by volume in the voluntary eMDR (Medical Device Reporting) program. *(Outcome)*	FY 2010: 47% (Target Exceeded)	40%	73%	+33%

Compliance, Enforcement, and Radiation Safety – Center Activities

Base Amount: $32,080,819 (BA: $32,080,819 / 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 FDA to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- promoting high-value effective care.

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. Recent enforcement efforts include:

- a consent decree against STERIS Corporation following a finding that the company significantly modified the STERIS System 1 (SS1) processor without FDA approval or clearance. SS1 is used in surgical and endoscopy suites for reprocessing medical devices. STERIS agreed to destroy used SS1 devices, components, parts and accessories. This action protected patients from a device that CDRH has not determined is safe or effective for its labeled claims, including claims that it sterilizes medical devices.

- an investigation into a specific model line of fetal heart rate monitors in conjunction with a device recall. After the recall, CDRH formed a working group to look into similar issues with other monitors and track relevant signals for adverse events.

- a recall for up to 200,000 defective Baxter Colleague Volumetric Infusion Pumps due to safety risks. Baxter was required to provide replacements or refunds to purchasers of their devices. CDRH worked with Baxter to develop a transition guide for customers to switch to FDA-cleared or approved pump alternatives.

CDRH also identified accuracy, interference, and infection control problems with glucose meters – used an estimated 42 billion times annually by diabetic patients. In FY 2010, CDRH held a public meeting to gather input on appropriate meter accuracy goals. CDRH, along with CDC and CMS, issued Public Health Notifications alerting users of the risk of pathogen transmission when blood glucose testing is performed at healthcare facilities without proper cleaning and disinfection procedures. CDRH is developing guidance and working with device manufacturers to address these important issues.

To address current public health needs related to electronic product radiation, CDRH administers the Electronic Product Radiation Control Provisions of the FD&C Act through its Radiological Health Program. 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 the past fiscal year, CDRH slashed by half its average timeframe for review of field establishment inspection reports to 64 days.

CDRH is leading an initiative to reduce unnecessary radiation exposure from three types of medical imaging procedures that are the greatest contributors to Americans' total radiation exposure from medical imaging: computerized tomography (CT scan), nuclear medicine studies, and fluoroscopy. The initiative

promotes the safe use of medical imaging devices, supports informed clinical decision-making, and increases patient awareness of their own exposure. In response to this initiative, industry voluntarily committed to build dose checking safeguards into CT scanners within the coming year. CDRH is also working with the Foundation for the National Institutes of Health (FNIH), the American College of Radiology, and others to establish a national radiation dose registry for CT scans.

Promoting Efficiency

To leverage its resources, CDRH is collaborating with foreign governments to ensure that imported medical devices and radiological products are safe and effective for the American public. During FY 2009 and FY 2010, CDRH delivered 14 major regulatory workshops for key stakeholders of foreign governments including China, India and Korea.

In addition, CDRH is developing a Common Audit Program (CAP) to dramatically enhance program efficiency, stretch FDA resources, and improve patient safety. CAP will establish device quality management system requirements that are consistent with each regulator's requirements. As a result, audits performed by any regulator will meet the requirements of all foreign partners. CAP allows CDRH to stretch its inspection resources by allowing CDRH to access and review reports of inspections conducted by trusted countries that use U.S.-recognized inspection standards. CAP will also provide uniform guidelines to industry, and reduce the cost of complying with multiple regulators and a web of overlapping and possibly inconsistent requirements. FDA will implement a pilot CAP program with Canada in CY 2011 and Australia in CY 2012. Common audits and shared results will expand oversight of foreign and domestic manufacturing facilities, allowing FDA and other regulators to deploy inspection resources more efficiently and reduce duplicate inspections. CAP will also improve the quality of manufactured products.

CDRH conducts public education and outreach to both industry and the research community to foster understanding of relevant laws and regulations, and to promote voluntary compliance with FDA standards. CDRH analyzes data to determine the root cause of reported problems associated with recalls, adverse events and industry quality system problems. CDRH communicates this information to industry through direct meetings and seminars and presentations at industry-sponsored events. CDRH also works with industry to resolve systemic issues and prevent future problems – activities designed to save industry unnecessary costs associated with recalls and enforcement actions.

Compliance, Enforcement, & Radiation Safety – Field Activities
Base Amount: $ 67,489,564 (BA: $67,489,564 / 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 and enforcement 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. This 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 goods.

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 and to detain all import entries that do not comply with applicable regulations.

As part of the recall program, CDRH determines the level (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) serve to eliminate the profit from violative activity and to provide non-compliant firms with the financial incentive to correct violations.

Public Health Outcome

ORA successfully managed the medical devices contract with the state of Texas with a total of 20 inspections including 8 QSIT Level 1 and 12 QSIT Level 2 inspections. In addition to completing contracted inspections, ORA worked with external stakeholders to train state investigators to perform audits and joint inspections. This training strengthened state inspector qualifications in conducting inspections. Leveraging relationships with state counterparts while providing training and guidance to the states provides U.S. consumers with an integrated safety network, ensuring a greater level of regulatory oversight of the device industry and assuring the products available in the domestic market are safe and effective.

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 the agency's guidance on regulatory actions and laboratory procedures. This process revision is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in US commerce that could harm consumers.

In FY2010, FDA classified and issued recall numbers for 334 Class I (most serious); 2,208 Class II; and 93 Class III recalls of medical device products. In FY 2010, the agency's MARCS-Compliance Management System indicated four approved injunctions for device products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

Since the Secretary's declaration of the 2009 H1N1 Flu Virus Public Health Emergency, FDA worked proactively to protect consumers by identifying, investigating, and taking regulatory or criminal action against individuals or businesses that promote illegal and fraudulent H1N1 influenza products, including test kits regulated by CDRH. FDA issued 30 warning letters to offending internet firms in FY 2010. Four of the 30 were FDA/Federal Trade Commission joint letters. As of November 2010, FDA issued a total of 95 warning letters covering 185 fraudulent H1N1 flu products, resulting in a compliance rate exceeding 80 percent.

To protect vulnerable consumers, FDA issued warning letters to eight internet firms promoting chelation (metal bonding) products with unproven claims to treat a range of diseases that include autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. Three firms were also cited for promoting unapproved test kits that purported to detect the presence of heavy metals to justify the need for chelation therapy.

ORA authorized the testimony needed in a sex trafficking case when the U.S. Attorney's office needed to prove that condoms are not manufactured in the state of NY and therefore were brought across state lines and used against minors. This cooperation and coordination demonstrates the broad public health impact of medical device surveillance.

In FY 2010, ORA established a dedicated foreign device cadre consisting of 10 experienced medical device investigators to augment the existing foreign inspection program. The cadre performed more than 80 foreign device firm inspections in their first year to provide assurance that products manufactured abroad are safe for use in the United States.

In the past fiscal year, ORA began staffing 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 on several ongoing cases including Devices Program products such as lasers.

In FY 2010 ORA conducted more than 1,400 domestic inspections of class II & III (greatest risk) medical device manufacturers and more than 250 inspections of class II & III device foreign manufacturers. ORA continues to use violative findings during inspections of foreign facilities to establish pre-emptive import controls. These internal actions provide increased surveillance of regulated products in violative firms to ensure a higher level of scrutiny if products are offered for import into the United States.

A portion of ORA inspections focuses on quality systems, including Corrective Action and Preventative Actions (CAPA). The review of CAPA data reveals process and product problems from multiple sources, both from within and outside of the manufacturer. These reports demonstrate potential issues to be investigated and corrected. ORA investigators evaluate this data to target specific areas of the production process and quality system to ensure all stages of the product life cycle are in compliance with FDA regulations. These inspections assure FDA that product components used in the manufacturing process and the process itself are in compliance with FDA regulations, providing greater assurance of the finished product meeting safety and efficacy standards for use in the U.S. market.

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 July 2010, this PREDICT enhancement was in use in FDA's Los Angeles, New York, San Francisco and Seattle Districts. FDA plans to expand this feature to additional districts.

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 recently implemented a joint initiative to create and issue a series of field advisories to assist ORA investigators. As a result of this initiative, ORA issued 12 field advisories in FY 2010. 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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 2010: 66% (Target Not Met)	90%	75%	-15%
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2010: 1,659 (Target Exceeded)	1,365	1,515	+150

Device Innovation and Regulatory Science – Center Activities
Base Amount: $47,086,810 (BA: $42,618,332 / UF: $4,468,478)

Public Health Focus

CDRH's Device Innovation and Regulatory Science activities focus on improving the timeliness and quality of feedback to industry and consumers regarding new technologies, and on providing critical evaluation tools that can ensure the safety and effectiveness of cutting edge innovations while speeding up the time from product development to market.

Through CDRH's Device Innovation and Regulatory Science activities, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- transforming health care
- promoting high-value effective care.

Public Health Outcome

CDRH's science activities are essential to assure that advances in science and technology translate into improvements in human health. CDRH relies on its scientific activities to identify the underlying mechanisms of device actions on the body and to develop the science-based questions, test methods, and tools necessary to assess the safety and effectiveness of medical products. These tests and tools are designed, validated, and provided to consensus standards organizations and industry.

CDRH develops state-of-the art computer simulations of devices to evaluate safety and effectiveness. Recent examples include developing and verifying computer models and highly accurate physical models of the head to simulate brain perfusion computed tomography (CT). These models estimate the dose to specific organs and estimate risks associated with the delivered dose. These tools improve premarket assessment of CT devices and enable industry professionals to use the dose necessary for the study without exceeding the threshold for damage.

CDRH also works with manufacturers to redesign existing devices with systematic safety problems. When device failures cause injuries, CDRH's scientific investigations provide in-depth analyses of the underlying causes. The findings from these analyses are then used to redesign the devices to ensure safe future products. CDRH engineers recently identified the cause of hazards with the Huber needle, a component of implantable ports used to give chemotherapy and other medicines to adults and children. As a result, CDRH recalled more than two million Excel Huber needles, worked with manufacturers to prevent problems in the manufacturing process, and developed test methods to enable continued monitoring.

CDRH is dedicated to adapting to the unique issues of emerging technologies while continuously improving regulatory pathways to support and foster medical product innovations. CDRH established a personalized medicine (PM) staff to address the new generation of medical products that provide patients with targeted medical treatment based on individual patient genetic attributes. The PM staff conducted a public meeting to gather input on aligning regulatory review requirements with realistic expectations and finalizing a guidance on regulatory requirements for companion diagnostics and therapeutics. CDRH announced that it is easing the pathway to market for mammography systems that produce computerized X-ray images of the entire breast. CDRH also released a "special controls" guidance for industry that describes the scientific evidence that will be needed for these systems to come to market.

CDRH is committed to quickly incorporating new science into its decision making while maintaining as much regulatory predictability as practical. In FY 2010, CDRH released a report for public comment that recommends concrete steps it can take to achieve this goal. CDRH also established a Council on Medical Device Innovation to facilitate medical device innovations that address unmet public health needs. The Council is composed of several government agencies, including Department of Defense, Defense Advanced Research Projects Agency, Center for Medicare and Medicaid Services, Federal Communication Commission, Veterans Administration, and Centers for Disease Control and Prevention. These efforts, including a public meeting to receive input from external constituencies, help ensure that reliable regulatory pathways are available to rapidly translate innovative concepts to safe and effective medical devices that address public health needs.

Promoting Efficiency

CDRH's science activities serves as a force multiplier, generating benefits for the stakeholders that CDRH serves, including the U.S. medical device sector.

CDRH science activities

- reduce cost of research and development for device manufacturers
- foster innovation and economic growth
- support economic development in the medical device sector.

For example, CDRH develops and shares with industry reliable tests, tools and methods for evaluating key characteristics of new devices and technologies. The availability of these standardized, well-validated methods reduces ambiguity and uncertainty as industry develops and submits data to FDA. The availability of these methods also allows FDA to interpret industry data more efficiently.

CDRH also performs laboratory investigations to clarify the underlying scientific mechanisms and parameters that govern the safety and effectiveness of new

types of technologies. An early, solid scientific understanding of performance-critical factors allows industry to focus on developing data for FDA review that is truly relevant, thereby increasing the efficiency of industry research. CDRH develops state-of-the art computer simulations of devices and their interactions with the body to efficiently provide fundamental insights into safety and effectiveness issues. CDRH and industry benefit from the ability of such models to analyze large numbers of scenarios and to determine which scenarios are meaningful for determining device performance. The CDRH models allow CDRH and industry to conduct extremely powerful assessments of device performance in a fast and efficient way.

Recent examples of laboratory investigations that promote efficiency include CDRH glucose sensing research that allows CDRH to provide prompt feedback to industry and improves industry's ability to develop products such as glucometers, continuous glucose monitor (CGM) devices, and electrochemical enzymatic biosensors. This glucose sensing research also directly advanced the development of a safe and effective "closed loop" artificial pancreas through glucose reading criteria that supports the sensor component of an artificial pancreas. The artificial pancreas is intended to ensure delivery of the appropriate amount of insulin to enable effective management of blood glucose levels.

CDRH scientists also recently developed the first phantoms (standards) for rapidly assessing Optical Coherence Tomography (OCT) image quality. OCT is currently being used in the health community at least 37,000 times per day to scan for eye diseases. The availability of standardized phantoms as test objects enhances academic and industry research and development efforts. These standards provide a more accurate, less costly, and highly efficient manner to clarify basic OCT issues and ensure the safety of American patients.

In addition, CDRH maintains laboratory collaborations with external scientific institutions and universities in the United States and around the globe. Recent collaborations include work with the National Science Foundation, National Institutes of Health, National Institute for Standards and Technology, National Institute for Disability and Rehabilitation Research, Defense Advanced Research Projects Agency, and dozens of public and private universities. Regular interactions with other scientific investigators enable CDRH's scientists and engineers to leverage expertise to meet ever-changing scientific and technical needs in a more efficient manner.

Device Innovation and Regulatory Science –Field Activities
Base Amount: $1,533,334 (BA: $1,533,334 / UF: $0)

Public Health Focus

ORA's Winchester Engineering and Analytical Center (WEAC) laboratory supports Device and Radiological Health Science activities by conducting test method development, validation and evaluation activities. ORA worked closely with CDRH to identify devices posing the greatest risk to the public and subsequently developed, and will continue to develop, analytical test methods for timely and efficient analyses.

Public Health Outcome

ORA continues to make advancements in device safety for consumers by leveraging internal and external stakeholders, conducting postmarket analytical methods development activities on pressing public health risks, and 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.

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. ORA's field laboratories have undertaken an effort to increase the number of medical gloves analyzed at an expedited rate utilizing a "high throughput" model previously adopted for food borne outbreaks. Increased equipment funding and test method development activities allowed regulatory labs to design, procure, and commission automated glove testing machines that shorten timeframes for analytical testing.

Promoting Efficiency

Increased efficiencies and capacity allowed ORA to analyze a higher volume of fundamental yet essential products such as medical gloves in reduced timeframes. These efforts support the timely release of industry products into U.S. commerce. These efficiencies also ensure that reliable medical products are available to the health care community, safeguarding medical practitioners and patients from ineffective medical devices.

ORA scientists 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. For example, these activities will 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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2010: 127 Analyses (Target Exceeded)	125	125	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2010: 1.429 Reviews (Target Exceeded)	1,175	1,175	Maintain

Mammography Quality Standards Act (MQSA) – Center Activities

Base Amount: $10,107,389 (BA: $4,104,389 / 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, FDA is able to achieve important HHS and Administration priorities:

- improving health care quality and patient safety
- promoting high-value effective care
- promoting wellness and prevention.

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 8,700 certified mammography facilities in the United States. As a result of the MQSA program, over 80 percent of the facilities are free of violations at the time of inspection, and less than 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, such as civil money penalties and certificate revocation and suspension.

Promoting Efficiency

MQSA maximizes the efficient operation of mammography facilities and reduces health costs by ensuring the quality of mammography services that contribute to the early detection of breast cancer. CDRH improved cost-effectiveness and efficiency within the MQSA program by approving multiple, alternative standards for manufacturers of full field digital mammography devices. These alternative standards allow mammography facilities to more efficiently correct quality control test failures. The efforts of the MQSA subprogram also eliminate redundant MQSA inspection testing. Finally, actions by the MQSA subprogram will make training more efficient and less intrusive for State partners. By the spring 2011, two-thirds of MQSA inspector training will be available online.

Mammography Quality Standards Act – Field Activities
Base Amount: $15,838,195 (BA: $2,761,195 / 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.

In FY 2010, ORA oversaw approximately 7,300 MQSA state inspections and monitored over 90 audits to state inspectors. To ensure high quality facility inspections conducted by the states, ORA coordinated with CDRH to offer annual

MQSA inspectors training courses to new state inspectors as well as to provide continuing education units 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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% (Target Met)	97%	97%	Maintain

Information Technology Investments – Devices and Radiological Health Program Activities (Base Amount displayed as a non-add item: $59,072,000)-

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in the systems described above IT infrastructure, unique center-specific systems, and enterprise-wide systems, CDRH-specific IT development efforts support the regulation of medical devices and radiation-emitting products. CDRH has information management objectives of increasing

transparency, collaboration, integration, knowledge management, business agility and improved efficiency throughout the medical device and radiological health total product life cycle. To meet these objectives, CDRH depends heavily on modernized IT, informatics standards and the migration from paper to standardized electronic submissions. In addition to maintaining and/or enhancing existing IT systems, CDRH leverages commercial off the shelf (COTS), government off the shelf (GOTS) and FDA technologies and initiatives to help achieve those objectives. For example, CDRH will utilize COTS social networking-type tools that are transforming communication and collaboration on the internet to improve collaboration and knowledge management both internally and externally.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2007 through FY 2011 for the Devices and Radiological Health Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	267,543,000	230,682,000	36,861,000	1544
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 Continuing Resolution	$366,900,000	$313,935,000	$52,965,000	1,801

Summary of the Budget Request

The FY 2012 budget request for the Devices and Radiological Health Program is $394,946,000. This amount is an increase of $28,046,000 above the FY 2010 Enacted Budget. The Center for Devices and Radiological Health amount in this request is $292,384,000, supporting 1,373 FTE. The Field amount is $102,562,000, supporting 511 FTE.

The base funding for the Devices and Radiological Health Program is $366,900,000, which includes $272,771,000 for the Center for Devices and Radiological Health activities and $94,129,000 for the Devices and Radiological Health Program Field activities.

The Devices and Radiological Health Program (Devices Program) is requesting budget authority and user fee resources to maintain its base program in FY 2012. Base program funding allows the Devices Program to conduct mission-essential activities in support of:

- Premarket Device Review
- Postmarket Safety
- Compliance, Enforcement, and Radiation Safety
- Device Innovation and Regulatory Science
- Mammography Quality Standards Act (MQSA).

These activities are critical to protecting and promoting the public health by assuring:

- safe and effective medical devices and radiological products
- manufacturing processes and industry compliance of regulations and laws
- medical device innovation and emerging technologies
- safe, high quality mammography facilities.

Premarket Device Review

Center Activities (Base Amount: $131,595,148)

FY 2012 increase for current law user fees (MDUFA): +$4,016,000; 18 FTE

Initiatives

Advancing Medical Countermeasures (MCM) Initiative (+$4,589,000; 19 FTE)

Pillar 1 – Optimizing the Review Process for MCM by Establishing Public Health and Security Action Teams (PHSATs): (+$3,865,000; 16 FTE)

Under Pillar 1, CDRH staff will enhance its MCM review capacity and provide expertise through Public Health and Security Action Teams (PHSATs) to ensure that MCM diagnostic and medical products and technologies receive necessary support throughout the product lifecycle.

CDRH will develop a regulatory pathway for radiation injury protection devices to facilitate and promote the development of personal biodosimetry devices for estimating radiation dose from an exposure. Availability of these devices will empower people to take actions necessary to decrease or eliminate the severity of injury from radiological and/or nuclear events.

CDRH will also develop a regulatory pathway to promote more rapid development of multiplex diagnostic devices, which are a new generation of diagnostic devices designed to simultaneously detect a large number of biological threat agents. CDRH will collaborate with the Department of Defense (DOD), the Centers for Disease Control and Prevention (CDC), and other external partners to develop multiplex diagnostic testing assays. Activities will include facilitating Emergency Use Authorizations (EUA) and pre-EUAs for chemical, biological, radiological and nuclear threats.

Similarly, CDRH will develop a regulatory pathway for portable ventilators and other personal protective equipment. CDRH will work with the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response to develop a portable ventilator for adult and pediatric use.

Pillar 3 – Optimizing the Legal, Regulatory and Policy Framework for Effective Public Health Response: (+$724,000; 3 FTE)

Under Pillar 3, CDRH will work with FDA's Office of the Commissioner to analyze gaps in regulation and optimize the legal and policy framework needed to support the activities described above, and others, to assure an effective emergency public health response.

Field Activities (Base Amount: $8,448,743)

FY 2012 increase for current law user fees (MDUFMA): +$186,000; 7 FTE

Postmarket Safety

Center Activities (Base Amount: $51,900,834)

FY 2012 increase for current law user fees (MDUFA): +$1,011,000; 4 FTE

Initiatives

Protecting Patients Initiative: Medical Device Registry (+$1,667,000; 4 FTE)

FDA will lead an effort to develop and implement a national strategy for the best public health use of health-related electronic data that incorporates unique device identifiers (UDIs) and leverages existing procedure and device registries.

The initiative will:

- establish a national strategy for developing national medical device registries and expanding existing procedure and device registries
- develop a roadmap for the effective and efficient incorporation of UDIs into health-related electronic data, including electronic records and claims systems
- identify the best proposal(s) for incorporating UDIs
- pilot efforts to create device type attributes and reference libraries.

These activities will harness the vast amount of untapped public health information on device safety and effectiveness available in health-related electronic data. The activities will also incorporate a critical piece of information -- specific device exposure. Without this information, evaluations of device safety and effectiveness are not possible.

Protecting Patients Initiative: Pediatric Safety (+$750,000; 3 FTE)

The funds support the integration of all available internal and external data on the pediatric population which will strengthen FDA's postmarket science base. FDA will purchase data from external sources and hire an epidemiologist to build the infrastructure to analyze pediatric postmarket device information. FDA will broaden the scope of targeted surveillance of pediatric device use and performance through the MedSun program by using Regional Representatives. FDA will hire and support travel for two Regional Representatives who will

- train staff from hospitals and home-health agencies to recognize if a device played a role in an adverse outcome
- assist staff in collecting the details of the problem so they may be reported to FDA
- conduct focus group discussions and interviews with health care providers
- work with clinical sites following a manufacturer's recall to evaluate the effectiveness of the change.

The successful integration of available postmarket information will benefit FDA, the sponsors of medical devices, and the public through an enhanced understanding of how devices move into wide-spread use in the clinical environment, and their effectiveness and safety in under-studied populations, including pediatrics.

This initiative enables FDA to:

- establish a centralized capacity to coordinate all CDRH pediatrics-related activities, including the development of devices to treat or diagnose uncommon conditions
- expand KidNet
- develop different methodological approaches to analyze data from external postmarket databases and integrate such data in FDA's post-approval decision making process, including key patient populations – children, women, and minorities.
- conduct high quality comparative effectiveness studies
- obtain increased quantity and quality reports about device problems used in the pediatric population, resulting in FDA taking actions to solve problems and improve safety in this vulnerable population
- build postmarket capabilities for the present and future monitoring of medical device safety and effectiveness, especially in the pediatric population.

Field Activities (Base Amount: $819,164,000)

No Initiative increases

Compliance, Enforcement, and Radiation Safety

Center Activities (Base Amount: $32,080,819)

Initiatives

Protecting Patients Initiative: Imported Medical Device Safety (+$1,500,000; 5 FTE)

Funding the Medical Device Safety initiative will allow CDRH to continue to build the capacity to ensure the safety of products shipped to the United States. Specifically, the initiative will allow CDRH to:

- hire and train five Center staff to support an audit program of foreign government inspections and an FDA increase in foreign and domestic medical device inspections
- increase the number of foreign assignments provided to FDA's Office of Regulatory Affairs by 10% over the 2010 level to ensure the quality and safety of imported products.

With this initiative, FDA will build its import safety program capacity to protect the American public. CDRH anticipates an increase in the Center's oversight of foreign manufacturing facilities by creating an audit program for high quality

inspections conducted on behalf of foreign governments with well-developed regulatory systems. To handle the additional workload and emerging technology, CDRH will develop a compliance review staff that is:

- well versed in FDA's Quality System Regulation
- knowledgeable of the ISO 13485 requirements that are used by many foreign regulators and serve as the basis of the manufacturing information shared with FDA
- capable of integrating information from both sources into the CDRH risk-based surveillance process.

With this initiative, the CDRH compliance review staff will be more vigilant of new innovations and technologies that medical device manufacturers incorporate into their manufacturing processes and medical products.

Protecting Patients Initiative: National Imaging Dose Registry (+$250,000; 1 FTE)

These funds will support the development of standards for safe and effective CT scanners and fluoroscopes, as well as a pilot dose registry program FDA is already actively participating in with the American College of Radiology in beginning development of a national radiation dose registry. FDA will also begin to develop an educational program to support medical imaging dose awareness. The focus will be on CT scans—the largest single contributor to public radiation dose, fluoroscopy, and nuclear medicine studies.

Funding the initiative will allow CDRH to:

- hire and train staff to support activities for standards development, dose reduction education, and support of a dose registry pilot
- establish and enhance relationships with professional organizations that collect medical imaging dose information—including the American College of Radiology and the Society of Interventional Radiology—to understand the status of their efforts and to identify areas for possible collaboration
- establish relationships with key stakeholders that advance education priorities.

With this initiative CDRH will establish design standards for safe and effective CT scanners and fluoroscopes and work with healthcare professional organizations to create a national radiation dose registry. The initiative will also support CDRH's preparation for projects to evaluate the feasibility of establishing meaningful dose metrics and capturing dose information in electronic health records. This allows healthcare providers to make better informed decisions as to which, if any, medical imaging studies a particular patient should undergo.

Field Activities (Base Amount: $67,489,564)

Proposed user fee (Medical Products Reinspection): +$3,424,000; 24 FTE

Initiatives

Protecting Patients Initiative: Increasing Medical Product Inspections (+$1,662,000; 6 FTE)

ORA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2015 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete hiring of 6 additional employees and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 14 domestic GMP surveillance inspections. By September 30, 2015, ORA will conduct an additional 14 foreign Radiological Health Inspections and 53 foreign GMP surveillance inspections for a total foreign inspection increase of 67 inspections.

Advancing Medical Countermeasures Initiative: (+$218,000; 1 FTE)

Under Pillar 1, ORA Field operations will conduct enhanced inspection and compliance activities, identify problems that impede MCM product development as early and efficiently as possible and provide technical assistance to minimize risk during MCM product manufacturing. This increase will support 14 additional domestic device inspections once the investigators reach full performance in FY 2014.

Proposed User Fee: International Courier (+$3,450,000; +15 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. The number of shipments continues to grow, and current FDA staffing does not match the growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of

imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

User fees for this activity allow increased import surveillance of FDA-regulated products at express courier hubs. FDA will:

- conduct entry reviews
- sample collections and physical exams to determine product admissibility into the U.S.
- initiate compliance actions to prevent release of unsafe products into U.S. commerce, and establish import controls to prevent future unsafe products from entering U.S. commerce.

Device Innovation and Regulatory Science

Center Activities (Base Amount: $47,086,810)

FY 2012 increase for current law user fees (MDUFA): +$792,000; 2 FTE

FY 2012 Initiatives

Advancing Medical Countermeasures (MCM) Initiative (+$3,621,000; 15 FTE)

Pillar 2 – Advancing Regulatory Science for MCM Development and Evaluation: (+$3,621,000; 15 FTE)

Under Pillar 2, CDRH will provide additional scientific support to test the safety and effectiveness of MCM diagnostic and medical products and technologies; monitor safety throughout the product lifecycle; and facilitate the availability of MCM products.

These activities will support important research designed to fill in development and evaluation gaps in existing MCM resources. Examples include evaluating the safety and effectiveness of decontamination procedures for personal protective equipment and other medical devices intended for reuse; and developing animal models for use in product development, including studies to assess the feasibility of using isolated cardiac myocytes (muscle cells) as an innovative dangerous agent detection system.

Pillar 2 activities will also include working with CDC to assure that devices in the Strategic National Stockpile are safe and effective, and developing a medical device shortages database to improve CDRH's ability to anticipate, prevent, minimize and respond to a medical device shortage.

FDA Regulatory Science and Facilities Initiative: Science and Innovation Leadership (+$500,000; 2 FTE)

This initiative will provide support for FDA-wide scientific leadership and coordination, workforce excellence, scientific collaboration, and the recruitment of next generation scientists in areas of emerging science.

Recruitment of Next Generation Scientists: FDA's Office of Chief Scientist and the Senior Strategic Advisory Leadership group will identify key areas of emerging science where FDA needs expertise. The Agency will recruit outstanding and newly independent scientists, with expertise in laboratory and population sciences, such as biostatistics, epidemiology, modeling, and risk sciences, to fill key positions to augment its existing workforce.

The requested FY2012 funds will allow CDRH to enhance expertise in the following forward-looking areas for which there is an urgent and critical need:

- *Systems of computerized devices*—to bring advanced knowledge in computer science, software engineering and networked systems to advance CDRH's ability to evaluate device systems that integrate "smart' devices which "talk to" each other directly and continually. These systems are increasingly being used by healthcare facilities to provide and manage procedures and patient care, physician decision support tools, laboratory and medical imaging management tools, and robotics, including next generation high-technology orthopedic prosthetic devices.
- *Innovative analytic methodologies*—to enhance expertise in the use of Bayesian statistics in clinical trials to incorporate innovative quantitative methods, including quantitative risk-benefit analysis and adaptive trial designs, to assess and connect different sources of information. These methodologies are critical for establishing and using a national Medical Device Registry and for conducting comparative effectiveness assessments using existing sources of healthcare-related information.

Through a more robust scientific leadership and coordination effort, FDA will be able to develop an overarching scientific strategy, and begin a multi-year process to implement a fully coordinated scientific agenda that meets the demands of the 21st century. This initiative will increase FDA's ability to use existing scientific resources more efficiently, and improve its ability to incorporate advances in biomedical research into medical product development and evaluation.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$900,000; 2 FTE)

Under the nanotechnology initiative, CDRH will conduct activities that support the following FDA-wide priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary

research to address product characterization and safety. Together, these priorities will improve FDA's ability to bring benefits of nanotechnology to bear while reducing its risks.

FDA Regulatory Science and Facilities Initiative: Medical Device Registry (+$2,333,000; 4 FTE)

Providing this funding allows the Center to:

- investigate and pilot proof-of-concept studies to understand the surveillance and observational methods needed to understand real world device safety and effectiveness using electronic healthcare data that incorporate UDIs
- investigate and conduct studies to assess optimal methods for surveillance and observational study of linked registry and longitudinal electronic healthcare data
- work within FDA Sentinel efforts to develop an infrastructure that will leverage the Agency for Healthcare Research and Quality's research and database infrastructure.

These activities will lay a strong foundation for understanding the surveillance and observational methodologies needed to optimize electronic healthcare data sources. In doing so, FDA will be in a better position to effectively detect and respond to device-related public health issues as they arise and to provide healthcare providers and patients with important, new information about the risk-benefit profile and comparative risk-benefit profile of higher risk medical devices.

With this initiative FDA will lead an effort to develop and implement the best methods for device surveillance and observational study in electronic healthcare databases that incorporate UDIs. Similar efforts will be undertaken to assess optimal methods for surveillance and observational study of linked registry and longitudinal electronic healthcare data. Additionally, the initiative will:

- significantly enhance the Sentinel Initiative effort in medical device surveillance and observational study
- provide the best methods to make optimal use of health-related electronic data that incorporates UDIs.

Field Activities (Base Amount: $1,533,334)

Initiatives:

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$276,000; 1 FTE)

For the nanotechnology initiative, ORA will conduct activities that support the following FDA-wide priorities:

(1) laboratory and product testing capacity
(2) scientific staff development and training
(3) collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Mammography Quality Standards Act (MQSA)

Center Activities (Base Amount: $10,107,389)

Increase for current law user fees: $0

Field Activities (Base Amount: $15,838,195)

Increase for current law user fees: $0

BA Increase for Pay Costs: +$753,000 (Center: $556,000; Field: $197,000)

Contract and Administrative Savings (Total Program: -$3,852,000)

The request for $329,102,000 in total budget authority for the Devices and Radiological Health Program also reflects a contract and administrative savings reduction of -$3,852,000. The Center's portion of these savings is -$2,872,000 and the Field's portion is -$980,000.

Center Activities

Contract and Administrative Savings (-$2,872,000; 0 FTE)

Center for Devices and Radiological Health (CDRH) will achieve contract and administrative savings by:

- using technology to further reduce high contractor costs associated with processing and data entry
- terminating contracts that do not fully meet program needs
- using technology to improve contract management
- reducing CDRH staff travel
- replacing traditional classroom training with online training modules
- reducing services provided by outside contractors.

Field Activities

Contract and Administrative Savings (-$980,000; -4 FTE)

The Office of Regulatory Affairs (ORA) will achieve contract and administrative savings by:

- reducing administrative support staff, both in headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA
- obtaining the best value for the American public through blanket purchase agreements and agency-wide approaches to contracting.

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Expedited PMA Received	4	6	6
Expedited PMA Approved	4	4	4
Expedited PMA – Performance	90% [1/]	70%	60%
PMAs Received (PDP and PMA)	48	45	45
PMAs Approved (PDP and expedited)	17	35	35
Original PMA performance	90% [1/]	70%	60%
PMA Supplement Panel Tracks Received	16	12	12
PMA Supplement Panel Track Approved	2	10	10
Panel Track PMA Supplement Performance	90% [1/]	70%	60%
Humanitarian Device Exemptions Received	7	6	6
Humanitarian Device Exemptions Approved	1	4	4
Average HDE FDA Review Time (FDA days approval)	374	300	300
PMA Supplements Received	158	160	160
PMA Supplements Approved	106	155	155
510(k)s Received (Trad., Special, Abbrev., 3rd party)	3,893	4,100	4,100
510(k)s Completed (All Decisions)	3,783	3,700	3,700
510(k) performance	98% [1/]	93%	80%
Investigational Device Exemptions Received	226	240	240
Investigational Device Exemptions Decisions	206	230	230
% Acted on Within 30 Days	98%	99%	99%
Investigational IDE Supplements	3,899	3,900	3,900
IDE Supplements (Approved/Total Decisions)	3,921	3,800	3,800
% Acted on Within 30 Days	99%	100%	100%
Total Standards Recognized for Application Review	898	900	940

[1/] FY 2010 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 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,536***	***2,493***	***2,533***
Bioresearch Monitoring Program Inspections	372	295	295
Pre-Market Inspections	42	68	68 [1]
Post-Market Audit Inspections	29	48	48
GMP Inspections	1,672	1,573	1,614 [1]
			0
Inspections (MQSA) FDA Domestic (non-VHA)	329	359	359
Inspections (MQSA) FDA Domestic (VHA)	37	33	33
			0
Domestic Radiological Health Inspections	96	157	157
			0
Domestic Field Exams/Tests	239	480	480
Domestic Laboratory Samples Analyzed	125	217	217
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***322***	***352***	***388***
Foreign Bioresearch Monitoring Inspections	20	25	25
Foreign Pre-Market Inspections	26	33	33
Foreign Post-Market Audit Inspections	36	19	19
Foreign GMP Inspections	251	286	327 [2]
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	32	26	26 [2]
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,858***	***2,845***	***2,921***
IMPORTS			
Import Field Exams/Tests	18,761	13,180	13,180
Import Laboratory Samples Analyzed	1,513	1,145	1,145
Import Physical Exam Subtotal	20,274	14,325	14,325
Import Line Decisions	8,822,633	10,942,777	13,572,408
Percent of Import Lines Physically Examined	0.23%	0.13%	0.11%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,168***	***8,496***	***8,496***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	***72***	***74***	***74***
Inspections (MQSA) by State Contract	7,060	7,356	7,356
Inspections (MQSA) by State non-Contract	1,091	1,120	1,120
GMP Inspections by State Contract	17	20	20
State Partnership GMP Inspections	72	74	74
State Contract Devices Funding	$79,000	$85,000	$92,000
State Contract Mammography Funding	$9,000,000	$9,630,000	$10,300,000
Total State Funding	**$9,079,000**	**$9,715,000**	**$10,392,000**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,098***	***11,415***	***11,491***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 14 premarket MCM inspections and an additional 14 GMP surveillance inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 14 Rad Health inspections and an additional 53 GMP surveillance inspections.

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table

(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$58,745**	**$58,531**	**$58,745**	**$60,294**	**$1,549**
Center	$58,745	$58,531	$58,745	$60,294	$1,549
FTE	210	246	246	215	5
Program Level FTE	**210**	**246**	**246**	**215**	**5**
Budget Authority	**$58,745**	**$58,531**	**$58,745**	**$60,294**	**$1,549**
Center	$58,745	$58,531	$58,745	$60,294	$1,549
Pay Increase (non add)				*$134*	*$134*
Transforming Food Safety and Nutrition (non-add)				*$414*	*$414*
FDA Regulatory Science and Facilities (non-add)				*$1,700*	*$1,700*
Administrative and Contract Savings (non-add)				*-$699*	*-$699*
Budget Authority FTE	**210**	**246**	**246**	**215**	**5**

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

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, such as nanomaterials, and to evaluate new safety concerns identified with established products. NCTR also conducts research on the risks and benefits of products – and thereby advances the FDA mission of protecting patients and consumers – across the full spectrum of products that FDA regulates. The research at NCTR supports FDA's strategic priorities 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.

- improve global public health through international collaboration including research and information sharing
- provide the public with the accurate, science-based information they need to use medicines and foods to improve their health
- understand how the human body reacts to exposure to toxic agents
- incorporate new technologies to improve the assessment of human exposure, susceptibility, and risk to potential adverse events
- increase the understanding of the interaction between genetics, metabolism, and nutrition.

In addition to conducting research in support of the FDA mission, NCTR provides expert technical advice and training to colleagues. This training enhances FDA's basis for sound science-based regulatory decisions that improve the health of the American people and it supports FDA's strategic priority to develop a world-class workforce.

NCTR receives federal appropriations to execute its mission under the legal authorities listed above. NCTR, established in 1971 as a national scientific resource, conducts research that translates knowledge and technology into processes that improve the ability of FDA and others to assess the safety of FDA-regulated products.

The public health benefits of NCTR's work for the American public include:

- early predictors of toxicity-risk from products that FDA regulates
- development and validation of, and guidance for, new technologies used to regulate foods and medical products
- regulatory tools that facilitate premarket review, postmarket safety assurance, and risk-based product safety decisions
- personalized nutrition and medicine including individualized therapy, dietary recommendations, and identification of disease susceptibility
- evaluation of the biological effects of potentially toxic chemicals and microorganisms
- key research data for high-priority safety issues, such as pediatric anesthetics
- analytical tools to rapidly detect food contamination
- methods that facilitate FDA-regulated product development to improve public health.

NCTR leads national and international collaborations and innovation among government, industry, and academic partners to leverage resources to:

- address regulatory review needs
- develop solutions to complex safety issues
- promote the international standardization and global harmonization of regulatory science.

NCTR executes its research responsibilities in three subprogram areas:

- Personalized Nutrition and Medicine
- Strengthen Surveillance and Risk Analysis
- Enhancing Medical Product Safety

Personalized Nutrition and Medicine

Base Amount: $24,249,936 (All BA)

Public Health Focus

NCTR conducts regulatory research to support Personalized Nutrition and Medicine by developing strategies and methods and providing resources for improving individual and public health. The overall goal of this research is to develop and implement research strategies that identify genetic, environmental, and cultural diversity factors that affect the course of health and disease. In collaboration with industry, academia, and other government agencies, NCTR works to define and characterize individual responses to FDA-regulated products, thus improving personal and public health.

Public Health Outcome

During the 20th century, data generated by the human genome project laid the foundation for one of the most significant scientific contributions to humankind – an understanding that while humans are genetically similar, each retains a unique genetic identity that contributes to the wide array of observable physical or biochemical characteristics. Much of the knowledge generated in biomedical research over the past century was based on the *average* response of a population to a food, drug, nutrient, or environmental chemical. NCTR research will lead to the identification of an *individual's* response.

Through development of a broad range of studies to characterize biomarkers – or indicators – of health, disease risk, and disease status, NCTR's research promotes Personalized Nutrition and Medicine and HHS priorities to Improve Patient Safety, Reduce Obesity, and Accelerate Scientific Advances in Quality Health Outcomes. These biomarkers will allow FDA to identify science-based individualized treatment therapies that will increase treatment effectiveness and reduce the rate of adverse events in patients. NCTR will continue to explore new approaches such as nutrigenomics – the study of relationships between nutrition and genetics – to better understand how individual attributes affect responses to drugs, foods, nutrients, and dietary supplements used individually and in combination.

Promoting Efficiency

Advances in personalized medicine supported by this subprogram have the potential to revolutionize health care. 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, and businesses and governments that pay health care costs will save time and money. All parties will 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.

Obesity Research – Obesity is a major public-health concern because of its relationship to metabolic disorders such as Type 2 diabetes and cardiovascular diseases. 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. NCTR is conducting research to identify what genetically predisposes individuals to obesity and the consequent development of metabolic syndrome disease such as diabetes and heart disease. Identifying the genes and dietary components that affect the differentiation of stem cells provides data essential to develop diagnostics and strategies for preventing or delaying the onset of nutrition-related chronic diseases. The data from this research will contribute to FDA's and industry's knowledge for designing healthier manufactured foods.

Obesity and Diabetes Research – NCTR conducts studies with the international and local communities to define the correlations between an individual's nutrition, health, and genetic profile. Scientists are working to define the relationship between obesity and the functions of micronutrients and microbiota in the gastrointestinal tract. To better understand a person's predisposition to obesity, research will be conducted using animal models to characterize how stem cells transform into fat cells. In addition, NCTR is pursuing how exposure to sex hormone-like compounds – found throughout the environment and occurring in natural and processed foods, food and drink containers, and medical devices – affects the body's ability to maintain a stable weight, changes food preferences and responses to stress, and increases an individual's vulnerability to obesity. This research will enrich FDA's and the medical community's knowledge about

the cause of obesity and will provide new information for public-health education and policy decisions.

NCTR works with international collaborations to improve global health. In January 2010, NCTR co-organized with the European Nutrigenomics Organization, a planning workshop to outline principles for creation and implementation of a publicly available Nutrition Phenotype Database. The database will capture, store, analyze, and retrieve data from emerging nutrition research in traditional food composition, frequency questionnaires, biomarkers, and the omics sciences. Omics sciences are fields of study in biology ending in "-omics" such as:

- genomics — study of all genes of a cell or tissue
- transcriptomics — study of messenger RNA molecules which can vary with external environment conditions
- proteomics — study of proteins
- metabolomics — study of chemical processes involving metabolites.

Individual genetic variations are being linked to biological responses, including how drugs are metabolized differently among individuals. Such knowledge will allow medical treatments to be optimized for each individual. Since food components/dietary agents can interact with or regulate a variety of molecular targets involved in metabolism and disease risk, nutrients may also alter the effects of drugs and disease susceptibilities among individuals. The Nutrition Phenotype Database will be a global gateway platform for scientists to integrate and analyze data gathered from nutrition studies conducted around the world, increasing the power of scientists to evaluate the role of nutrition in health and disease.

With its international partners, NCTR will also develop a program called the International Type 2 Diabetes Network to recruit and analyze individuals with newly diagnosed Type 2 diabetes to evaluate and record how genes in individuals with Type 2 diabetes differ among the world's populations. This information will be captured in a database of DNA variations in genes predicted to define drug responsiveness and efficacy and develop a greater understanding of gene-nutrient interactions. While this project involves international collaborations of more than ten countries and benefits the international community, the United States population is one of the most diverse in the world, and the information generated will also be directly applicable to Americans.

Since 2008, FDA/NCTR and USDA/Agricultural Research Service have had an ongoing partnership with a community development center in the Mississippi Delta region of Arkansas to conduct community-based participatory research (CBPR) that studies the effects of dietary intake and its influence on the development of obesity-associated diseases. This ongoing collaboration analyzes dietary intake patterns, micronutrient levels in the blood samples of children and adults, and calories expended. In 2010, scientists from NCTR

analyzed data from a 2009 CBPR study using standard statistical approaches and novel methods to assess individual responses. The study was replicated in 2010, with both interventions involving improved nutrient intakes. The goal was to assess the effects of dietary intake and its influence on the development of obesity-associated diseases such as Type 2 diabetes. Preliminary results showed sex-specific differences in children's response to dietary interventions. The standard statistical approaches found that individuals in Town A (pop. > 1000, 1 food store with fresh vegetables, ~20 miles from a supermarket) had significantly better nutrient intake and serum vitamin levels compared to individuals in Town B (pop. < 1000 people, no fresh markets, and ~30 miles from a supermarket). If the 2010 study data is confirmed, these results have implications for the development of recommendations for nutrient intakes targeted to individuals in differently resourced communities.

In FY 2011 and beyond, NCTR will expand the CBPR project by including school and community-based programs across Arkansas, other locations in the U.S., and international sites. The expanded CBPR will include the association of an individual's response to improved nutrient intakes with their genetic makeup and the likelihood of developing obesity and Type 2 diabetes. By the end of FY 2011, NCTR plans to analyze the DNA sequence of 400 candidate genes from the CBPR participants involved in the obesity and Type 2 diabetes study.

Obesity and Stem Cell Research – Researchers from the NCTR Stem Cell Laboratory presented their initial findings on micronutrients and the effects of different types of fat on stem-cell development at an international nutrigenomics meeting in New Zealand in February 2010. NCTR and the Arkansas Biosciences Institute also hosted a workshop in April 2010, to provide an opportunity for scientists to network and establish new collaborations for stem-cell research. NCTR's continuing research in this area will provide FDA and the medical community insight into the relationship between nutrition and adult obesity. 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.

MicroArray and Sequencing Technologies Quality Control – NCTR initially organized the MicroArray Quality Control (MAQC) project with participants from across government, academia, and industry to focus on the reproducibility of gene expression experiments. Their efforts resulted in an FDA companion guidance document for pharmacogenomics — the study of genetic variation's effects on individual responses to drugs — data submissions.

In FY 2010, the second phase of the MicroArray Quality Control (MAQC-II) project was completed under the leadership of NCTR scientists. The MAQC-II results are expected to substantially impact the clinical and regulatory use of genomic data. It is anticipated that findings from MAQC-II will lead to an FDA guidance document to aid industry in developing and validating models for

genetic research. NCTR is currently engaging the scientific community -- including FDA's other Centers and the National Institutes of Health -- to develop guidelines to ensure the reproducibility of genomic research.

The third-phase of the FDA-led MAQC effort, also known as the Sequencing Quality Control (SEQC) project, has reached its first milestone in FY 2010. The project established a baseline reference, which can be used to standardize and streamline research in RNA sequencing. A manuscript describing this finding is being developed. 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.

A pilot study is being conducted at NCTR and CDER to support the feasibility of a fourth phase of this effort, MAQC-IV. 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.

Genomics – In 2009, researchers at NCTR established a Genomics Laboratory for analyzing and re-sequencing genes and have analyzed 46 human and eight primate DNA structures. Individual genetic variations are being linked to biological responses, including how drugs are metabolized differently among individuals. Establishing expertise in the area of genomics is essential for FDA's regulatory mission to enable evaluation of new products and services that are developed on the basis of genomic information. Genomic experiments conducted at NCTR confirm that the full spectrum of adverse genetic mutations induced by chemical agents is detected by the Mouse Lymphoma Gene-Mutation Assay (MLA) – an approved scientific test method used by researchers to detect gene mutation and chromosomal damage. This genomics research has provided definitive proof that the MLA is capable of detecting most, if not all, of the chromosomal mutations known to be involved in human cancer development and other genetically based human disease.

NCTR scientists have also recently completed research that capitalizes on newly developed molecular techniques and techniques to conduct microscopic examination of genetic components of the cell, including chromosomes, genes, and gene products.

NCTR also participated in the Human Variome Project, (http://www.humanvariomeproject.org/), an international consortium of scientists and doctors working to electronically capture and index information on all genetic variations affecting human disease and to link geographically specific databases to international databases. These efforts will generate datasets necessary for

linking individual genetic variation to responses to food, environmental influences, medical treatments, and drugs. This knowledge will allow medical treatments to be optimized for each individual.

Biomarker Development – 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. These biomarkers can be directly measured in humans and could improve FDA's ability to evaluate the safety of candidate therapies before using them in humans and to detect drug-induced organ toxicity earlier.

The results of several key studies conducted by NCTR scientists 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.

Biomarkers are also critical for assessment of drug toxicity. NCTR is researching acetaminophen to expand available data. The majority of research data related to postmarket evaluation of acetaminophen usage is limited to acute pediatric overdose. The data generated from the NCTR research will be used to establish second-generation biomarkers of acetaminophen toxicity in future risk-assessment studies of children receiving therapeutic doses of acetaminophen and children receiving acetaminophen overdoses.

In FY 2010, using microarray-filtered analysis validated by real-time Polymerase Chain Reaction, a scientific technique widely used to amplify DNA, NCTR scientists identified 1,640 different sex-expressed genes, 26 of which were molecular transporters. All of the identified genes are potential sex-specific biomarkers and may be important biomarkers for drug toxicity and efficacy. Understanding the modulation of these biomarkers and their effect on risks will greatly improve patient benefits.

NCTR is also conducting research on cardiotoxicity biomarkers which will increase the understanding of cardiac tissue injury during drug exposure. The biomarkers for cardiotoxicity identified in mice will be potentially valuable tools for earlier detection of organ toxicity during preclinical and clinical safety evaluations.

This earlier detection may 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 heart toxicity. On the whole, this information may prove valuable in designing optimal drug regimens or novel interventions to minimize drug-related toxicity to the heart in clinical practice.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
262401: Develop biomarkers to assist in identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease in support of personalized nutrition and health. *(Output)*	FY 2010: Patterns were identified from analysis of 2009 CBPR data and preliminary analysis of 2010 CBPR data in serum biomarkers that can be used to monitor dietary intervention protocols to reduce obesity (Target Met)	Identify patterns in serum biomarkers to use in monitoring dietary intervention protocols to reduce obesity	1) Develop analytical methods to assess drug-induced heart damage 2) Identify target genes for obesity and the consequent development of metabolic syndrome diseases and heart disease	N/A

Strengthen Surveillance and Risk Analysis

Base Amount: $13,946,063 (All BA)

Public Health Focus

FDA is responsible for ensuring the safety of foods, food ingredients, and bioengineered foods; defending the food system against terrorist attacks; and identifying food-related health hazards. NCTR's Strengthen Surveillance and Risk Analysis subprogram supports these responsibilities and the HHS priority to implement a 21st Century Food Safety System through research that integrates results with the public-health mission of other FDA Centers and the Office of Regulatory Affairs (ORA). Through these collaborative projects, new methods and risk-based techniques continue to be developed to protect the American public from naturally occurring and intentional contamination of the food supply and the environment. NCTR is expanding FDA's capability to identify, assess, rapidly respond to, and reduce food-related health threats.

Public Health Outcomes

NCTR develops methods to assess and manage risks associated with food products that are adulterated, intentionally contaminated, or otherwise found to be detrimental to human health. These methods enable FDA Centers and other agencies to:

- rapidly determine the source of the contaminant
- closely monitor imported foods to identify contamination with traditional and nontraditional biological agents
- more quickly issue health alerts to the public and to state and local public-health agencies during an outbreak associated with consumption of contaminated foods
- improve modeling of risk-assessment data to analyze the safety of imported food.

Through food protection research, NCTR will continue to develop the tools and science necessary to improve understanding of food-security vulnerabilities and the most effective ways to minimize them. NCTR research will lead to:

- rapid, reliable, and cost-effective methods to detect contaminants in food
- new understanding of mechanisms that contribute to a contaminant's toxicity and the relationship to levels of exposure
- new methods to assess mechanisms of antimicrobial resistance in foodborne pathogens, which will help mitigate their spread
- strategies to reduce the occurrence of multi-drug resistant microorganisms and key pathogens in the U.S. food supply.

The research conducted by NCTR contributes to FDA's mission of increasing food protection for the American public.

Promoting Efficiency

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. Protecting the food supply and preventing significant negative health and economic effects associated with food-related illness is a fundamental part of FDA's mission and a central focus of the Strengthening Surveillance and Risk Analysis subprogram.

NCTR's research in the area of strengthening surveillance and risk analysis will more rapidly identify foodborne pathogens and their sources. Furthermore, the research will more rapidly determine the spread of antibiotic resistance and the increased virulence of foodborne pathogens. The research conducted within this subprogram will also improve our ability to identify the sources of bacterial contamination along the food supply chain and thereby help avoid the health care costs and other economic burdens associated with foodborne illnesses.

Genomic Knowledge Base – NCTR, in collaboration with CFSAN and USDA, continues the development of an integrated genomic knowledge base that incorporates the tools developed for the ArrayTrack™, a DNA microarray data management, mining, analysis, and interpretation software system. A manuscript describing the utility of ArrayTrack™ for characterizing bacterial foodborne pathogens was published in the journal *BMC Bioinformatics*. Additional tools that will be integrated in the knowledge base will 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 should help to accelerate our understanding of foodborne pathogens and aid in identifying their sources. The knowledge base can also provide tools for the analysis of genetic information to complement surveillance data collected by government agencies, which will facilitate development of improved food safety regulations in response to evolving threats.

Rapid Detection Tools and Methodologies – NCTR currently has two rapid detection methodologies, RAPID-B and OMNIPrint, undergoing validation and development.

- RAPID-B:
  LITMUS, LLC, licensed and is deploying this NCTR patented method for real-time, on-site surveillance of food for bacterial contamination. Food Emergency Response Network (FERN) level-2 validation of RAPID-B's assay for *E. coli* O157 was performed in 2009 with over 9 food matrices analyzed including salad, cookie dough, salami, spinach, jalapeño peppers, and ground beef. Results of RAPID-B were more accurate than the reference method. RAPID-B prototype assays for *Salmonella* spp., *Listeria* spp. and *Listeria* monocytogenes, *Vibrio* spp., *Campylobacter* spp. have already been developed and plans are being made for their validation. Future development includes assays 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 assay for *Mycobacterium tuberculosis* and its CRADA partner successfully applied it in human sputum as a pilot study. The RAPID-B assay is capable of acquiring and reporting results in less than 15 minutes per sample with a limit of detection of < 10 bacterial cell counts/ml.

- OMNIPrint:
  OMNIPrint is a method which can detect bacterial or chemical contamination in foods or drug ingredients at a concentration of 0.01 to 0.1% by weight in 15 seconds/sample. Real-time characterization is not precise but can be used to recognize variant samples, to indicate the probable contamination as biological or chemical, and to flag suspicious products for further analysis.

FDA will benefit by quick identification of biological or chemical contaminants before food and drugs reach the market. Another benefit will be the increased number of import samples examined for potential contamination. The ultimate goal is to better protect American consumers by more rapidly assessing the threat of foodborne pathogen contamination.

NCTR scientists discovered in FY 2010, a new and potentially patentable technique called Direct Impact Corona Ionization (DICI) mass spectrometry. This technique enables plasma vaporization of whole-cell bacteria to produce information-rich spectral fingerprints that can accurately identify bacteria and could prove invaluable to rapid detection methods.

In 2010, NCTR scientists developed a new classification algorithm for predicting *Salmonella* serotypes 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 the serotypes of unknown *Salmonella* isolates based on the analysis of Pulse Field Gel fingerprinting. This statistical method will improve FDA's ability to rapidly classify novel isolates of foodborne pathogens during outbreaks. The result of this study is newly published in *Journal of Clinical Microbiology* (Sept. 2010, p. 3122-3126).

Antibiotic Resistance – Antibiotic resistance developed from agribusiness use of antibiotics in the food chain is a continuing problem. Since FDA sets antimicrobial drug-residue limits in animal products, NCTR research includes the evaluation of the incidence and mechanisms of drug resistance. This knowledge will help FDA establish better strategies for antibiotic use and help determine the spread of multi-drug resistance and increased virulence of foodborne pathogens and can be used to aid risk assessments.

In FY 2010 NCTR scientists completed a study characterizing the genetic basis for multidrug-resistance in *Salmonella (*enterica serovar Heidelberg 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. Follow-up work on this study aims to determine what factors impact the development and dissemination of antimicrobial resistance in *Salmonella* serovar associated with food animals and human infections.

To aid in risk assessment, scientists from NCTR and ORA's Arkansas Regional Laboratory characterized virulence genes in 81 strains of *Aeromonas veronii* isolated from farm-raised catfish, indicating resistance to multiple antibiotics. These studies illustrate that farm-raised catfish can serve as reservoirs for multiple virulence and antibiotic resistance genes. Although adequate cooking should eliminate pathogenic bacteria, undercooking, or cross-contamination of

utensils during the preparation of catfish, is a concern for spread of sickness and a possible spread of antibiotic resistance.

In addition, NCTR continues to research factors that lead to infections caused by *Salmonella* which cause many cases of serious illnesses each year in the United States. NCTR scientists published a review describing molecular bacteria fingerprinting. These fingerprinting methods can be used as part of a strategy to track the sources of *Salmonella* contamination in the preharvest, poultry-production environment. Improved source-tracking methods and strategies enable FDA investigators to identify the sources of bacterial contamination along the farm-to-fork continuum and suggest intervention strategies. Another research effort aims to develop improved polymerase chain reaction (PCR)-based 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 sampling by regulatory laboratories. The PCR-based methods offer a rapid means to detect *Salmonella* and corresponding antibiotic-resistance markers in food samples simultaneously.

Bisphenol A (BPA) – BPA is an industrial chemical that is used in the production of polycarbonate plastics and epoxy resins widely used in consumer products, including storage containers for foods and beverages, and in medical devices. The primary source of exposure to BPA for the majority of people is likely through the diet, with the highest estimated daily intake of BPA occurring in infants and children. In FY 2010, NCTR conducted research in partnership with the National Institutes of Health to determine if BPA administered to a pregnant nonhuman primate crosses the placenta and exposes the fetus to measurable levels of BPA *in utero*.

The study indicated considerable differences between neonatal rodents and non-human primates, with the primates showing significantly less age-related changes than rats, for internal exposure to the bioactive form of BPA. These studies predict that BPA effects observed in neonatal rodents would be more sensitive indicators of potential toxicity in primates. Data from these animal models will be combined with data from human bio-monitoring data to improve the prediction of internal exposures of target tissues in human infants and fetuses to the bioactive form of BPA (*Toxicology and Applied Pharmacology*, 2010). As a result of this research, FDA will gain an improved understanding of the pharmacokinetic profile of BPA and the associated risk of exposure to BPA in various stages of development.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
264101: Develop risk assessment methods and build biological dose-response models in support of food protection. *(Output)*	FY 2010: 1) Developed and validating field-rugged technologies for rapid screening of samples to rule in, or rule out, contamination with select foodborne pathogens applicable to fresh produce (Target Met) 2) Research completed on Bisphenol A (BPA) resulting in the publication of data to improve the prediction of internal exposures of target tissues in human infants and fetuses. (Target Met)	1) Rapid detection toolkits for foodborne pathogens applicable to fresh produce; evaluate in field situations 2) Approved protocols developed and initiated for Bisphenol A (BPA), a component in baby bottles and formula containers	Expand Rapid B system to include new pathogen-specific (PS) assays (tests)	N/A

Enhancing Medical Product Safety
Base Amount: $20,549,001 (All BA)

Public Health Focus

To enhance the safety of medical products, to support FDA's Medical Product Safety priorities, and to support the HHS priority to Improve Health Care Quality and Patient Safety, NCTR scientists conduct research to identify early predictors of toxicity for medical products. NCTR also develops, validates, and provides guidance to FDA medical-product centers for the use of new medical technologies and evaluates the biological effects of potentially toxic chemicals. NCTR research helps FDA to integrate new technologies and standards into the risk-assessment and regulatory-review process at all stages of the product lifecycle.

Public Health Outcome

This research, which provides biomarkers of risk for FDA reviewers and guidance to regulators, will decrease the uncertainty, time, and expense of product development and improve FDA's ability to protect the public health. The

integration of new technologies and standards provides enhanced risk assessment for reviewers and a stronger base for public-health assurance for new products.

Promoting Efficiency

NCTR's research to support the Enhancing Medical Product Safety subprogram has the potential to save lives, increase patients' quality of life, and generate savings for all those who pay the cost of health care. NCTR's bio-imaging capabilities are enhancing the development of noninvasive biomarkers used to track the effects of strokes in a noninvasive manner. Using these biomarkers also offers the possibility of preventing recurring strokes and reducing the need for costly and dangerous surgical procedures.

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]. As a result, 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 economically and patient health) of withdrawing drugs after they are on the market.

Imaging– NCTR completed the development of a Bio-Imaging Facility in Fall 2009 that houses the small animal Magnetic Resonance Imaging (MRI), Spectroscopy (MRS), and MicroPET technologies. The instruments in the Bio-Imaging Facility operate at higher-field strengths and with less variability than clinical instruments, providing investigators opportunities for more complex experimental designs and resulting discoveries. As with clinical applications, the noninvasive nature of these technologies enables continued monitoring of animals, providing new possibilities for biomarker discovery for safety and efficacy of FDA-regulated products.

NCTR's bio-imaging capabilities will enhance the development of noninvasive, clinically translatable central nervous system MRI biomarkers of disease progression and drug efficacy. These biomarkers have the potential to serve as important tools that will bring new insight into the step-by-step development of stroke complications — a leading cause of mortality and disability in the U.S. — related to micro-vascular disorders, as well as new safety-assessment tools for therapeutics devised to treat stroke victims.

In addition, NCTR scientists developed a tool to discriminate up to nine categories of brain tissue in Magnetic Resonance Spectroscopy (MRS) images with 96% accuracy. This tool was designed to aid physicians with medical decisions based upon MRS images. The improved MRS-spectrum processing holds promise to aid physicians in the practice of medicine. The process could

reduce the need for surgical procedures, in itself improving the quality-of-life for patients.

NCTR continues to develop 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 to establish if the tumor has returned or if it is solely the presence of scar tissue. There is an effort underway to locate images from such patients so that model systems can be developed and validated to help distinguish tissue status.

Pediatric Anesthetics – NCTR scientists are evaluating the neurological effects of pediatric anesthetic use in developing nonhuman primates, an animal model closely related to humans. Studies conducted on animals exposed to ketamine, an anesthetic widely used in pediatric medicine, suggest that cell death from ketamine exposure continues much longer than previously thought. Concern over the use of ketamine anesthesia in pediatric medicine increased after animal experiments demonstrated increased neuronal-cell death when exposures occur during periods of rapid-brain development. Completed research demonstrates 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. Using a variety of tools, scientists will determine if the use of anesthetics during development is associated with memory and learning deficits or other changes in the central nervous system.

NCTR established a zebrafish facility in Spring 2010 to provide adult fish and embryos for toxicity assessments because they share many developmental and genetic similarities with humans and can provide information on ways to minimize risk associated with the pediatric use of general anesthetics. In addition to zebrafish studies, previous studies with nonhuman primates helped to identify developmental periods during which sensitivity to ketamine, a pediatric anesthetic, is greatest. These non-human primates' offspring will be used for further research on the effects of pediatric exposure to general anesthetics and will result in the development of translatable biomarkers for studying pediatric products.

These research findings will help the medical community understand the relationship between the amount, type, duration, and frequency of pediatric anesthetic use and its adverse effects on children in order to provide rapid screening tests and understand pathways of toxicity and prevention for pediatric anesthetics.

Nanotechnology – Recently, nanomaterials have received enormous national attention as new analytical tools for biotechnology and in the life sciences. Under

certain conditions some of these nanomaterials have been shown to produce toxicity. NCTR scientists are conducting research to determine if manganese or iron nanoparticles cross the blood-brain barrier in rodents and to determine if exposure to these nanoparticles produces neurotoxicity. Data from this study will provide a better understanding of the toxicity of these nanomaterials in products for human use, such as over the counter drugs, cosmetics, or dietary supplements.

Nanomaterials, such as nanoscale zinc oxide and titanium oxide are often found in sunscreen and cosmetics. These nanomaterials could penetrate the skin or be absorbed in the gut following ingestion. Studies at NCTR have shown that nanoscale titanium dioxide does not penetrate the skin of mice and rabbits; however, insufficient information exists on the skin penetration of nanoscale zinc oxide. 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 the safety of these materials. In addition, there is potential that externally applied cosmetics containing nanoscale materials could impact the microbial ecology of the skin, which may affect human health by breaking the permeability barrier encouraging bacterial growth on the skin. NCTR will evaluate the effect of cosmetics and sunscreens on model microorganisms that are representative of the human skin microbiota to evaluate the potential risk of skin exposure to nanomaterials. This research will provide the scientific underpinnings necessary to determine the potential health effects of skin exposure to nanomaterials.

In addition to cosmetics, the greatest risk of consumer exposure to nanoparticles is from food packages containing nanomaterials, due to potential migration of nanoparticles into food or drinks. 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 because of their applications as antimicrobial agents in food packages. Developing methods to measure the extent of nanosilver migration from food-contact nanomaterials will allow FDA to determine the magnitude of the problem. Since the use of food-contact nanomaterials has been increasing in the last ten years, the risk associated with the migration of nanoparticles into the food should be studied.

To strengthen FDA's nanotechnology product-evaluation capability, in FY 2010 the NCTR/ORA Nanotechnology Core Facility was opened, equipped, and staffed with a Senior Electron Microscopy Technician and a Staff Fellow with expertise in nanotechnology. The Nano Facility is providing support to FDA through materials characterization — external techniques to probe into the internal structure and properties of a material — analytical support, and electron microscopy support for a broad range of nanomaterial studies. In FY 2010, Standard Operating Procedures were established for:

1) Transmission Electron Microscope (TEM)
2) tissue preparation for TEM

3) particle-size determination with more SOP development in progress.

The Nano Facility is supporting various collaborative studies with FDA/ORA, National Institute of Environmental Health Sciences/National Toxicology Program, National Cancer Institute/Nanotechnology Characterization Laboratory, and the United States Air Force on quantification and migration of nanosilver, particle-size determination of nanosilver, and toxicity of nanomaterials on cultured brain cells and on cells used in genotoxicity assays. The results of a study on nano- and submicron-particles of titanium dioxide contained in sunscreens was published in *Toxicological Sciences,* 2010. The results suggest that use of the sunscreens does not result in internal exposure to the nano- and submicron-particles of titanium dioxide

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.

Liver Toxicity – Since both prescription drugs and over-the-counter medication can contribute to this problem, liver toxicity is of great concern to FDA. To address this public-health issue, a Liver Toxicity Knowledge Base (LTKB) is being developed at NCTR to provide a resource for FDA to improve the safety of drugs, biologics, and dietary supplements. In 2010, NCTR scientists developed a set of criteria to select drugs for the Liver Toxicity Knowledge Base (LTKB) project and collected risk factors and mechanistic data for them from literature. A high-content assay was performed on these drugs. In addition, a systematic approach to characterize the potential risk of liver injury of these drugs was developed for this project. LTKB is a content-rich resource being developed to aid understanding of liver toxicity and enable the development of predictive tools for identifying liver toxicity issues along the various stages of drug development.

In FY 2010, NCTR submitted a manuscript on drug-induced liver injury (DILI) by sex. While it is known that DILI is more common in females, it is unclear how common this potential sex-based sensitivity may be and the contributing factors. Scientists analyzed preclinical, clinical, and post-market reports to determine the weight of evidence in support of sex-biased sensitivity to DILI. The analysis indicated that care must be taken when interpreting the “apparent” female-biased DILI since the actual number of patients exposed to drugs is difficult to estimate by sex. In addition, the pre-clinical data has limited ability to predict sex-biased DILI in humans. Nevertheless, several significant factors were found to contribute to sex-biased DILI including drug type, age, and injury type—in descending order of influence.

In addition, the Hepatotoxicity Working Group formed by NCTR with experts from FDA, pharmaceutical industry, and academia continue to identify research needs

surrounding drug-induced liver injury. NCTR will collaborate 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" 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.

Bioinformatics Infrastructure – Pharmacogenomics (PGx), an emerging scientific field focused on clinical and safety biomarker identification, is identified in the Critical Path Initiative as a major opportunity for advancing medical product development. PGx requires a bioinformatics infrastructure to review and understand how sponsors reach their biological conclusions, to ensure the incorporation of PGx data into regulatory processes and to realize benefits of PGx for public health.

NCTR-developed ArrayTrack™ — the integrated DNA microarray data management, mining, analysis, and interpretation software system — allows for the addition of new capabilities to handle priorities and evolving technologies and can be used to support Pharmacogenomics. Initially ArrayTrack™ was used predominately to analyze and manage large amounts of DNA data; however, it is being expanded to facilitate the review of other types of data. ArrayTrack™ 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 custom analytical tests developed at FDA's Center for Food Safety and Nutrition and USDA, 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. In FY 2010, NCTR also enhanced the ArrayTrack™ tool by adding a protein and metabolite panel and a Gene Ontology for Functional Analysis (GOFFA) library, as well as a Support Vector Machine for outcome prediction and data mining.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
263101: Use new omics technologies and pattern-recognition algorithms to analyze imaging data for early-stage disease diagnosis and to study how an FDA-regulated compound or product interacts with the human body. *(Output)*	FY 2010: 1) Developed drug selection criteria for the Liver Toxicity Knowledge Base, collected data, performed high-content assays, and developed a systematic approach to characterize the potential risk of liver injury of these drugs. Tool is being piloted. (Target Met) 2), Established zebrafish facility for toxicity assessments and have eliminated some potential candidates, narrowing search and evaluating data to identify translatable biomarkers. (Target Met)	1) Create a demonstrable tool to use in the drug-review process based upon the liver toxicity knowledge base 2) Develop translatable biomarkers for studying pediatric products (such as ketamine, methylphenidate, etc.)	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) 3) Build a knowledge base to annotate existing drug-risk factor associations of immune-related drug reactions	N/A
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. *(Output)*	FY 2010: Molecular signature and biomarker functions developed in ArrayTrack™ to support VXDS (Target Met)	Develop molecular signature and biomarker modules in ArrayTrack™ to support VXDS	Develop 3D/4D Quantitative Spectrometric Data-activity Relationship (QSDAR) models for predicting endocrine disruptor activity	N/A
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)*	FY 2010: Established and implemented three SOPs for research protocols to detect nanoscale materials in FDA-regulated products in collaboration with ORA/ARL. (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)	Develop new characterization methods for nano-based zinc oxide within FDA-regulated products	N/A

Information Technology Investments – National Center for Toxicological Research Activities (Base Amount displayed as a non-add item: $7,676,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

Science is the foundation of the FDA regulatory decision-making process and is vital to FDA's role in protecting and promoting the health of American consumers. In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts to enhance the efforts of interdisciplinary scientists as they conduct peer-reviewed research essential to identifying health and safety issues related to new and existing FDA-regulated products. Some examples include advances in IT that will provide the necessary tools to allow electronic-data retrieval through expanded network and data-storage capabilities. Initiatives such as the Janus project will provide FDA with a standardized data warehouse with linked analytical tools. These initiatives will enrich the regulatory desktop environment by making structured scientific data and knowledge from external and internal sources readily available for the conduct of science-based risk/benefit assessments. Additionally, identification of IT platforms and tools, including innovative analytical tools and science algorithms–mathematical procedures–will enable computational sciences to address the critical-path goal of personalized nutrition and medicine.

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Five Year Funding Table with FTE Totals

The following table shows a five year funding history for the National Center for Toxicological Research's program level and budget authority resources.

Fiscal Year	Program Level	Budget Authority	User Fees	FTE
FY 2007 Actual	$42,056,000	$42,056,000	$ 0	183
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 Continuing Resolution	$58,745,000	$58,745,000	$ 0	246

Summary of the Budget Request

The FY 2012 budget request for the National Center for Toxicological Research is $60,294,000 supporting 215 FTE. The amount is an increase of $1,549,000 above the FY 2010 Enacted.

The base funding for the National Center for Toxicological Research Program is $58,745,000, which supports research in the following three subprogram areas:

- Personalized Nutrition and Medicine
- Strengthen Surveillance and Risk Analysis
- Enhancing Medical Product Safety.

Within these subprogram areas, NCTR conducts research on the risks and benefits of products — and thereby advances 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, tobacco and foods. The goal of these programs is to enable FDA to make sound, science-based regulatory decisions and improve the health of the American people.

Personalized Nutrition and Medicine

Center Activities (Base Amount: $24,249,936)

Initiatives None requested.

Strengthen Surveillance and Risk Analysis

Center Activities (Base Amount: $13,946,063)

Initiatives

Transforming Food Safety and Nutrition Initiative: Expanding Laboratory Capacity and Capability for Food Safety (+$414,000 BA; 1 FTE)

Many hazardous chemicals go undetected in food samples due to:

- the highly specific nature of current chemical testing methods
- an insufficient number of field portable and hand-held instrumentation devices

- an inadequate and understaffed laboratory infrastructure to assist FDA in preventing and responding to foodborne contamination.

Developing new, rapid-detection devices and methods will:

- shorten the response time
- increase the number of samples analyzed
- identify chemicals that might otherwise go undetected
- lead to a low cost rapid screen for food contamination.

The ability to more rapidly identify contamination will protect the public health by reducing the number of foodborne illnesses.

Using these funds, FDA/NCTR will support one FTE and will build on existing capacity and capability by:

- developing and deploying rapid detection tests
- supporting the FDA Analytical Tools initiatives by identifying new biomarkers and metabolomic profiles
- developing *in vitro* assays for measuring toxicity and replacing animal models.

Enhancing Medical Product Safety

Center Activities (Base Amount: $20,549,001)

Initiatives

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$1,700,000; 4 FTE)

For this Nanotechnology Initiative, NCTR will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing risks.

BA Increase for Pay Costs: +$134,000 (all Center)

Contract and Administrative Savings (Total Program: -$699,000)

The request for $60,294,000 in total budget authority for the National Center for Toxicological Research also reflects a contract and administrative savings reduction of -$699,000.

Center Activities

Initiatives

Administrative and Contract Savings Initiative (-$699,000)

NCTR will achieve contract savings by reviewing contracts for research support and identifying activities that NCTR workforce can perform.

NCTR Program Activity Data (PAD)

The following table lists the NCTR Program Activity Data (PAD).

NCTR Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
RESEARCH OUTPUTS			
Research Publications	165	160	165
Scientific Presentations	190	178	175
Patents (Industry)	6	6	5
LEVERAGED RESEARCH			
Federal agencies (Interagency Agreements)	4	8	5
Nongovernmental organizations	15	20	16
ACTIVE RESEARCH PROJECTS			
Personalized Nutrition and Medicine	64	60	60
Strengthen Surveillance & Risk Analysis	42	42	42
Enhancing Product Safety	55	50	54
Total Active Research Projects	***161***	***152***	***156***

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FIELD ACTIVITIES – OFFICE OF REGULATORY AFFAIRS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted [1]	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$878,996**	**$869,112**	**$879,351**	**$1,101,268**	**$223,730**
Program Level FTE	**4,230**	**4,235**	**4,235**	**4,900**	**670**
Budget Authority	**$847,475**	**$847,000**	**$846,017**	**$963,698**	**$117,681**
Pay Increase (non add)				*$1,952*	*$1,952*
Transforming Food Safety and Nutrition (non-add)				*$115,144*	*$115,144*
Protecting Patients (non-add)				*$6,630*	*$6,630*
Advancing Medical Countermeasures (non-add)				*$1,310*	*$1,310*
FDA Regulatory Science and Facilities (non-add)				*$830*	*$830*
Administrative and Contract Savings (non-add)				*-$8,185*	*-$8,185*
Budget Authority FTE	**4,133**	**4,151**	**4,151**	**4,347**	**214**
User Fees	**$31,521**	**$22,112**	**$33,334**	**$137,570**	**$106,049**
PDUFA	$11,795	$8,024	$13,608	$17,463	$5,668
FTE	55	54	54	64	9
MDUFMA	$1,556	$1,825	$1,556	$1,832	$276
FTE	11	13	13	18	7
ADUFA	$250	$546	$250	$315	$65
FTE	2	2	2	2	0
AGDUFA	$143	$144	$143	$160	$17
FTE	1	1	1	1	0
MQSA	$13,077	$9,510	$13,077	$13,077	$0
FTE	8	8	8	8	0
Center for Tobacco Prevention	$4,700	$2,063	$4,700	$6,250	$1,550
FTE	20	6	6	26	6
Voluntary Qualified Importer Program (VQIP) User Fee				61,000	$61,000
FTE				265	265
Generic Drugs				$6,737	$6,737
FTE				12	12
Food Reinspection				$9,375	$9,375
FTE				66	66
Recall User Fee				$10,036	$10,036
FTE				25	25
Medical Product Reinspection User Fees				$6,725	$6,725
FTE				46	46
International Courier User Fee				$4,600	$4,600
FTE				20	20
User Fees FTE	**97**	**84**	**84**	**553**	**456**

[1] The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the $2 million Gulf Spill one time supplemental provided in PL. 111-212. The $2 million is not included in the +/- FY 2010 Enacted column.

Authorizing Legislation:

The Office of Regulatory Affairs is a unit of the Food and Drug Administration through which FDA enforces those statutes for whose administration this agency has been assigned responsibility. Specifically, FDA administers the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq. ("FDCA"), and designated sections of the Public Health Service Act (42 U.S.C. §§ 238, 241, 242, 242a, 242l, 242o, 243, 247b-20, 262, 263, 263a 264, 265, 300u, et seq., 300aa-25, et seq., 300aa-1 note, 300cc-12(a)(1) and (2)(B), (b) and (c), 300cc-14(c), 300cc-17(d) and (e), 300ff-72(a)(1)(A) and (B) and (a)(2), et seq.).

In addition, as enumerated in Staff Manual Guide 1410.10(A), the Secretary of Health and Human Services has redelegated to the Commissioner of Food and Drugs the functions vested in the Secretary under the following miscellaneous 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), which is a part of ORA, is authorized to conduct criminal investigations, execute search warrants, make arrests, and carry firearms under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372). OCI also conducts criminal investigations under the Public Health Service Act (42 U.S.C. 262) and the Federal Anti-Tampering Act (18 U.S.C. 1365), if the tampering involves an FDA-

regulated consumer product.

Allocation Method: Direct Federal/intramural

Program Description and Accomplishments

FDA's Office of Regulatory Affairs (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. 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 has 4,230 FTE in the United States. Over 85 percent of ORA's staff are stationed in five regional offices, 20 district offices, 13 laboratories, and 177 resident posts and border stations.

As a separate entity within ORA, Office of Criminal Investigations (OCI) personnel are located throughout the field organization in 32 field offices, resident offices, and domiciles throughout the United States. FDA maintains offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming.

In addition to executing its operations through 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 staffs attend and participate in ORA-sponsored training courses.

The Office of Information Management (OIM) supports the Regulatory Affairs Program by maintaining its legacy systems and databases for managing and tracking its review programs, monitoring and tracking adverse event activities, and conducting various compliance activities.

ORA's activities cross-cut FDA's major initiatives, including Transforming Food Safety, Protecting Patients, and Advancing Medical Countermeasures. However to best correlate with the budget presentation, ORA's program description and accomplishment section follows the six product programs -- Foods, Drugs, Biologics, Animal Drugs and Feeds, Devices and Radiological Health, and Tobacco.

Foods Program

Prioritizing Prevention

Base Amount: $107,199,000 (All BA)

Public Health Focus

ORA 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
- ensuring preventative controls are in place throughout the entire food supply chain, from the point of production, to delivery into the U.S. supply chain and ultimately, consumption by the public.

Public Health Outcome

In 2010, ORA – along with regulated industry, other government agencies and foreign regulatory bodies – participated in more than 50 outreach events at a variety of symposiums and conferences. ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advancement of FDA policies and initiatives to internal and external stakeholders.

In FY 2010, FDA awarded a $1 million cooperative agreement to the International Food Protection Training Institute (IFPTI). IFPTI supports the Integrated Food Safety System (IFSS) for regulatory and public health partners through its establishment of a catalog of existing food safety/food defense courses for the Partnership for Food Protection. In FY 2010, ORA offered five of these courses at the IFPTI facility.

In FY 2011, the Institute will continue to work with ORA personnel in obtaining its goal of establishing a comparable national training curricula for Federal, State, local, territory and tribal food safety inspectors. This curriculum will serve as the foundation for ensuring consistency in training across all regulatory levels.

In FY 2010, ORA awarded funds to five associations under the Small Scientific Conference Grant and to 27 state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources the associations and regulatory agencies needed to convene meetings of key stakeholders to foster communication and collaboration on a range of topics including food safety and food security/protection, intervention and prevention through the review of food supply vulnerabilities.

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 are proactive and generate efficiencies for industry, consumers and FDA because they help anticipate and prevent food safety problems. In addition to protecting public health, preventing such problems leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	FY 2010: 5 labs (Target Met)	5 data exchange additions/conversions	5 data exchange additions/conversions	Maintain

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Base Amount: $273,955,000 (All BA)

Public Health Focus

To strengthen bio-security, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses including sample analysis, product testing and methods development to enable ORA to develop solutions for specific regulatory problems.

These activities minimize consumers' risk of exposure to adulterated food products by preventing the marketing of 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 an ORA priority.

ORA continues to advance regulatory science, increasing the breadth of its analytical capacity while improving laboratory efficiencies and outputs. One way ORA accomplishes these advances is the continued development of laboratory methods. The international aquaculture industry, for example, is concentrated in developing countries that lack regulation on drug use in food-producing animals.

Several antibiotics and other drugs are approved for use in aquaculture to improve productivity and increase yield. However, FDA continues to find a significant number of

unapproved drugs in seafood products, leading to concerns about product safety and drug withdrawal times. These conditions require FDA evaluation on a case-by-case basis.

Some of the unapproved antibiotics and drugs used in today's food products are carcinogens, some are toxic to the immune system, and some have other health impacts such as allergic reactions and adverse drug side effects. Since the products are not labeled as containing the drug, they can cause unexpected health risks to the consumer. There is a growing concern that subclinical doses of antibiotics can contribute to the development of multidrug resistant pathogens.

To protect consumers from potentially harmful residues in the food they eat, it is important that agency oversight of food commodities include an analytical assessment for the presence of drug residues. ORA continues to develop analytical methods and expand field laboratory capabilities, which are imperative to meeting the ongoing issues and concerns related to food products.

Public Health Outcome

ORA continues to use the Chemistry and Microbiological Mobile Laboratories in support of food defense initiatives and surveillance of import and domestic produce. The Mobile Laboratories are designed for high throughput screening of samples to expedite analytical timeframes and subsequent release of import shipments, which is crucial for perishable products such as produce. In 2010, supported by 132 volunteers from the ORA field laboratories, the ORA Mobile Laboratories were deployed for 35 weeks. A total of 8,015 samples of domestic and imported produce were analyzed. One deployment, focused on imported produce from Central and South America and Caribbean Islands, found a combined seven percent violation rate for *Salmonella*, enterohemorrhagic E. coli and pesticides. The finding resulted in an increase of Import Alerts calling for the detention without physical examination of affected products.

In FY 2010, ORA re-invigorated the use of environmental sampling during domestic food facility inspections to assess the environmental conditions in which products are manufactured. These samples signal FDA about areas of concern within a production environment and have led to numerous cases of industry electing to retain or destroy products that were manufactured in suspect conditions but have not yet been proven to be contaminated. Through surveillance efforts and joint FDA and industry action, ORA assures that potentially adulterated commodities do not enter the U.S food supply. ORA also increased the states' surveillance activities on behalf of FDA by including in the Food Inspection Contract program several electives such as conducting environmental sampling during the inspection. In FY 2010, seven states chose to include this elective which called for the completion of up to 1,500 environmental sample collections within the year.

In FY 2010, ORA developed a new method to detect polycyclic aromatic hydrocarbons (PAHs) in oysters, shrimp, crabs and finfish. This method is currently being used to

determine the concentration of PAHs in seafood from the Gulf of Mexico. Based on this test FDA can confirm that these chemicals in the Gulf seafood are below a level that causes public health concern. This new method is being used for all samples collected and analyzed in support of determining whether the Gulf waters remain safe for commercial fishing. The method is deployed to eighteen FDA and state labs participating in FDA's chemistry cooperative agreement with FERN. Each lab can test approximately 20 samples every 24 hours using this method as compared to the existing method which is capable of testing 25 samples every five to seven days.

In FY 2010, ORA purchased new equipment for field laboratories and developed new methods that allow a single test to detect specific drug residues in aquaculture and honey products, and confirm the levels of drug residues present. ORA's equipment purchase expanded its laboratory capacity by extending its capabilities to analyze seafood products for the presence of nitrofurans (known carcinogens) into three additional ORA field laboratories. The multi-residue analytical method ORA developed and implemented can analyze and confirm the presence of 18 different drug residues in shrimp products. The multi-residue method developed and implemented for honey allows for the detection of 17 different drug residues. Due to increased sampling stemming from joint actions with U.S Customs and Border Protection and OCI, ORA field resources collected and analyzed 150 percent of FDA's target for FY 2010.

In FY 2010 ORA reevaluated and initiated changes to procedures involved in joint surveillance with facilities and products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) and other organizations. The changes effect information sharing with the United States Department of Agriculture (USDA) and Occupational Safety and Health Administration (OSHA) regarding facilities such as the Wright County Egg Facility in Iowa. The agencies are redesigning processes, including inspection, test results and oversight of proposed corrective actions by firms, to address contamination with Salmonella and other diseases and filth. The agencies are also evaluating information disclosure between CFSAN, the Environmental Protection Agency (EPA) and USDA on fresh produce safety at the farm and packing house. The information requested will assist CFSAN in concluding which production practice standards best protect the public health if required by regulation, while creating minimal economic and environmental impact. ORA personnel are mediating information disclosure to OSHA regarding food facilities contained in the Food Facilities Database. These efforts will improve prevention and federal and state responses to outbreaks and contamination.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of the mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY 2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas. The joint effort called for ORA and state sampling of milled wheat products such as milled wheat flour, wheat bran and wheat germ intended for use in the human food supply to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up inspections with sampling of finished foods manufactured using the milled wheat products that exceeded FDA advisory

levels. FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, which consolidated the previous process of an initial test to determine the presence of mycotoxins and a confirmation test for regulatory determination and action.

In 2010, ORA's Prior Notice Center (PNC) was able to expand its prior notice electronic targeting system capabilities, increase intelligence-related food shipment data mining, and create new targeting criteria to more effectively detect food shipments linked to high risk persons and firms. Additionally, the PNC performed more than 81,000 reviews of prior notice submissions, exceeding FDA's goal by 1,000 reviews.

ORA is increasing efficiencies in reviewing import entries through the implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources to allow for a more informed review of specific product entries. Data supporting product compliance will aid ORA to quickly process and release those entries while data more indicative of concerns or violations will result in the entries being flagged for additional ORA scrutiny. PREDICT allows 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 2010 ORA contracted with a third party to perform on site firm verifications of foreign food facilities that have registered with FDA as required by the Bioterrorism Act (BTA) of 2002. This contract allows for physical verification of a foreign firm at the location identified in the registration not only to confirm the existence of the facility but to verify the information supplied in the registration. On-site findings are then reported to FDA for appropriate follow up action, which includes for-cause inspection of the facility, addition of facilities to import alert where the manufacturing capabilities are not what was purported in the registration, and increased review of prior notice submissions to ensure accurate data is submitted.

In FY 2010, ORA evaluated handheld portable analytical tools for use in the early detection of contaminated food products. ORA has qualified a variety of tools and has begun 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. The analytical screening capacity and commodity range for each tool varies. Portable tools return analytical screening results within minutes of implementation of the test, providing ORA field personnel with data to help make appropriate regulatory determinations. These tools provide for the release of safe shipments into U.S. commerce and detention of shipments with violative screenings for further analysis by ORA field laboratories. The first tier of tools has been deployed to several ORA field offices. These are the first in a series of portable analytical tools that will be deployed to ORA field investigators to screen a variety of products for a multitude of safety concerns.

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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214201: Number of prior notice import security reviews. *(Output)*	FY 2010: 81,618 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2010: 170,392 (Target Exceeded)	140,000	160,000	+20,000
214203: Number of Filer Evaluations. *(Output)*	FY 2010: 1,277 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2010: 8,658 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2010: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Base Amount: $111,446,000 (All BA)

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 U.S. laws and regulations.

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

Public Health Outcome

ORA investigators conduct physical inspections of regulated domestic and foreign food establishments.

In FY 2010, ORA increased the number of firms by 144 that were targeted for foreign inspection coverage. Innovations included using risk factors to target firms to inspect, establishing dedicated foreign inspection cadres, and enhancing efficiencies associated with the foreign inspection program and process. The increased coverage provides a better understanding about the compliance status associated with firms that ship to the U.S.

ORA started the Dedicated Foreign Food Cadre in July of 2009. The 13 cadre members bring over 160 years of experience conducting independent and complex inspections and developing compliance cases which very often have resulted in regulatory actions. In FY 2010 the cadre contributed significantly by augmenting the existing foreign inspection program and exceeding the number of foreign food establishments inspected in the previous year by 144 inspections.

During FY 2010, ORA issued 668 Import Alert notices identifying modifications to human food products, food ingredients, and dietary supplements. These notices encompass various food and dietary supplement commodities and manufacturers. Some were a result of ORA import surveillance activities of regulated products at the time they were offered for import into the U.S. Others resulted from for-cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers. Notable products covered under this process include shipments of tuna containing Salmonella Paratyphi implicated in illness outbreaks in 22 states and black pepper implicated in a multistate salmonelosis poisoning episode.

In FY 2010, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA personnel are working closely with other government agencies on several ongoing cases including products in the human food program.

In FY 2010, FDA received new authorities under the Prevention of Salmonella enteritidis

in Shell Eggs during Production, Storage, and Transportation Rule. In an effort to enforce the requirements of the rule, FDA is establishing and implementing a multi-tiered internal approach to:

- identify inspection requirements, resources, and tools
- develop and implement training of ORA field staff
- initiate inspections of facilities for evaluation of egg safety for prevention of Salmonella enteritidis (SE).

Initial inspections of a large producer in Iowa resulted in recalls of shell eggs. Eleven firms initiated recalls associated with the Salmonella enteritidis in shell egg event. There were 156 direct accounts and 3,982 sub-accounts (customers downstream, i.e, distributors, food service establishments, institutions, manufacturers and retail outlets) of Wright County Egg and Hillandale Farms of Iowa for which audit checks were performed.

Trade submission of accurate prior notice data for imported food shipments ensures ORA can complete meaningful bio-security risk assessments. In order to ensure compliance, ORA made more than 800 informed compliance calls to the trade in 2010 to obtain accurate prior notice data and inform/remind the trade community and regulated industry of the requirements. In conjunction with CBP, ORA executed compliance enforcement actions against more than 1300 imported food/feed shipments where the inadequate prior notice data was so egregious it restricted ORA's ability to perform meaningful risk assessments. These compliance actions required the trade community to submit accurate prior notice data for risk assessment before the imported food or feed shipments were allowed to enter the US.

FDA's global efforts in China and India have contributed to surveillance inspections. Investigators working in China and India have conducted for-cause and surveillance inspections. This facilitates follow up on critical issues (for-cause inspection) in a timely manner. Additionally, these international offices are providing more confidence building and joint activities with foreign regulatory agencies.

In FY 2010, ORA awarded food inspection contracts to 41 State agencies and one territory. These contracts provide states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections, which enhances an integrated food safety system. The contracts also include a subset of high risk industries such as juice and seafood Hazard Analysis Critical Control Point (HACCP) and low acid canned foods/acidified foods. Additionally, these contracts allow the states the option to include additional investigative mechanisms such as environmental sampling to assist in strengthening and protecting the food supply from unintentional and deliberate contamination and prevent food safety problems before they occur.

ORA also monitors recalls of food products that have been found to present safety concerns and assures the adequacy of the firm's recall to effectively remove the defective product 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 FY 2010, FDA classified and issued recall numbers for 2,235 Class I (most serious); 564 Class II; and 139 Class III recalls of food products compared to 492 Class I, 1816 Class II, and 473 Class III recalls in 2009.

In FY 2010, FDA's MARCS-Compliance Management System indicated 19 approved injunctions, six seizures of food products (including dietary supplements) and 82 emergency permit controls.

ORA's Office of Enforcement (OE) and Office of Criminal Investigations (OCI) also focus on enforcement. In March 2009, the Office of Enforcement assumed the responsibility for the Agency's Debarment Program, putting Agency-wide procedures in place to ensure that more rapid, transparent and consistent debarment actions are taken. These efforts also included hiring a full-time Regulatory Counsel to initiate and process debarment proceedings and creating and maintaining a page on FDA's website where all pending and completed debarment actions are listed and publicized, enhancing public health protection by assuring that businesses and individuals who deal in FDA regulated products do not procure the services of a debarred person. It is critical to ensure that the individuals who engaged in misconduct not be trusted with patient safety and the public's health. OE initiates a comprehensive review of cases referred quarterly by OCI and other cases referred by other sources throughout FDA for potential debaree candidates. In FY2010, as a result of these referrals and reviews, OE has debarred thirteen individuals with criminal convictions from participating in certain aspects of food and drug industry. Three of these thirteen individuals debarred include FDA's first food importer debarments.

OE managed the collaboration of information disclosure between CFSAN and with the Federal Trade Commission (FTC) regarding companies marketing caffeinated alcohol beverages, a food not generally recognized as safe and an unapproved new drug.

OCI's significant case activity in FY 2010 included 39 arrests and 26 convictions with fines and restitution in excess of $68.0 million. Two cases are highlighted below:

The July 2010 sentencing of a seafood wholesaler CEO culminated in an OCI investigation into the illegal importation of $15.5 million of misbranded and adulterated Vietnamese catfish, which led to a conviction of five companies and eight individuals associated with various Vietnamese catfish processors, U.S. importers, and seafood wholesalers. The investigation tackled the long-standing practice of mislabeling seafood to avoid Customs anti-dumping duties and an FDA import alert against antibiotic-tainted Vietnamese catfish. The defendants were ordered to pay $444,000 in fines, ordered to forfeit $12,197,930, and pay $64,173,839 in restitution. Additionally, the subjects of the investigation were sentenced to a total of 97 months of incarceration, six months home confinement and 162 months of probation.

The second case led to a 44 count indictment in August 2010, charging a U.S. honey

importer, 11 business executives and four affiliated companies for conspiring to import $40 million of falsely labeled and adulterated Chinese-origin honey tainted with unapproved antibiotics and avoid Customs anti-dumping duties and an FDA import alert designed to intercept honey containing unapproved antibiotics. The indictment not only seeks the forfeiture of $78 million in unpaid anti-dumping duties, but addresses the denial of a fair market for U.S. honey producers and the deliberate violation of laws designed to protect the U.S. food supply.

In FY 2010, FDA's 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 state personnel use provide reliable support for regulatory action consistent with FDA's guidance on regulatory actions and laboratory procedures. This is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in US commerce.

Promoting Efficiency

Examples of FDA efforts to promote efficiency through the Strengthening Efficiency Subprogram include the ORA Food Inspection Contract Program. The Food Inspection Contract Program and similar contracts, grants and cooperative agreements that the Field 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. The FDA support for state inspections often supplements two-to-three state-funded food inspections, thereby increasing the reach of state food safety programs.
FDA also benefits through closer involvement with state food safety efforts and often gains valuable data on inspections funded with state resources. Through these grants and cooperative agreements, ORA increases the efficiency of an integrated food safety system by assuring state inspectors are better trained and more proficient, increasing the capabilities of states to respond to food incidents and outbreaks.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214205: Number of high-risk food inspections. *(Output)*	FY 2010: 6,926 (Target Exceeded)	6,750	8,850	+2100

Improving Response and Recovery

Base Amount: $49,360,000 (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. To rapidly respond to outbreaks and facilitate recovery, ORA leverage its regulatory partnerships.

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 is continuing to 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 pathogen to the source and origin of the food exposure whether from plant, farm, or human contamination sources.

ORA continues to devote resources to the prompt and efficient response to foodborne outbreaks and events associated with FDA regulated commodities. 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 nation-wide to mitigate food defense and safety issues.

Molecular techniques are available that provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide evidence for rapid trace back to contamination sources. All microbiology laboratories are equipped 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 foodborne pathogens. The data informs and directs inspections.

Public Health Outcome

Examples of these partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, and 50 State Meetings.

ORA has 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 FDA districts, to explore, develop, implement, and share best practices. This work enables Federal and state partners to improve their systems to more quickly and effectively stop an outbreak and mitigate the concern. When possible and appropriate, the partners can also 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.

In FY 2010, ORA held a national RRTconference with all state and federal partners. The conference was devoted to sharing information, discussing adaptation of best practices and identifying next steps to achieve key objectives over the next year. FDA and its partners shared concepts and national initiatives affecting response, discussed metric development, increased engagement with the Council to Improve Foodborne Outbreak Response (CIFOR), and explored way to enhance programs involving the Center for Disease Control (CDC). Conference participants identified areas of strengths in each individual program for broader implementation across all RRTs. The teams worked through various operational challenges, and defined goals aligning FDA and other national priorities with those identified by state partners.

In FY 2010, ORA also implemented procedures to distribute weekly situation reports with the states as well as each RFR with the respective affected state to ensure early involvement of state counterparts in emergencies and outbreaks.

During recent potential public health crises involving food products such as peanuts, cookie dough and non-fat dry milk, FDA staff quickly developed specialized web pages to assist the industry and consumers by providing them with:

- up-to-date information about the outbreak
- the status of FDA's investigation
- FDA's and CDC's recommendations to avoid becoming ill
- FDA's response efforts
- important links to additional information.

The additional information included industry guidance documents, consumer updates, recall information, FDA contact information, informational videos, social media tools, and information about how to report complaints.

Also, during large-scale, high profile, Class 1 recall situations, FDA created, posted and maintained searchable databases in real-time to ensure the public can quickly identify recalled products. The databases allow consumers to search recalled products in a single, easily accessible location with understandable terms including brand name, UPC code, or product description.

Through FERN, FDA continues to provide training and proficiency testing to its member laboratories. Ten proficiency tests were completed in FY 2010 in all three disciplines of microbiology, chemistry, and radiology. Training courses are also provided in the three disciplines. FERN participated in a Department of Homeland Security directed Integrated Consortium of Laboratory Networks harmonized check sample analysis as a test of the Laboratory Network concept. Menu 2010, a nationwide exercise of the radiological laboratories, involved 35 labs participating in the methodology-driven exercise.

FDA continues to enhance its IT interconnectivity with 44 contracted states. These states, which include 23 that conduct Seafood HACCP inspections, report inspectional information electronically into the electronic State Access to FACTS (eSAF) system for enhanced information sharing. FDA has several projects underway to further increase information sharing through eSAF, with a current focus on recall audit checks and inspection audits, aligned with efforts towards state compliance with the Manufactured Food Regulatory Program Standards. This promotes collaboration between FDA and the states that perform this work and will allow the sharing of data in an efficient and secure manner

In response to the Deepwater Horizon Spill, ORAs Chemistry Mobile Laboratory units were deployed to Tallahassee, FL in the summer of 2010. While located at the Florida Department of Agriculture campus, ORA field chemists collaborated with the Gulf Coast Seafood Lab on the development and validation of an applicable screening method for the testing of Volatile Organic Compounds (VOCs) in seafood. ORA labs have analyzed more than 300 composite re-opening samples, 100 surveillance samples and 100 baseline samples from affected Gulf State waters for presence of oil contaminants. A composite sample is a mix of several individual animals.

Tens of closed state harvesting areas were re-opened based on ORA's testing of collected samples. The ORA Chemistry Mobile Laboratories and ORA field laboratories continue to provide public health assistance for local seafood merchants during the recovery phase of the Deep Water Horizon Oil spill that occurred in the late spring of 2010. Both the Chemistry Mobile Laboratory and several field laboratories have been or are being equipped to either screen for VOCs or Polycyclic Aromatic Hydrocarbons (PAH) in seafood harvested from areas in the Gulf that were directly impacted by the oil spill.

In FY 2010, ORA identified and established a High Throughput Environmental testing laboratory designed to serve as a single point resource in the analyses of up to 86,000 environmental samples per year. The dedicated laboratory will serve as the primary

resource for several large scale environmental sampling assignments that will be completed in FY 2011.

As a result of foodborne outbreaks and emergencies, ORA has re-invigorated the use of environmental sampling in facilities that are directly or indirectly associated with an outbreak or emergency. This inspection resource provides FDA with a comprehensive evaluation of the environment in which a food commodity is manufactured and has aided in identifying sources and routes of contamination within a facility. ORA is better able to make informed regulatory determinations and work with regulated industry to contain the contamination and identify all affected products for removal or retention from introduction into the U.S. supply chain.

Promoting Efficiency

Improving the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams helps 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.

The Reportable Food Registry (RFR) is an example of how FDA uses technology to prevent food safety threats from leading to consumer illness or death. RFR provides a reliable mechanism to track patterns of adulteration in human food products. FDA investigates reports of RFR to assure that contaminated foods are contained and recalled before illness or injury occurs.

ORA's continued use of grants and contracts with the states continues to leverage working relationships with state counterparts at the local level to improve surveillance activities, enhance an integrated food safety system and respond to public health threats in a timely and efficient manner. These programs assist FDA efforts during trace-back investigations, provide greater inspection coverage for ORA, and enhance food safety and defense through increased communication and integration of key stakeholders.

During FY 2010, FDA field laboratories implemented FDA and National Oceanic and Atmospheric Administration test methods to allow FDA to rapidly and efficiently evaluate and clear seafood products from the Gulf Coast region that may have been affected by contamination from the Deep Water Horizon oil spill. Thanks to these test methods, all gulf coast waters were re-opened for business by the end of FY 2010. During FY 2011, the ORA field laboratories and the mobile chemistry laboratory will continue to evaluate and clear seafood products affected by the oil spill. Having the mobile chemistry laboratories on site in the Gulf Coast increase allows FDA to more efficiently test and clear seafood products. FDA works closely with local seafood merchants, providing analytical results in a timely manner so that merchants can quickly evaluate the safety of their seafood in the shortest time.

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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2010: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Reinventing Cosmetics Safety

Base Amount: $3,489,000 (All BA)

ORA covers 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 marketplace.

Human Drugs Program

Provide Field Support to the Human Drugs Program

Base Amount: $135,980,000 (BA: $127,674,000 / UF: $8,306,000)

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 postmarket 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.

As part of both New and Generic Drug Review, ORA focuses on assessing whether the methods and facilities used for the manufacturing, processing, and testing of products submitted under a New Drug Application (NDA) and an Abbreviated New Drug Application (ANDA) are adequate to ensure strength, quality, and purity.

ORA inspects establishments to verify their ability to manufacture the product to the

specifications stated in the application. ORA also confirms the authenticity of the data contained in the application and reports any information that 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 an 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, including 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.

From a drug quality perspective, 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 the marketing of, or remove from the market, violative drug products, thereby ensuring these 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 the oversight and monitoring of drug industry recalls, assuring that the industries' recall efforts progress satisfactorily and are effective in removing defective products from commerce.

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 also 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 New Drug Review, 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 CGMP. 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. For example, in FY 2010, ORA entered into a 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 use 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. ORA field laboratories participated in the collaborative standards assessments of approximately 27 percent of the overall USP reference standards in existence prior to FY 2010.

In addition, in FY 2010 ORA worked with the Center for Drug Evaluation and Research (CDER) to identify handheld portable analytical tools for use in 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 deployed two classes of portable analytical tools. 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.

ORA continues to develop a High Throughput Drug Laboratory (HTDL) model, a highly efficient process to facilitate a high volume of sample analyses in the laboratory without requiring additional time or resources to accomplish the work. In FY 2010, ORA initiated an HTDL model targeting various cough and cold medications. The model allowed for the analysis of more than 450 products over a six week timeframe in a

single ORA field laboratory assessing product potency and reviewing product labels to assure compliance with FDA regulations.

The process incorporated a series of enhancements, including the use of technologically advanced equipment, streamlined electronic documentation, and a specialized assignments for the collection of the commodities, while maximizing existing ORA laboratory and field resources. The results of the model showed a decrease in the average time for completion of sample analysis from 37 hours per sample to seven hours per sample while increasing the number of samples the laboratory completed in six weeks. In addition, the laboratory was able to significantly increase the total number of samples analyzed in a single month, advancing from 25 samples per month to 360 samples per month.

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. In FY 2010, ORA worked with CBP in Operation Safeguard to monitor these shipments through targeted blitzes at various mail and courier facilities. These blitzes detected counterfeit and unapproved versions of approved medications. Additionally, ORA participated in Operation Pangea III, a global collaborative effort among government agencies in 43 countries, to perform targeted blitzes throughout the year for counterfeit drug products sold via the internet.

During FY 2010, ORA issued or updated five Import Bulletins and issued 81 notices 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. 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 exceeded the performance goal targets for high risk foreign drug surveillance inspections by working with its Global offices and continued staffing of the ORA's dedicated foreign drug cadre. The cadre, consisting of 15 experienced drug investigators, augments the existing foreign inspection program. In response to post-marketing complaints of contamination of purported sterile 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 adverse drug experience reporting, which resulted in subsequent recalls of three marketed products.

In April 2010, FDA worked with industry to notify consumers of a voluntary recall of infant and children's liquid products due to manufacturing deficiencies which may have

affected the quality, purity or potency of the products. The recall encompassed several lots of products under various brand names such as Tylenol, Motrin, Zyrtec and Benedryl that were distributed within the United States and several other countries. ORA expended numerous resources towards the completion of facility inspections, sample collections and analyses and recall activities to assess the extent of the issues and assure the products of concern were removed from the U.S. market while working to minimize the suspect products' impact on the public health.

ORA monitors recalls of human drugs that have been found to present safety concerns to assures that a firm's recall is adequate to effectively remove defective product 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 FDA's recall program. In FY 2010, FDA classified and issued recall numbers for 158 Class I (most serious); 389 Class II; and 321 Class III recalls of human drug products.

In FY 2010, FDA's MARCS-Compliance Management System indicated seven approved injunctions and three seizures for drug products. These actions helped protect patient safety by assuring that manufacturers comply with laws and regulations.

Some examples of recent enforcement actions include:

- **Fraudulent Chelation Products.** FDA issued warning letters to eight internet firms promoting chelation products with unproven claims to treat a range of diseases that include autism spectrum disorder, cardiovascular diseases, Parkinson's disease, Alzheimer's disease, macular degeneration, and other serious conditions. Three firms were also cited for promoting unapproved test kits that purported to detect the presence of heavy metals to justify the need for chelation therapy. As a result of FDA's action, hundreds of thousands of consumer dollars will be saved, and patients, many of them children, will be referred to available proven therapies for diseases such as autism.

- **Fraudulent H1N1 Flu Virus Products.** Since the HHS Secretary's declaration of the 2009 H1N1 Flu Virus Public Health Emergency and throughout FY 2010, FDA has taken an aggressive, proactive approached to identify, investigate, and take regulatory or criminal action against individuals or businesses that promote illegal or fraudulent H1N1 influenza products including CDER-regulated drugs. In FY 2010, FDA issued 30 warning letters, including four FDA and Federal Trade Commission (FTC) joint letters, to offending internet firms. As of November 2010, a total of 95 warning letters covering 185 fraudulent H1N1 flu products have been issued, resulting in a compliance rate exceeding 80 percent. The impact of FDA's actions will also mean a savings of hundreds of thousands of consumer dollars, and patients, many of them children and the elderly, will be referred to available proven therapies for H1N1.

ORA's 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. The increasing globalization of crime has created new challenges to law enforcement. In instances of criminal activity, OCI is expanding efforts to develop cases that address the marketing of counterfeit products. 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.

During FY 2010, OCI made 254 arrests, and secured 269 convictions with fines, restitutions and other monetary penalties in excess of $54 million.

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

- **Counterfeit Drugs:** During the course of 2008, 2009, and 2010, FDA issued a series of alerts on its website concerning tainted weight loss pills and counterfeit drugs. Initial alerts focused on "Superslim," "2 Day Diet," and "Meitzitang", among other purported weight loss products believed to have been imported from China and being marketed as dietary supplements or nutritional products. FDA stated in these initial alerts that the items posed a very serious health risk to consumers, because, based on analysis, they were found to be drugs that contained undeclared active pharmaceutical ingredients, including Sibutramine (a controlled substance), antidepressants, potent diuretics available only by prescription, and drugs not approved in the United States. In later alerts, FDA warned the public about counterfeit versions of the brand name drug Alli, a popular over-the-counter weight loss drug manufactured by Glaxo-Smith Kline. The counterfeit versions of Alli were sold in the United States through internet auction websites and other approaches.

  OCI initiated an investigation in January 2010 targeting the manufacturer of these products. Investigation determined that a foreign national was the individual responsible for illegally manufacturing and importing the counterfeit weight loss medication. The foreign national was arrested in March 2010. A second defendant in the United States was also arrested on the same date.

- **Failure to File Field Alert Reports with FDA:** An OCI investigation led to the March 2010 guilty plea by a pharmaceutical manufacturer for two felony counts of failing to file field alerts with FDA regarding manufacturing problems. The problems related to oversized tablets of propafenone and dextroamphetamine sulfate that failed to meet product specifications. The Court sentenced the company with the maximum fine of $23,437,382, as well as ordering restitution payments to the Medicare program in the amount of $1,762,368 and the Medicaid program in the amount of $573,000 to reimburse the programs for their expenditures for drugs from the pharmaceutical manufacture that were consumed by program beneficiaries during 2008.

- **Medical Technician Sentenced to 30 Years in Prison:** An OCI investigation

led to a successful prosecution in February 2010, when a surgery "scrub" technician at a Denver medical center and a Colorado Springs surgery center was sentenced to 30 years in federal prison after pleading guilty to product tampering and obtaining a controlled substance by deceit. The defendant had Hepatitis C while working at both facilities. The defendant was accused of stealing a powerful narcotic drug, Fentanyl, from surgical patients, injecting herself with the narcotic, and then returning the same used syringes with saline back on the surgical tray. Patients who needed the pain medication during surgery did not receive it. What they did receive, however, was exposure to the defendant's Hepatitis C. Multiple patients at Denver's Rose Medical Center have subsequently tested positive for Hepatitis C that can be linked back to the defendant.

OCI Proactive Ongoing Initiatives:

- **Internet Investigations – OCI conducts** drug investigations involving the Internet and addresses some of the most egregious examples of public health threats. OCI conducts 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 and masquerading behind the anonymity of the Internet offer counterfeit and unapproved drugs to U.S. consumers, deliberately circumventing U.S. Customs and FDA regulations solely for monetary profit. Suspect web sites are researched, and possible violations are identified.

  OCI field offices receive investigative assignments, which often include undercover buys, and other resource intensive activities, such as subpoenas and search warrants, requiring the analysis of hundreds or even thousands of emails, and voluminous financial data. OCI continues to 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 drugs that threaten the health and safety of the American public.

- **Operation Pangea -** For the past three fiscal years, OCI has participated in Operation Pangea, which is an International Internet Week of Action (IIWA). For FY 2010, OCI coordinated with the Office of Enforcement (OE) and CDER, to target 138 websites for illegal activity associated with prescription drugs. After months of planning**,** in less than one week CDER issued warning letters against the websites. OCI worked directly with the domain name registrars, Internet service providers, and payment providers and was successful in getting 136 of the 138 websites permanently shut down. The project received positive press, and was the highlight of 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)

- **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, but cloxacillin, an ingredient in the same class of antibiotics as penicillin. The substitution can result in injury or death for consumers who are allergic to the drug.

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 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.

Promoting Efficiency

Through its pre-approval inspection coverage, ORA:

- prevents unsafe and ineffective drugs from being marketed to the public
- assures that a manufacturing establishment named in a drug application is capable of manufacturing a drug in compliance with Current Good Manufacturing Practice (CGMP)
- assures that submitted data are accurate and complete.

Through the post-approval program:

- ORA audits NDA and ANDA establishments of approved products to assure that any changes in manufacturing and process control are in compliance with CGMP regulations
- assures that all changes are documented in supplemental applications or annual reports
- confirms that NDA/ANDA requirements concerning Adverse Reaction Reports, NDA Field Alerts, Annual Reports are being met.

This program covers both foreign and domestic establishments. In addition, 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.

ORA has developed comprehensive firm history reports, reducing the amount of time an investigator spends researching a firm's history, allowing for a greater focus on inspections.

ORA also achieves program efficiencies from a drug quality standpoint in a variety of ways.

The Government Wide Quality Assurance Program (GWQAP) has expanded access to increasing numbers of foreign regulators, providing FDA evaluations of a firm's compliance with cGMPs, which allows foreign governments to make purchase decisions based upon a firm's compliance status.

The ORA/ US Pharmacopoeia (USP) collaboration assures that methods used by regulated industry are robust, comprehensive and use the most current technology. In addition, it allows for the maintenance of a high level of expertise in ORA field laboratories and increased vigilance as more complex pharmaceuticals are received for evaluation. These efforts also enhance ORA drug product surveillance through the promotion of the manufacturing of safe, unadulterated and effective pharmaceutical products.

PREDICT allows ORA to focus resources on high risk commodities, assuring that imported products are safe and effective for use by U.S. consumers. Expedited clearance of low risk product also ensures that products are available in the U.S. market, providing consumers and health care providers with the commodities of necessity.

ORA continues to resource violative findings 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.

ORA collaborates with other government agencies, resulting in more efficient interagency information sharing. For example, in FY 2010, ORA began staffing the Commercial Trade Analytical Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the 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 products in the drug program.

ORA coordinates information sharing with the Veteran's Administration (VA) regarding the regulatory compliance of drug establishments,resulting in the VA's removal of violative products from its hospitals. Because of this information sharing, the VA has implemented stricter policies to ensure products purchased are produced in compliance with FDA's GMPs to ensure the quality of medical products available on the Federal Supply Schedule.

As it pertains to post market safety oversight, Congress has required that adverse drug experience information relating to all prescription drugs be made available to FDA. Therefore, the primary focus of the inspectional program is to determine if the regulated industry is submitting all adverse drug experience reports to FDA in accordance with regulatory time frames. The secondary focus of this program is to verify completeness and accuracy of ADE data submitted to FDA. In so doing, FDA is able to take appropriate action to protect the public health when necessary.

As a result of OCI's investigative efforts that uncovered fraudulent and criminal activity and led to numerous arrests, convictions, and fines/restitution, ORA identified and removed 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY2010
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2010: 705 (Target Exceeded)	700	750	+50

Biologics Program

Provide Field Support to the Biologics Program

Base Amount: $44,069,000 (BA: $40,073,000 / UF: $3,996,000)

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 postmarket 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 2010, Field Biologics exceeded the inspection goal of 1,000 registered domestic blood bank and biologics manufacturing inspections by inspecting 1,073 blood banks and biologics manufacturing establishments. ORA surpassed the goal of 518 human tissue manufacturing inspections by conducting 564 inspections, an increase of 130 from FY 2009.

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 detain all import entries not in compliance with applicable regulations.

Biologics and vaccines are typically not shipped through normal trade channels but more frequently enter through mail and courier facilities. ORA monitors these shipments through targeted blitz operations at various mail and courier facilities to detect counterfeit and unapproved versions of approved medications.

ORA is active in vaccine surveillance and enforcement. Since the HHS Secretary's declaration of the 2009 H1N1 Flu Virus Public Health Emergency and throughout FY 2010, FDA has proactively identified, investigated, and taken regulatory or criminal action against individuals or businesses that promote illegal fraudulent H1N1 influenza products. In FY 2010, FDA issued:

- thirty warning letters, including four FDA/FTC joint letters, to offending internet firms
- 95 warning letters covering 185 fraudulent H1N1 flu products, resulting in a compliance rate exceeding 80 percent.

ORA monitors recalls of human biological products that present safety concerns 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 FY2010, FDA classified and issued 2,724 recalls. Two were class I (most serious); 2,088 class II, and 634 class III recalls of biological products.

In instances of criminal activity, ORA's OCI is expanding efforts to develop cases that address the marketing of counterfeit products. During FY 2010, OCI made five arrests, and secured three convictions with fines, restitutions and other monetary penalties in excess of $1.1 million.

In July 2010, an OCI investigation led to the indictment of an individual for conducting a clinical trial on more than a dozen multiple sclerosis patients without an approved Investigational New Drug Application (IND) or Institutional Review Board (IRB) oversight. The clinical trial was referred to as "amniotic stem cell implants," and involved surgically implanting placental tissue in the abdomens of patients. An FDA-issued warning letter did not deter the actions of the individual; in fact the individual raised the price of the implants from $5,000 to $10,000. After being indicted and arrested, pretrial conditions for release called for the individual to shut down two websites and to perform no work in the medical field. The trial is pending.

In February 2010, an OCI investigation led to the successful prosecution of a biotech company for violation of Title 42 USC §§ 264, 271, regulations to control communicable diseases and Title 21 CFR §§ 1271(a) and (c), registration of human cells, tissues, and cellular and tissue-based products. The owner of the company was selling expired product and not adhering to manufacturing procedures. The Court ordered the defendant to pay a $100,000 fine and associated costs for destroying the tissue seized by OCI in connection with the investigation.

In September 2010, an individual was sentenced to five years probation and fined

$75,000 after he was identified as being involved in the diversion of blood derivatives. The OCI investigation revealed the individual illegally obtained blood derivatives through his business even though he did not have the patient population to support the purchase of those derivatives. Once he obtained the derivatives, he diverted them to other individuals or pharmacies and personally profited from the sales.

In October 2009, as a result of ORA's continued oversight of the American Red Cross (ARC) Amended Consent Decree of Permanent Injunction, FDA issued two Adverse Determination Letters to the ARC and assessed $16.166 million in fines in June 2010. The violations included failure to properly implement and consistently follow a problem management standard operating procedure and for failure to control suspect blood products.

Promoting Efficiency

ORA provided basic and advanced training to all investigators conducting inspections in the Biologics program area. This cadre forms a dedicated team of investigators with specialized training and experience, whose primary responsibility is to conduct inspections of all biological product manufacturers. This team approach ensures consistent inspections of these manufacturers and application of the regulations while ensuring experienced investigatory staff are performing timely, comprehensive and efficient investigations. In addition, the team approach provides consistency in inspections, communicating regulatory requirements and documenting violations, providing efficient uniform inspectional findings and guidance to the industry. This consistency leads to greater program efficiency within this program..

The ORA team works collaboratively with CBER's product specialists to conduct inspections of biological product 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 U.S. consumers.

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 result 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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2010: 1,073 (Target Exceeded)	1,000	1,000	Maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2010: 564 (Target Exceeded)	518	533	+15

Animal Drugs and Feed Program

Prioritizing Prevention

Base Amount: $12,372,000 (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 ORA priority.

Public Health Outcome

ORA views state-based grant programs such as the Small Scientific Conference (SSC) and Food Protection Task Force grants (FPTF) as an important mechanism for providing feed safety and feed defense program coordination. SSC and FPTP grants foster communication, cooperation, and collaboration within the states and among State, local, and tribal food protection, public health, agriculture, and regulatory agencies, enabling states to strengthen food protection systems.

ORA's focus on prevention includes non-research international harmonization activities. ORA's work with FDA's Office of International Programs' (OIP) Beyond our Borders offices in China, India and Latin American enables cooperation between FDA and its counterpart regulatory authorities. This cooperation improves the safety and quality of food and animal feed and other FDA regulated products exported to the United States and enhances the level of food safety and public health protection provided to consumers in the United States.

In FY 2010, ORA awarded five associations with SSC grants and 27 state and local groups FPTF grants. These grants focus on topics of intervention and prevention by reviewing feed supply vulnerabilities, performing risk-based inspections, sampling, and surveillance to enhance an integrated feed safety system.

ORA outreach efforts ensure up-to-date communication of emerging issues and

advance FDA policies and FDA initiatives to internal and external stakeholders. ORA participated in more than 50 outreach events at a variety of symposiums and conferences attended by regulated industry, other government agencies and foreign regulatory bodies.

Promoting Efficiency

ORA'sgrant and contract programs increase ORA's focus on prevention. Grants such as the SSC and FPTF provide for enhanced evaluation of feed supply vulnerabilities, risk-based inspections, sampling, and surveillance as a means of bolstering an integrated feed safety system and U.S. feed defense efforts.

ORA was recently accepted into the Pharmaceutical Inspection Co-operation Scheme (PIC/S). PIC/S allows a more effective 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 continues to provide state partners with training on the latest risks facing feed safety and BSE prevention, providing knowledge and skills and abilities to support ORA's efforts of protecting public health through public and industry education.

Through these outreach events FDA ensures transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. ORA personnel identify areas where regulated industry can work as partners in protecting the public health. These efforts 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
Base Amount: $13,843,000 (All BA)

Public Health Focus

To strengthen bio-security, 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 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.

Public Health Outcome

ORA uses 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.

During FY 2010, ORA issued several notices identifying modifications to animal feed and drug related Import Alerts encompassing various animal feed and drug commodities and manufacturers. These actions were a result of ORA import surveillance activities 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.

In FY 2010, ORA began staffing the Commercial Targeting and Analysis Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA personnel are working closely with other government agencies on several ongoing cases including products in the animal feed and animal drug program.

ORA continues to conduct routine surveillance examinations, sampling, and analysis to ensure the compliance, safety and security of animal feeds. In January 2010, FDA issued a press release warning consumers not to use a packaged dog treat product due to concerns that the product had been contaminated with Salmonella. FDA became aware of the issue when routine surveillance sample collection and analyses found the product to be contaminated.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of the mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY 2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas.

The joint effort called for ORA and state sampling of grain by-products intended for use in animal feed to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up with sampling of finished feeds manufactured using the milled wheat products, grains or grain by-products that exceeded FDA advisory levels.

FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, consolidating into a single test the previous testing process comprised of an initial test to determine the presence of mycotoxins and the confirmation test for regulatory determination and action. These efforts increased ORA

analytical efficiencies.

ORA continues to award contracts and grants to the states to increase collaborative efforts, leverage existing resources and bolster an integrated feed safety system. In FY 2010, ORA-awarded contracts included:

- 19 Tissue Residue program contracts to states to provide for completion of 260 tissue residue inspections by state inspectors
- 27 FPTF grants to state and local groups
- SSC grants to five associations allowing for increased interactions at operational levels to assure uniformity and consistency in enforcement activities.
- contracts awarded to 36 states under the Feed Safety BSE Contract program in FY 2010. These contracts help FDA establish an expanded level of inspection coverage and surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

In FY 2010, ORA initiated a nationwide investigation to collect and analyze samples of import and domestic distiller grain samples for the presence of antibiotic residues. ORA developed a new analytical method to confirm the presence of residues and determine residue levels using a single method to screen for 21 drugs. Additionally, ORA purchased and outfitted two ORA field laboratories with new equipment to complete this testing, expanding the available ORA laboratory resource network.

Promoting Efficiency

ORA is increasing efficiencies in reviewing import entries through the implementation of PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting). PREDICT gathers intelligence from various sources for a more informed review of specific product entries. Data in support of a product being compliant aids ORA to quickly process and release those entries while data more indicative of concerns or violations results in entries being flagged for additional ORA investigator scrutiny. PREDICT allows ORA to target its resources in a more strategic manner. PREDICT expedites clearance of low risk products and allows 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. 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. These actions provide for the increased examination and sampling of products manufactured under violative conditions to

ensure a higher level of scrutiny when those products are offered for import into the United States.

ORA oversight of grants and cooperative agreements with the states has aided in enhancing and developing new and existing programs intended to safeguard products intended for animal use and has furthered the development of an integrated feed safety system. In utilizing these grants and cooperative agreement funds, ORA has increased integrated feed safety system by assuring better trained state inspectors, increasing state capabilities to respond to feed incidents and outbreaks.

ORA achieves efficiencies by leveraging resources with state Tissue Residue Inspection partners by identifying the causes of illegal drug residues and obtaining compliance through voluntary or regulatory actions. Additionally, ORA strengthens surveillance and risk analysis activities by utilizing experienced state-employed veterinarians in the investigation of animal producers identified by USDA/Food Safety and Inspection Service (FSIS) as having involvement in tissue residue violations to identify the causes of the residues and pursue appropriate enforcement actions as necessary.

ORAs expansion of prior notice bio-security targeting capabilities and intelligence data mining has allowed ORA to provide an increased focus on import shipments that pose the highest risk of an intentional act of bio-terrorism. These advances have increased bio-security review efficiency and provide FDA with an increased 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
Base Amount: $12,087,000 (All BA)

Public Health Focus

One of ORA’s main food and 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.

Public Health Outcome

Currently the best approach to improve the safety and security of food and feed is to utilize resources to expand targeting and follow through on potentially high-risk areas.

ORA and experts from the Center for Veterinary Medicine (CVM) review risk-based scenarios of bioterrorism and develop criteria that targets animal feed and feed ingredients that pose an increased risk for intentional contamination. ORA implemented this science and risk-based screening criteria, thereby strengthening FDA's defense of the animal feed industry.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. To continue to ensure compliance, ORA made more than 800 informed compliance calls to the import trade community and regulated industry in FY 2010 to obtain accurate prior notice data and inform the trade community of the existing requirements.

In conjunction with CBP, ORA executed compliance enforcement actions against more than 1300 imported food and feed shipments where the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful bio-security risk assessments. The actions required resubmission of accurate prior notice data before the imported food and feed shipments were allowed to enter the U.S.

ORA's Ruminant Feed Ban cooperative agreements with the states enhance an integrated feed safety system. The agreements support the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs, and they assure a broader regulatory framework for the U.S. feed supply.

In FY 2010, FDA classified and issued recall numbers for 40 Class I (most serious); 126 Class II; and 31 Class III recalls of animal products. In FY 2010, FDA's MARCS-Compliance Management System indicated three approved CVM injunctions.

An OCI investigation led to a guilty plea from the owner of a veal feed business for misbranding violations under the Food, Drug and Cosmetic Act. The company owner was directing the contract farmers to use feeding protocols that included the routine addition of formaldehyde and potassium permanganate to the veal calves' feed. These are "drugs" within the meaning of the FDCA, and they are not approved for use in veal calf meat intended for human consumption. In October 2009, the company owner signed a guilty plea agreement on behalf of its company that resulted in criminal fine of $550,000. The owner and the company were also ordered to pay special assessments.

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 is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in US commerce.

Informing the import trade community of the importance of submitting accurate prior notice data via informed compliance calls, compliance actions and/or joint cases with CBP serves to increase the reliability and specificity of ORA bio-security assessments and targeting. As such, 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.

Ruminant Feed Ban contract programs enhance FDA efforts to build an integrated feed safety system by increasing ORA and state ability to locate and visit companies involved in the manufacture, distribution, and transportation of animal feed as well as animal feed operations and to verify their compliance with the BSE/ruminant feed ban.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2010: 279 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2010: 567 (Target Exceeded)	490	490	Maintain

Improving Response and Recovery
Base Amount: $9,832,000 (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. ORA continues to 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 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.

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 developed 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.

Currently ORA has 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 more 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 responded to numerous pet foods and animal feed RFRs in FY 2010. Significant resources were expended into nationwide investigations, sample collections and analyses of a variety of products for various contamination concerns including animal feed contamination leading to animal death and Salmonella contamination of pet treats.

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 diminishes unnecessary costs at the federal, state, and local levels resulting from poor coordination or communication during a response.

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.

ORAs continued use of grants and contracts with the states continues to leverage working relationships with state counterparts at the local level to improve surveillance activities, enhance an integrated feed safety system and respond to public health threats in a timely and efficient manner. These programs assist FDA Agency efforts during trace-back investigations, allowing for greater inspectional coverage for ORA and

enhance feed safety and defense through increased communication and integration of key stakeholders.

Provide Field Support to the Animal Drugs Program
Base Amount: $5,077,000 (BA: $4,684,000 / UF: $393,000)

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). The field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA also perform inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed.

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 OCI 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.

Promoting Efficiency

ORA have provided training in the conduct of inspections of animal drug manufacturers and non-clinical laboratories, increasing the consistency of these inspections. ORA

works collaboratively with CVM when significant violations are observed during inspections, evaluate adverse event reports in consultation with CVM and 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY2010
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2010: 279 (Target Exceeded)	250	250	Maintain

Devices and Radiological Health

Provide Field Support to the Devices Program

Base Amount: $94,129,000 (BA: $80,003,000 / UF: $14,126,000)

Public Health Focus

The ORA field advises FDA leadership on device enforcement, import, inspection, and laboratory policies. Through nationwide field offices, ORA conducts risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess their compliance with the Quality Systems regulations. This work includes inspections of re-processors of single-use devices and manufactures or 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 goods.

ORA works with the Center for Devices and Radiological Health (CDRH) in the initial phases of the product life cycle by conducting 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 when the product is marketed for patients. 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 postmarket 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 postmarket safety of products already available to the public for use.

Public Health Outcome

A major focus for ORA in 2010 was the leveraging of information and communication with other local, state, and federal entities to increase efficiency and broaden the scope of public health coverage for the American consumer.

ORA successfully managed the medical devices contract with the state of Texas for a total of 20 inspections, including eight Quality Systems Inspection Technique (QSIT) Level one and 12 QSIT Level two inspections. In addition to completing contracted inspections, ORA worked with external stakeholders to train state investigators to perform audits and joint inspections. This training strengthened state inspector qualifications in conducting inspections. Leveraging relationships with state counterparts while providing training and guidance to the states provides U.S. consumers with an integrated safety network, ensuring a greater level of regulatory oversight of the device industry and assuring the products available in the domestic market are safe and effective.

In addition to cooperation with states for inspections, ORA worked with states to leverage resources to improve other enforcement activities. 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 revision is associated with an increase in the number of enforcement actions and a decrease in the time and resources required to prevent the continued distribution of adulterated products in US commerce that could harm consumers.

ORA also worked closely with other federal agencies to combat public health issues in a more efficient manor. In FY 2010, ORA began staffing the 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 on several ongoing cases including Device Program products such as lasers.

The collaboration efforts of ORA to improve efficiency and performance also occurred internally. Some ORA inspections focus on quality systems, including Corrective Action and Preventative Actions (CAPA). Review of CAPA data reveals process and product

problems from multiple sources, both from within and outside of the manufacturer. These reports demonstrate potential issues to be investigated and corrected. ORA investigators evaluate this data to target specific areas of the production process and quality systems to ensure all stages of the product life cycle are in compliance with FDA regulations. These inspections assure FDA that product components used in the manufacturing process and the process itself are in compliance with FDA regulations, thus providing greater assurance in the finished product meeting safety and efficacy standards for use in the U.S. market.

ORA's WEAC lab continues 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 postmarket surveillance information about devices.

ORA's field laboratories have undertaken an effort to increase the number of medical gloves analyzed at an expedited rate utilizing a "High Throughput" model previously adopted for food borne outbreaks. Increased equipment funding and test method development activities have allowed regulatory labs to design, procure, and commission automated glove testing machines that shorten timeframes for analytical testing.

Promoting Efficiency

In 2010, 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 FDA's current initiatives and provided up-to-date information to consumers and medical professionals about device safety concerns. These FDA communications ensured efficient and timely public health response and industry and consumer awareness.

ORA scientists are fostering communication between the public and private sectors on solutions that meet both the requirements of business and the broader needs of protecting the public from harmful medical devices. These measures will enable manufacturers worldwide to more efficiently conduct product development and manufacturing of billions of needles representing savings for manufacturers while ensuring the safety of consumers.

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 July 2010, this PREDICT enhancement was in use in FDA's Los Angeles, New York, San Francisco and Seattle Districts. FDA has plans to expand this feature to additional districts.

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. In FY 2010, ORA and CDRH implemented a joint initiative to create and issue a series of field advisories to assist ORA investigators. ORA issued 12 field advisories. 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	FY2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2010: 392 (Target Exceeded)	300	300	Maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2010: 1,659 (Target Exceeded)	1,365	1,515	+150

Tobacco Act Program

Regulation and Compliance Activities

Base Amount: $4,700,000 (All UF)

Public Health Focus

ORA supports the Tobacco 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 are geared to help reduce the reality that more than 400,000 Americans still die from tobacco-related illnesses every year and tobacco-related health care costs exceed $100 billion annually.

Public Health Outcome

In order to enforce tobacco regulations and to comply with the statute, FDA continues to contract 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" (also known as the "Re-issued 1996 Final Rule"), as well as with other provision 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 2010, ORA carried out a multi-tiered approach towards initial implementation of requirements under Sec 101 of the Smoking Prevention and Tobacco Control Act. In order to analytically enforce the requirements established in Sec 101, prior to implementation of the regulation ORA created and implemented two sampling assignments supporting tobacco product analysis for determining base line analytical findings for flavoring agents. The pre-emptive measures established base line analytical findings to be used for comparative analysis for appropriate regulatory actions once the regulation was implemented. ORA analyzed more than 200 cigarette products for the presence of flavoring compounds, completing more than 650 individual analyses. ORA also instituted import controls by establishing and implementing two active import bulletins calling for increased surveillance of imported tobacco products. ORA has also invested in new technology to equip its laboratories with the necessary equipment for enforcement of the Act.

ORA continues to work with internal and external stakeholders to:

- identify analytical capabilities and laboratory capacity
- determine product composition
- identify product adulteration and contamination concerns
- establish standards to make determinations of product authenticity as well as identification of counterfeit product
- share data, databases and analytical expertise
- continue to work on method development to screen tobacco related products for composition and presence of flavors and contaminants.

Promoting Efficiency

The pre-emptive analyses completed by ORA will ensure that commodities regulated under the Smoking Prevention and Tobacco Control Act can be examined and analyzed and that FDA can make appropriate regulatory determinations in a timely and efficient manner. Efforts to ensure appropriate laboratory technologies are in place within FDA and work with internal and external stakeholders to develop methods and share data prior to full implementation of the Act will ensure FDA has the resources and scientific footing to make appropriate regulatory determinations across all facets of the Act. The pre-emptive efforts will assure that products not fit for use under the new regulation will remain out of the hands of U.S. consumers.

Information Technology Investments –Field Activities (ORA) (Base Amount is included in the applicable Program Description and Accomplishments sections.)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts to enhance FDA's ability to collect, store and analyze large volumes of regulatory, scientific, and risk-based data and provide the necessary tools for personnel in field offices to carry out their mission and help ensure the safety and security of imported and domestic products regulated by FDA. While continuing maintenance of existing IT systems, the Mission Accomplishment and Regulatory Compliance Services (MARCS) program is integrating, reengineering and enhancing FDA's Office of Regulatory Affairs' most critical legacy systems, replacing outdated and failing technology.

MARCS improves the efficiency of FDA Field Operations staff by:

- making existing functionality and data much easier to use
- reducing redundancy with shared technology services
- employing an integration contract paradigm to reduce risk
- enhancing the ability to store and retrieve findings obtained during both import and domestic investigations and inspections
- improving targeting identification 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 improvements to processing the import data it receives through automated compliance targeting assessment algorithms using a screening tool known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) within its imports program in MARCS, scheduled to complete deployment in FY11.

The Automated Laboratory Management (ALM) program will integrate with MARCS and will process and analyze large volumes of data on samples of many products and substances in their laboratories in the field and improve automation of information sharing. The Regulatory Business Information Services (RBIS) program is integrating reporting needs and services for both ALM and MARCS, reducing redundancy and

increasing efficiency. These modernization projects along with the ongoing operations and maintenance of the ORA systems will measurably improve FDA's ability to inspect and investigate facilities and products both foreign and domestic, and improve coordination with other agencies to enhance public health and the safety of American consumers.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2007 Actual	$522,658,000	$505,753,000	$16,905,000	3,290
2008 Actual	$573,181,000	$555,450,000	$17,713,000	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 Continuing Resolution	$879,351,000	$846,017,000	$33,334,000	4,235

Summary of the Budget Request

The FY 2012 budget request for ORA is $1,101,268,000, supporting 4,900 FTE. This is an increase of $223,730,000 and 670 FTE over the FY 2010 Enacted Budget.

The base funding for the Field Program is $877,538,000. The base provides ORA with funding to protect consumers and enhance public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products. ORA serves as the traditional “eyes and ears” of FDA through its network of investigators and laboratory analysts to enforce the 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 related to the Family Smoking Prevention and Tobacco Control Act.

With this budget request, ORA will continue to further implement an Integrated Food Safety System (IFSS) by supporting its regulatory and public health partners. Grants used to improve, strengthen, and standardize regulatory activities among all partners will help ensure consistent oversight, application and enforcement of food safety laws and regulations. ORA will fill select, critical infrastructure positions in support of IFSS and will hire and train new investigators in support of biosimilars and medical countermeasures initiatives. FDA has also submitted a legislative proposal and corresponding user fee request to augment the increasing import coverage staffing needs at international express couriers.

FOODS

Prioritizing Prevention

Field Activities (Base Amount: $107,199,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System – FMSA Sections 201, 205, 209 and 210 (+$3,725,000; 13 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:

- hire 3 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 1 FTE to serve in Headquarters for program oversight and as a program auditor and 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards
- hire 2 FTE at Headquarters and 4 FTE as field state liaison to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire 2 FTE to develop and validate certification testing instruments.

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention - Preventive Controls on Farms – FSMA Section 105 (+$3,537,000; 6 FTE)

This investment supports the regulation of on-farm and post-harvest handling of fresh fruits and vegetables. Developing and disseminating knowledge and build capacity within and outside FDA will reduce the risk of foodborne illness and enhance public confidence in the produce supply. ORA will conduct the following activities with the resources in this sub-program:

- hire 2 FTE to manage the program, provide assistance to State Regulators, and provide funding to State Regulators to attend the train-the-trainer courses and the Produce Safety Alliance training course.
- hire 4 FTE to serve as program and national Produce Safety experts
- develop a curriculum to train personnel assigned to produce safety compliance, inspection and enforcement activities. Provide training to FDA laboratory personnel regarding new training methods and detection protocols developed by the science program within FDA to use on produce directly from farms and on-farm/postharvest environmental

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention - Preventive Controls for Food Processing – FMSA Section 110 (+$8,919,000; 2 FTE)

Investments allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- develop preventive controls-based inspection training and update GMP training to address preventive controls
- administer training on preventive controls to both FDA and State investigators on preventive controls. These resources will fund approximately 3,380 personnel – ORA inspection personnel and State, Tribal, and Territorial regulatory partners – to attend a one-week training course utilizing a combination of face- to-face and distance learning mediums.

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention - Retail Food Code – FSMA Section 210 (+$2,955,000; 2 FTE)

Investments will allow FDA to promote widespread state and local enrollment in, implementation of, and accountability for the FDA Retail Food Program Standards. ORA will conduct the following activities with the resources in this subprogram:

- establish contracts, cooperative agreements, or grants for State, local, territorial, and tribal agencies seeking to institute innovative compliance and enforcement strategies that promote improved and sustained managerial control of key operational risk factors
- hire a contract monitor and state liaison.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

<u>Field Activities</u> (Base Amount: $273,955,000)

FY 2012 increase for current law user fees (VQIP): +$61,000,000; 265 FTE

FY 2012 Food Safety Training – FFSMA Section 209: +$8,000,000 / 0 FTE

FDA will spend $8.0 million on food safety training. FDA will develop and implement a national food safety training system to provide the knowledge and skills required for regulators and public health partners at all levels of government. FDA will also develop a related certification system to ensure the competency of the workforce. These resources support the authorities enacted by Congress in section 209 of the Food Safety Modernization Act. This investment will help ensure that FDA maintains a skilled national workforce to ensure that the food industry is meeting food safety standards.

Initiatives

Transforming Food Safety and Nutrition Initiative: Import Oversight for Food – FSMA Sections 201, 301, 302, 305, 306 and 307 (+$12,444,000; 52 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 3 FTE to establish equivalence standards and assess whether other nations' food safety systems are comparable to ours and establish standards for third-party certification for imported food
- hire 14 FTE to develop, implement and conduct VQIP inspections
- hire 1 FTE to liaison with Customs and Border Protection to develop, evaluate and share voluntary programs
- hire 22 FTE to implement Import Accountability Verification Program
- hire 5 FTE in Headquarters Operations to handle Import Alerts, Import Bulletins, assignments, guidance documents, procedures, training, bond mitigation and compliance review
- hire 2 FTE to increase security review capacity at the Prior Notice Center
- hire 5 FTE to increase enforcement expectations, Import Alerts/Import Bulletins recommendations, refusals and mitigations.

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+$1,868,000; 8 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. The system will provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire 1 FTE to serve as a National Work Plan Manager and 1 FTE to serve as National Work Plan Analyst. These FTE will assist ORA with its movements towards an integrated national Workplan
- hire 3 FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire 2 FTE to serve as Scientific Coordinators and 1 FTE as IT Specialist. These resources will support the states as FDA moves to national standards for laboratories

Transforming Food Safety and Nutrition Initiative: Nutrition for Better Health – 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) (+$6,289,000; 2 FTE)

FDA will partner with State, local, territorial, and tribal regulatory partners to establish inspection programs to evaluate compliance with the new menu labeling standards. ORA will conduct the following activities with the resources in this subprogram:

- establish Menu Labeling contracts targeted to state agencies or subdivisions of a state, county or city government with the regulatory authority to administer rules or policies that govern the inspections of restaurants and similar retail food establishments chains
- develop training for state inspectors to include a web-based course and reference document
- hire 1 FTE to serve as Commissioning Agent and 1 FTE to serve as a Contract Monitor.

Transforming Food Safety and Nutrition Initiative: Laboratory Capacity and Capability (+$19,184,000; 80 FTE)

Using budget authority funding, ORA will build on existing capacity and capability through the hiring of an additional 80 laboratory analysts and technicians.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$277,000; 1 FTE)

ORA will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Proposed User Fee: International Courier (+690,000; 3 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities, and the number continues to grow. These shipments are often destined for individual consumers or for illegal distribution. The user fee resources for this activity allow increased import surveillance of FDA-regulated products at express courier hubs.

Current FDA staffing does not match the expected growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

With this new user fee, FDA will:

- conduct entry reviews

- sample collections and physical exams to determine product admissibility into the U.S.
- initiate compliance actions to prevent release of unsafe products into U.S. commerce
- establish import controls to prevent future unsafe products from entering U.S. commerce.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Field Activities (Base Amount: $111,446,000)

FY 2012 increase for current law user fees (Reinspection): +$6,825,000; 48 FTE

FY 2012 increase for current law user fees (Recall): +$9,397,000; 23 FTE

Initiatives

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+$32,328,000; 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. The system will 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 twenty states grants, cooperative agreements or inter-agency agreement between federal agencies
- 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 and Nutrition Initiative: Import Oversight for Food – FMSA Sections 201, 301, 305, 306 and 307 (+$12,435,000; 44 FTE)

Investments will allow FDA to implement preventive controls in food processing facilities. ORA will conduct the following activities with the resources in this subprogram:

- hire 2 FTE to perform periodic audits of Foreign Food Safety System Comparability Program
- hire 2 FTE to perform period audits of the Commodity Specific Export Certification Program
- hire 2 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

- hire 3 FTE to serve as foreign inspection trip planners
- hire 19 FTE to expand existing foreign inspection program
- hire 1 FTE to begin developing a foreign workplan.

Improving Response & Recovery

Field Activities (Base Amount: $49,360,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System – FMSA Sections 201, 301, 302, 305, 306 and 307 (+$467,000; 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. The system will provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- fund 1 FTE to develop and implement trackback procedures
- fund 1 FTE to ensure consistency with Council to Improve Foodborne Outbreak Response (CIFOR) guidelines.

Reinventing Cosmetics Safety

Field Activities (Base Amount: $3,489,000)

HUMAN DRUGS

Field Activities (Base Amount: $135,980,000)

FY 2012 increase for current law user fees (PDUFA): +$3,992,000; 8 FTE

FY 2012 increase for proposed user fee (GDUFA): +$6,737,000; 12 FTE

FY 2012 proposed user fee (Medical Products Reinspection): +$2,630,000; 18 FTE

Initiatives

Advancing Medical Countermeasures Initiative: (+$655,000; 3 FTE)

Under Pillar 1, ORA field operations will conduct enhanced inspection and compliance activities, identify as early and efficiently as possible problems that impede MCM

product development, and provide technical assistance to minimize risk during MCM product manufacturing. With these resources, ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance, ORA will be able to conduct ten MCM inspections by FY 2014 and an additional 13 foreign MCM inspections by FY 2015.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$277,000; 1 FTE)

For the nanotechnology initiative, ORA's Arkansas Regional Laboratory will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Protecting Patients Initiative:
Section 351 of the Public Health Service Act (42 U.S.C. 262), Biosimilars (+$420,000; 2 FTE)

FDA will hire the scientific, analytical, regulatory, and legal staff to address the broad regulatory issues relating to biosimilars. FDA will also provide essential advice in pre-IND and pre-application meetings, and review submissions. These funds will also support the acquisition of additional laboratory capacity to develop physical reference standards needed for biosimilar review and assuring manufacturing quality.

ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance, ORA will be able to conduct eight domestic pre-approval NDA inspections by FY 2014 and five foreign pre-approval NDA inspections by FY 2015.

Protecting Patients Initiative: Increasing Medical Product inspections (+$3,324,000; 16 FTE)

FDA will strengthen human drug safety through increased inspections and enforcement activities including foreign drug GMP surveillance inspections and foreign generic drug bioequivalence laboratory inspections. FDA will hire and begin training new investigators in FY 2012. These new investigators will reach full performance in FY 2015 for foreign inspections. Increased foreign drug inspections will include 46 GMP surveillance inspections and 15 generic drug bioequivalence laboratory inspections.

Proposed User Fee: International Courier (+460,000; 2 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. Current FDA staffing does not match the growth in import volume. Couriers expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee. The user fee resources will support increased import surveillance of FDA-regulated products at express courier hubs

FDA will conduct entry reviews, sample collections and physical exams to determine product admissibility into the U.S., initiate compliance actions to prevent release of unsafe products into U.S. commerce and establish import controls to prevent future unsafe products from entering U.S. commerce.

This user fee supports patient safety and reduces health care costs by keeping unapproved and counterfeit products out of U.S. commerce.

BIOLOGICS

Field Activities (Base Amount: $44,069,000)

FY 2012 increase for current law user fees (PDUFA): +$1,676,000; 1 FTE

FY 2012 increase for current law user fees (MDUFMA): +$90,000; 0 FTE

FY 2012 proposed user fee (Medical Products Reinspection): +$537,000; 3 FTE

FY 2012 Initiative

Advancing Medical Countermeasures Initiative: (+$437,000; 2 FTE)

Under Pillar 1, ORA field operations will:

- conduct enhanced inspection and compliance activities
- identify as early and efficiently as possible problems that impede MCM product development
- provide technical assistance to minimize risk during MCM product manufacturing.

With these resources, ORA will hire and begin training new investigators in FY 2012. Once the new investigators reach full performance, ORA will be able to conduct nine MCM inspections by FY 2014.

Protecting Patients Initiative:

Section 351 of the Public Health Service Act (42 U.S.C. 262), Biosimilars (+$210,000; 1 FTE)

FDA will begin development of scientific and regulatory policies to build a strong biosimilars review program to facilitate the review and availability of follow-on biologics.

Protecting Patients Initiative: Increasing Medical Product Inspections (+$830,000; 4 FTE)

FDA will strengthen human tissue safety through increased inspections and enforcement activities including both foreign and domestic human tissue. FDA will hire and begin training new investigators in FY 2012. These new investigators will reach full performance in FY 2014 for domestic inspections and FY 2015 for foreign inspections. Increased tissue inspections will include 68 domestic inspections and two foreign inspections.

ANIMAL DRUGS AND FEED

Prioritizing Prevention

Field Activities (Base Amount: $12,372,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+$467,000; 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 animal food and feed supply, and sustainable multi-year infrastructure investments. This system 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 1 FTE to develop and validate certification testing instruments.
- fund 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention - Preventive Controls for Food and Feed Processing – FSMA Section 110 (+$674,000; 0 FTE)

- Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will administer training on preventive controls to FDA and State

investigators. These resources will fund approximately 270 people – ORA investigators and State, Tribal, and Territorial inspectors – to attend a one-week training course using a combination of face-to-face and distance learning mediums.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Field Activities (Base Amount: $13,843,000)

FY 2012 Initiatives

Transforming Food Safety and Nutrition Initiative: Import Oversight – FSMA Sections 201, 301, 302, 305, 306 and 307 (+$233,000; 1 FTE)

This investment supports a comprehensive prevention-focused import feed and pet food safety program that will rely on the food supply chain such as:

- feed and animal food manufacturers
- processors
- packers
- distributors
- importers.

This program provides assurances that the feed and pet food imported to the United States are safe and meet regulatory requirements. ORA hire one FTE to assist in the development, implementation and conduct of Voluntary Qualified Importer Program (VQIP) inspections.

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 ($700,000; 3 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:

- hire 1 FTE to serve as a National Work Plan Analyst. This FTE will assist ORA with its movements towards an integrated national standards Workplan
- hire 1 FTE to serve as an Official Establishment Inventory (OEI) Coordinator for the field
- hire 1 FTE to serve as a Scientific Coordinator. This resource will support the states as FDA moves to national standards for laboratories

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Field Activities (Base Amount: $12,087,000)

FY 2012 increase for current law user fees (Reinspection): +$2,550,000; 18 FTE

FY 2012 increase for current law user fees (Recall): +$639,000; 2 FTE

Initiatives

Transforming Food Safety and Nutrition Initiative: Import Oversight – FSMA Sections 201, 302, 305, 306 and 307 (+$234,000; 1 FTE)

Investments support a comprehensive prevention-focused import food and feed safety program that will rely more heavily on those in the food supply chain – food and fee manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. With the resources in this subprogram ORA will hire one FTE to expand existing foreign inspection program

Transforming Food Safety and Nutrition Initiative: Food Safety through Prevention – Integrated Food Safety System - FSMA 201, 205, 209 and 210 (+$685,000; 3 FTE)

This initiative incorporates CFSAN, CVM, ORA, and HQ/OC activities to achieve an integrated food safety system. Budget authority funds for this initiative will enable FDA to support an increase of 33 tissue residue inspections.

Improving Response and Recovery

Field Activities (Base Amount: $9,832,000)

Animal Drug

Field Activities (Base Amount: $5,077,000)

FY 2012 increase for current law user fees (ADUFA): +$65,000; 0 FTE

FY 2012 increase for current law user fees (AGDUFA): +$17,000; 0 FTE

FY 2012 proposed user fee (Medical Products Reinspection): +$134,000; 1 FTE

Initiatives

Protecting Patients Initiative: Increasing Medical Product Inspections (+$184,000; 1 FTE)

FDA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2014 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This component will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete its hiring of additional employee and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 17 domestic Animal Drug Manufacturing /Type A Medicated Articles Inspections.

DEVICES AND RADIOLOGICAL HEALTH

Field Activities (Base Amount: $94,129,000)

FY 2012 increase for current law user fees (MDUFMA): +$186,000; 7 FTE

FY 2012 proposed user fee (Medical Products Reinspection): +$3,424,000; 24 FTE

Initiatives:

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+$276,000; 1 FTE)

For the nanotechnology initiative, ORA will conduct activities that support the following FDA-wide priorities:

- laboratory and product testing capacity
- scientific staff development and training
- collaborative and interdisciplinary research to address product characterization and safety.

Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing risks.

Advancing Medical Countermeasures Initiative: (+$218,000; 1 FTE)

Under Pillar 1, ORA field operations will conduct enhanced inspection and compliance activities, identify as early and efficiently as possible problems that impede MCM product development and provide technical assistance to minimize risk during MCM product manufacturing. This budget increase will support up to 14 additional device inspections once the investigators reach full performance in FY 2014.

Protecting Patients Initiative: Increasing Medical Product Inspections (+$1,662,000; 6 FTE)

FDA will strengthen medical device and radiological health safety through increased inspections and enforcement activities. FDA will hire and begin training new investigators in FY 2012. These new investigators will reach full performance in FY 2014 for domestic inspections and in FY 2015 for foreign inspections. Increased inspections will include 14 domestic GMP surveillance inspections, 53 foreign GMP surveillance inspections, and 14 foreign radiological health inspections.

Proposed User Fee: International Courier (+$3,450,000; 15 FTE)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. The number of shipments continues to grow, and current FDA staffing does not match the growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

FDA will conduct entry reviews, sample collections and physical exams to determine product admissibility into the U.S., initiate compliance actions to prevent release of unsafe products into U.S. commerce and establish import controls to prevent future unsafe products from entering U.S. commerce.

TOBACCO

Field Activities (Base Amount: $4,700,000)

FY 2012 increase for current law user fees: +$1,550,000; 6 FTE

FDA will continue to develop and award State and Territorial government contracts to enforce the provisions of the new law that are applicable to retailers including the new regulation that restricts the sale of cigarettes and smokeless tobacco to minors and also restricts the advertising, marketing, and promotion of these products. The FY 2012 goal for this initiative is to contract with all U.S. States and Territories to assist with inspections and enforcement.

BA Increase for Pay Costs: +$1,952,000

Contract and Administrative Savings (Total Program: -$8,185,000; -46 FTE)

The request for $963,698,000 in total budget authority for Field Activities also reflects contract and administrative savings reduction of -$8,185,000.

Field Activities

Contract and Administrative Savings (-$8,185,000; -46 FTE)

ORA will achieve contract and administrative savings by:

- reducing administrative support FTE, both in headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA
    - obtaining the best value for the American public through blanket purchase agreements and agency-wide approaches to contracting.

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***8,745***	***10,099***	***12,099***
Domestic Food Safety Program Inspections	5,942	8,291	**To be determined**
Imported and Domestic Cheese Program Inspections	335	204	
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	479	545	
Domestic Fish & Fishery Products (HACCP) Inspections	2,082	1,361	
Import (Seafood Program Including HACCP) Inspections	339	375	
Juice HACCP Inspection Program (HACCP)	288	250	
Interstate Travel Sanitation (ITS) Inspections	998	1,057	
Domestic Field Exams/Tests	3,749	2,400	2,400
Domestic Laboratory Samples Analyzed	12,173	10,305	10,305
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***354***	***994***	***1,044***
All Foreign Inspections	354	994	*1,044* [1]
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,099***	***11,093***	***13,143***
IMPORTS			
Import Field Exams/Tests	170,392	140,200	140,200
Import Laboratory Samples Analyzed	30,374	26,549	26,549
Import Physical Exam Subtotal	**200,766**	**166,749**	166,749
Import Line Decisions	9,737,919	10,520,261	11,365,456
Percent of Import Lines Physically Examined	2.06%	1.59%	1.47%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	81,618	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,736***	***11,767***	***10,643***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***189***	***1,000***	***1000***
State Contract Food Safety (Non HACCP) Inspections	8,555	10,500	10,800
State Contract Domestic Seafood HACCP Inspections	1,098	1,200	1,250
State Contract Juice HACCP	76	100	125
State Contract LACF	84	60	75
State Partnership Inspections	189	1,000	500
State Contract and Grant Foods Funding	$16,372,900	$12,007,867	$12,968,497
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$16,705,000	$17,634	$17,730
Total State & Annual FERN Funding	**$33,077,900**	**$12,025,501**	**$12,986,227**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***19,024***	***23,860***	***24,786***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 264 foreign food inspections.

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***132***	***100***	***100***
Domestic Inspections	132	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**0**	**0**	***5***
Foreign Inspections	0	0	5
IMPORTS			
Import Field Exams/Tests	3,792	0	2,000
Import Laboratory Samples Analyzed	357	230	230
Import Physical Exam Subtotal	**4,149**	**230**	**2,230**
Import Line Decisions	1,883,221	2,098,494	2,338,374
Percent of Import Lines Physically Examined	0.22%	0.01%	0.10%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***132***	***100***	***105***

Combined Field Activities – ORA
Program Activity Data

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,159***	***2,236***	***2,236***
Pre-Approval Inspections (NDA)	154	197	197 [1]
Pre-Approval Inspections (ANDA)	63	91	91
Bioresearch Monitoring Program Inspections	548	558	558
Drug Processing (GMP) Program Inspections	1,174	915	915
Compressed Medical Gas Manufacturers Inspections	231	285	285
Adverse Drug Events Project Inspections	79	147	147
OTC Monograph Project and Health Fraud Project Inspections	31	221	221
Domestic Laboratory Samples Analyzed	1,908	888	888
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***639***	***587***	***587***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	201	117	117 [2]
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	106	62	62
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	214	231	231 [3]
Foreign Drug Processing (GMP) Program Inspections	380	490	490 [4]
Foreign Adverse Drug Events Project Inspections	5	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,798***	***2,823***	***2,823***
IMPORTS			
Import Field Exams/Tests	7,696	6,200	6,200
Import Laboratory Samples Analyzed	253	405	405
Import Physical Exam Subtotal	**7,949**	**6,605**	**6,605**
Import Line Decisions	409,728	473,758	547,794
Percent of Import Lines Physically Examined	1.94%	1.39%	1.21%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***146***	***146***	***146***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	124	124	124
State Partnership Inspections: GMP Inspections	22	22	22
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,944***	***2,969***	***2,969***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014 for medical countermeasure (MCM) and biosimilar domestic inspections. During the full performance year (FY 2014), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 10 MCM and 8 biosimilar domestic pre-approval NDA inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015 for medical countermeasure (MCM) and biosimilar foreign inspections. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 13 MCM and 5 biosimilar foreign pre-approval NDA inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015 for foreign generic drug bioequivalence laboratory inspections. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 15 foreign bioresearch monitoring inspections.

[4] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increases for inspections will allow ORA to conduct an additional 46 foreign GMP surveillance inspections.

Combined Field Activities – ORA
Program Activity Data

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,902***	***2,091***	***2,116***
Bioresearch Monitoring Program Inspections	106	180	180
Blood Bank Inspections	1,061	1,100	1,100
Source Plasma Inspections	158	225	225
Pre-License, Pre-Market) Inspections	18	30	30
GMP Inspections	29	25	25 [1]
GMP (Device) Inspections	5	10	10
Human Tissue Inspections	552	545	570 [2]
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***57***	***73***	***73***
Bioresearch Monitoring Program Inspections	10	5	5
Foreign Human Tissue Inspections	13	15	15 [3]
Blood Bank Inspections	7	10	10
Pre-License Inspections	4	10	10 [4]
GMP Inspections	22	30	30
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,959***	***2,164***	***2,189***
IMPORTS			
Import Field Exams/Tests	90	100	100
Import Line Decisions	51,307	65,159	65,790
Percent of Import Lines Physically Examined	0.18%	0.15%	0.15%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,959***	***2,164***	***2,189***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 9 domestic MCM vaccine inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 68 domestic human tissue inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 2 foreign human tissue inspections

[4] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 8 foreign vaccine biosimilars manufacturer inspections

Combined Field Activities – ORA
Program Activity Data

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,181***	***1,938***	***1,750***
Pre-Approval /BIMO Inspections	53	79	79
Drug Process and New ADF Program Inspections	229	205	205 [1]
BSE Inspections	1,721	1,486	1,205
Feed Contaminant Inspections	42	25	25
Illegal Residue Program Inspections	362	400	454 [2]
Feed Manufacturing Program Inspections	222	141	141
Domestic Laboratory Samples Analyzed	2,250	2,458	2,458
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***52***	***66***	***66***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	29	45	45
Foreign Drug Processing and New ADF Program Inspections	37	33	33
Foreign Feed Inspections	3	10	10 [3]
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,233***	***2,004***	***1,816***
IMPORTS			
Import Field Exams/Tests	5,202	3,600	4,550
Import Laboratory Samples Analyzed	755	740	740
Import Physical Exam Subtotal	**5,957**	**4,340**	**5,290**
Import Line Decisions	237,039	237,162	237,285
Percent of Import Lines Physically Examined	2.51%	1.83%	2.23%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,401***	***6,054***	***5,670***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***124***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,385	5,800	5,200
State Contract Inspections: Feed Manufacturers	416	350	425
State Contract Inspections: Illegal Tissue Residue	176	550	650
State Partnership Inspections: BSE and Other	124	300	300
State Contract Animal Drugs/Feeds Funding	$2,532,300	$2,950,000	$2,937,853
BSE Cooperative Agreement Funding	$2,893,500	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$408,700	$401,000	$429,395
Total State Funding	**$5,834,500**	**$6,351,000**	**$6,367,248**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,758***	***8,358***	***7,786***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 17 animal drug inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 33 tissue residue inspections.

[3] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 12 foreign animal feed inspections.

Combined Field Activities – ORA
Program Activity Data

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,536***	***2,493***	***2,533***
Bioresearch Monitoring Program Inspections	372	295	295
Pre-Market Inspections	42	68	68 [1]
Post-Market Audit Inspections	29	48	48
GMP Inspections	1,672	1,573	1,614 [1]
			0
Inspections (MQSA) FDA Domestic (non-VHA)	329	359	359
Inspections (MQSA) FDA Domestic (VHA)	37	33	33
Domestic Radiological Health Inspections	96	157	157
			0
Domestic Field Exams/Tests	239	480	480
Domestic Laboratory Samples Analyzed	125	217	217
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***322***	***352***	***388***
Foreign Bioresearch Monitoring Inspections	20	25	25
Foreign Pre-Market Inspections	26	33	33
Foreign Post-Market Audit Inspections	36	19	19
Foreign GMP Inspections	251	286	327 [2]
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	32	26	26 [2]
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,858***	***2,845***	***2,921***
IMPORTS			
Import Field Exams/Tests	18,761	13,180	13,180
Import Laboratory Samples Analyzed	1,513	1,145	1,145
Import Physical Exam Subtotal	20,274	14,325	14,325
Import Line Decisions	8,822,633	10,942,777	13,572,408
Percent of Import Lines Physically Examined	0.23%	0.13%	0.11%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,168***	***8,496***	***8,496***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	***72***	***74***	**74**
Inspections (MQSA) by State Contract	7,060	7,356	7,356
Inspections (MQSA) by State non-Contract	1,091	1,120	1,120
GMP Inspections by State Contract	17	20	20
State Partnership GMP Inspections	72	74	74
State Contract Devices Funding	$79,000	$85,000	$92,000
State Contract Mammography Funding	$9,000,000	$9,630,000	$10,300,000
Total State Funding	**$9,079,000**	**$9,715,000**	**$10,392,000**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,098***	***11,415***	***11,491***

[1] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct and additional 14 premarket MCM inspections and an additional 14 GMP surveillance inspections.

[2] For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 14 Rad Health inspections and an additional 53 GMP surveillance inspections.

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TOBACCO ACT PROGRAM

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table[1]
(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$216,523**	**$64,418**	**$216,523**	**$454,751**	**$238,228**
Center	$211,823	$62,355	$211,823	$448,501	$236,678
FTE	174	84	84	366	192
Field	$4,700	$2,063	$4,700	$6,250	$1,550
FTE	20	6	6	26	6
Program Level FTE	**194**	**90**	**90**	**392**	**198**
User Fees	**$216,523**	**$64,418**	**$216,523**	**$454,751**	**$238,228**
Center	$211,823	$62,355	$211,823	$448,501	$236,678
FTE	174	84	84	366	192
Field	$4,700	$2,063	$4,700	$6,250	$1,550
FTE	20	6	6	26	6
User Fees FTE	**194**	**90**	**90**	**392**	**198**

[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. FY 2010 Actual collections totaled $193.114 million and do not appear in the above table.

The FDA Tobacco 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

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 areas:

- protecting the public health
- scientific standard-setting and product review

- compliance and regulation
- public education and outreach.

To achieve these goals, FDA relies on its statutory authorities. For example, some of these authorities include:

- restricting the marketing of tobacco products to minors
- requiring new health warning labels for cigarettes and smokeless tobacco products
- prohibiting marketing measures that are misleading to consumers
- establishing tobacco product standards
- requiring Good Manufacturing Practice standards for the manufacturing of tobacco products
- requiring industry reporting of tobacco product ingredient and constituent data, including a description of the nicotine content and delivery mechanisms
- initiating enforcement actions against regulated industry for violations of the Tobacco Control Act.

Major Accomplishments

Meeting all of the statutory deadlines in FY 2010 and to date in FY 2011, FDA successfully implemented several provisions of the Tobacco Control Act and undertook additional activities to protect children and adolescents from dangerous tobacco products.

In March 2010, FDA issued *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*. These regulations restrict the access and appeal of cigarettes and smokeless tobacco products to children by:

- prohibiting the sale of cigarettes and smokeless tobacco to persons under the age of 18
- prohibiting the sale of cigarettes that contain less than 20 cigarettes per package
- prohibits the sale of cigarettes and smokeless tobacco in vending machines, self-service displays, or other impersonal modes of sales, except in very limited situations
- prohibiting the distribution of free samples of cigarettes and restricting the distribution of free smokeless tobacco samples
- prohibiting a tobacco company from sponsoring an athletic, musical, social, or cultural event, or any team or entry in those events
- prohibits gifts or other items in exchange for buying cigarettes or smokeless tobacco products
- requires that audio ads use only words with no music or sound effects
- prohibits the sale or distribution of items, such as hats and tee shirts, with tobacco brands or logos.

To ensure compliance with these new regulations, which became effective on June 22, 2010, FDA awarded 15 enforcement contracts to States through a competitive procurement process. States receiving those contracts were: Alabama, Arizona, Arkansas, Colorado, Idaho, Illinois, Kansas, Maine, Maryland, Massachusetts, Mississippi, Missouri, Pennsylvania, Tennessee, and Washington. This exceeds FDA's FY 2010 goal of contracting with 25 percent of U.S. States and Territories to enforce its regulations in retail establishments. It is FDA's intent to contract with up to 75 percent of U.S. States and Territories in FY 2011 and with every U.S. State and Territory that elects to participate in the enforcement program by the end of FY 2012.

Also to help ensure compliance with *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, FDA held five retailer training sessions across the United States. These training sessions were designed to provide information to retailers about how to comply with the Tobacco Control Act and other regulations issued by FDA, including the ban on sale of flavored cigarettes that took effect in 2009. Topics discussed included information on what tobacco products are regulated; the prohibition of selling cigarettes and smokeless tobacco products to persons under the age of eighteen; and prohibitions of cigarette sales in self-service displays and vending machines, except in very limited circumstances. Retailer training sessions were held in Boston, Atlanta, Chicago, Dallas and Los Angeles. More than 175 retailers attended the events in person, and more than 1,200 retailers participated through a web cast or by phone.

In June 2010, regulations requiring larger rotational health warning labels for smokeless tobacco products and prohibiting the use of misleading descriptors like "light," "low," and "mild" and similar descriptors on cigarette packages took effect.

Also in June 2010, FDA launched the "Break the Chain of Tobacco Addiction" public education campaign. The purpose of this campaign is to educate the nation's one to two million tobacco retailers and to raise awareness among the American public about FDA's new regulations intended to protect kids by restricting youth access to, and the advertising and promotion of, cigarettes and smokeless tobacco products. The "Break the Chain of Tobacco Addiction" has employed a mix of traditional, web, phone, and social media to reach the retailers, industry, state and local entities, partners, and the public with the latest FDA tobacco regulation information. Evaluation data shows growing numbers of audiences using the information and sharing it online and via other outlets.

On October 1, 2010, the Secretary of Health and Human Services published the "Enforcement Action Plan for Promotion and Advertising Restrictions," which details FDA's current thinking on how the Agency will enforce the requirements established by the Tobacco Control Act, including the restrictions on the distribution of free samples of tobacco products. The action plan includes an enforcement strategy with the following components:

- Tobacco Marketing Surveillance - covering both the review of marketing materials submitted to FDA as well as active monitoring of other advertising and promotional resources, including, but not limited to, Internet websites
- State and Territorial Tobacco Retailer Compliance Check Inspection Program, FDA Inspections, and Imports Program
- Enforcement Tools
- Education to Encourage Voluntary Compliance

On November 12, 2010, FDA published a proposed rule *Required Warnings for Cigarette Packages and Advertisements* for public comment. This rule requires new health warning labels, consisting of nine new textual statements and color graphics depicting the negative health consequences of smoking, to be placed on all cigarette packages and advertisements. These new warning labels will appear on the front and back panels of cigarettes and occupy the upper 50 percent of each panel. The health warnings in cigarette advertisements will occupy 20 percent of the advertisement. On December 7, 2010, FDA published a consumer research study on the proposed graphic health warnings for cigarette packages and cigarette advertisements in the *Federal Register* for public comment. The final graphic health warning regulations will be issued by June 22, 2011.

FDA also issued several draft guidance documents informing industry of the Agency's current thinking on related topics, including: (1) Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents; (2) Draft Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers; and (3) Draft Guidance for Industry: Tobacco Retailer Training Programs.

FDA sponsored eight Tobacco Products Scientific Advisory Committee (TPSAC) meetings or Subcommittee meetings since March 2010:

- March 30-31, 2010: Full Committee meeting focusing on the public health impact of menthol in cigarettes
- June 8-9, 2010: Constituents Subcommittee meeting focusing on criteria for drafting a proposed list of harmful/potentially harmful constituents contained in tobacco products and smoke
- July 7, 2010: Constituents Subcommittee meeting finalizing the preliminary recommendations for criteria for drafting a list of harmful/potentially harmful constituents
- July 15-16, 2010: Full Committee heard industry presentations on the public health impact of menthol in cigarettes
- August 30, 2010: Full Committee heard presentation of Constituents Subcommittee's preliminary recommendation of proposed criteria for developing a list of harmful/potentially harmful constituents and made a recommendation to FDA of criteria for developing a list
- September 27, 2010: Menthol Report Subcommittee meeting

- October 7,2010: Full Committee meeting focused on the public health impact of menthol in cigarettes
- November 18, 2010: Full Committee meeting focused on the public health impact of menthol in cigarettes.

Protect the Public Health from the Harmful Effects of Tobacco Use –
Center Activities
Base Amount: $38,225,000 (All UF)

Public Health Focus
The Tobacco Control Act provides FDA with the authority to regulate tobacco products based on whether such regulation "will benefit the health of the population as a whole."[1] The overarching public health goal is to reduce the morbidity and mortality from use of tobacco products, and to minimize youth acquisition and use of tobacco products.

Public Health Outcome
In FY 2011, FDA will continue to build on the regulatory and enforcement activities to protect the public health that began in FY 2009, including:

- prohibiting the sale of cigarettes with characterizing fruit and clove flavors -- cigarettes that have special appeal for children
- issuing and enforcing *"Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*"
- prohibiting the use of descriptors like "light," "low," and "mild" on tobacco products
- requiring new larger rotational health warnings on smokeless tobacco products
- implementing regulations that require color graphic health warnings depicting the negative effects of smoking to be placed on all cigarette packages and in advertising.

FDA also will develop and expand the systems needed to gather evaluation data to measure and evaluate the impact of the Tobacco Control Act.

Promoting Efficiency

Public Health Program Efficiency
In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products is a pediatric disease. Congress also found that virtually all new users of tobacco products are under the minimum legal age to purchase such products, and that children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use and are more influenced by tobacco

[1] Section 2 (36) of the Family Smoking Prevention and Control Act (PL 111-31).

marketing than are adults. Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market.[2]

Preventing youth initiation would result in enormous public health benefits to society. 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 $75,000,000,000 in savings attributable to reduced health care costs."[3]

FDA regulations and guidance documents protect the public health by significantly minimizing the exposure of youth to tobacco products 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 advertising and promotion of cigarettes and smokeless tobacco products 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 on cigarette packs and in cigarette advertisements that depict the harmful effects of smoking.

Tobacco Industry Program Efficiency

FDA implements the public health actions of this program in a manner intended to require compliance by the regulated industry, but also to convey significant program efficiencies for the regulated tobacco industry. This is done by effectively communicating the requirements of the new regulations, but allowing FDA enforcement discretion, when appropriate and permitted by statute. For example:

- FDA allowed the tobacco retailers a 'sell-off' period for both flavored cigarettes and those labeled as 'light, low or mild'
- FDA implementation of the new graphic health warnings on cigarette packages will provide tobacco manufacturers with a 15-month period to allow for both creation of new package production lines and to 'sell-off' legacy products. The extended period between the effective date of the final regulations and the date FDA will begin enforcement actions will assist industry to plan and implement the new requirement.

Performance Measures

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

[2] Sections 2(1), (4), (20), (23), (24)) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).
[3] Section 2(14) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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)	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.	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.	N/A

Tobacco Product Scientific Standard-Setting and Tobacco Product Review - Center Activities

Base Amount: $64,100,000 (All UF)

Public Health Focus

In order to protect the public health, the Tobacco Control Act authorizes FDA to conduct scientific programs to provide data necessary to inform regulations and guidance documents to implement many provisions of the law, including those related to the manufacturing and marketing of tobacco products.

Public Health Outcome

Specifically, FDA is using science to develop tobacco product standards for substantially equivalent tobacco products, modified risk tobacco products, and new tobacco products. In FY 2011, FDA issued substantial equivalence guidance to industry and issued regulations that would establish procedures for requesting an exemption from the substantial equivalence requirements law.

As required by the Tobacco Control Act, FDA will continue to work on establishing a list of harmful and potentially harmful ingredients and constituents in tobacco products. This list will be developed in part from a framework that was initially developed by TPSAC in 2010. FDA also plans to review substantial equivalence applications, new product applications, and modified risk applications as they are received by the Agency.

Promoting Efficiency

Public Health Program Efficiency

Tobacco use is the leading cause of preventable death in the United States. Public health efficiencies are derived from the tremendous direct and indirect health benefits realized by developing and implementing tobacco product standards for substantially equivalent tobacco products, modified risk tobacco products, and new tobacco products.

FDA has taken a number of science-based regulatory actions in setting tobacco standards 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. The overall public health goal is not to permit the manufacture, sale or distribution of any cigarette, roll-your-own, or smokeless tobacco product that is of more risk to the public health than a product on the market as of February 15, 2007, a date required by statute.

Tobacco Industry Program Efficiency

Significant program efficiencies accrue to the tobacco industry for each of the individual regulatory actions, guidance, or technical assistance documents articulated above.

FDA achieves these efficiencies by setting scientific standards for tobacco product regulation and establishing the regulatory framework and processes for FDA review and issuance of marketing orders - to allow distribution and sale in the United States - 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. This also includes flexibility and enforcement discretion as appropriate. For example:

- FDA has provided significant technical assistance to small tobacco manufacturers in understanding guidance and regulations related to substantial equivalence For example, technical assistance includes how manufacturers might provide documentation to FDA with respect to predicate products.
- FDA has provided significant flexibility to tobacco manufacturers with respect to supplementing initial substantial equivalence reports, which has allowed companies the opportunity to continue marketing certain products while FDA conducts substantial equivalence evaluations.
- FDA will provide regulations, guidance and standards for new tobacco products and those to be purported as modified risk tobacco products. These regulatory documents will allow industry resources to focus on research and development targeted to FDA’s articulated standards for evaluation.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. *(Output)*	FY 2010: Held 6 TPSAC meetings focusing on the public health impact of menthol in cigarettes and established a list of harmful/ potentially harmful constituents in tobacco products and smoke. (Target Met)	Identify potential set of harmful ingredients; establish criteria for evaluating testing methods	Establish a list of harmful and potentially harmful ingredients and constituents in tobacco products and tobacco smoke. TPSAC to issue a report on dissolvable tobacco products. Issue a proposed rule or draft guidance that establishes requirements or contains recommendations regarding the scientific evidence required for assessment and ongoing review of modified risk products.	N/A

Compliance and Regulatory Activities - Center Activities
Base Amount: $64,118,000 (All UF)

Public Health Focus
The Tobacco Control Act requires the issuance of regulations in accordance with certain timetables. For example, in FY 2011 the Tobacco Control Act requires FDA to issue regulations that require color graphics depicting the negative effects of smoking to be placed on all cigarette advertisements and packages.

Public Health Outcome
In order to enforce tobacco regulations and to comply with the statute, FDA continues to contract with U.S. State and Territorial governments to conduct compliance check inspections to ensure that retail establishments are not selling tobacco products to persons under the age of 18, and are complying with all other aspects of the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" and the Tobacco Control Act. FDA is currently on track to meet the FY 2011 goal of contracting with 75 percent of U.S. States and

Territories to assist FDA with compliance and enforcement activities. It is FDA's intent to contract with every U.S. State and Territory that elects to participate in the compliance and enforcement program in FY 2012.

Also, FDA will continue to allocate significant resources to enforce all of the statutory requirements of the Tobacco Control Act. FDA will continue to initiate programs to provide small business and others with assistance in meeting the regulations.

Promoting Efficiency

In enacting the Tobacco Control Act, Congress is affirming that tobacco use is the foremost preventable action contributing to premature death in America. Tobacco use causes more than 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking. [4] Declines in youth and adult cigarette smoking have stalled in recent years and data released in December 2010 provide evidence of an increase in youth smoking. The Monitoring the Future (MTF) survey, funded by the National Institute on Drug Abuse, found that past 30-day smoking among 8th graders increased from 6.5 percent in 2009 to 7.1 percent in 2010, while among 10th graders it rose from 13.1 percent to 13.6 percent.[5] Preventing youth initiation would result in enormous public health benefits to society.

The nation's 1-2 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. Accordingly, FDA generates significant efficiencies that accrue to these retailers and the general public as FDA builds and implements its retailer-focused compliance and enforcement program.

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 regulations and to assist tobacco retailers to appreciate their role in protecting America's youth from initiation of tobacco product use as required by the Tobacco Control Act.

FDA will continue to enforce these new regulations by continuing to contract with U.S States and Territories. For example, in FY 2010, FDA provided direct technical assistance to tobacco product retailers at five regional training sessions that allowed in-person attendance and participation by the retail community by phone and web-based access. FDA held these technical assistance training sessions in Atlanta, Boston, Chicago, Dallas, and Los Angeles.

FDA also provided direct financial support to U.S. States and Territories through the award of an estimated $55 million in contracts in FY 2011 for State-based enforcement

[4] Section 2(13) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).
[5] National Institute on Drug Abuse. "Smoking stops declining and show signs of increasing among younger teens." www.monitoringthefuture.org December 14, 2010

and compliance programs to assist FDA with enforcing the requirements of the Tobacco Control Act. This program also significantly increased efficiencies by providing a uniform framework for FDA enforcement through a robust training program for credentialed State and Territorial officials and by reducing in the possibility of duplication of services for tobacco enforcement activities at the State and local levels.

Compliance and Regulatory Activities - Field Activities
Base Amount: $4,700,000 (All UF)

Public Health Focus
In order to ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigation, and inspections of regulated industry.

Public Health Outcome
In FY 2010, the Office of Regulatory Affairs (ORA) carried out a multi-tiered approach towards initial implementation of requirements under Section 101 of the Tobacco Control Act. In order to analytically enforce the requirements established in Section 101, ORA created and implemented two sampling assignments in support of tobacco product analysis for determination of base line analytical findings for flavoring agents prior to implementation of the regulation. The pre-emptive measures established base line analytical findings to be used for comparative analysis for appropriate regulatory actions once the regulation was implemented. ORA analyzed more than 200 cigarette products for the presence of flavoring compounds, and completed more than 650 individual analyses. ORA also instituted import controls through the establishment and implementation of two active import bulletins calling for increased surveillance of imported tobacco products.

FDA will continue to conduct surveillance, investigations, and inspections of regulated industry to ensure compliance with the requirements of the Tobacco Control Act and any implementing regulations as they become effective.

Promoting Efficiency
FDA will continue to engage in these enforcement activities, which include laboratory-based support for enforcement actions 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 of importance to FDA tobacco product regulation, 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, and assure compliance with FDA requirements such as Good Manufacturing Practices, when promulgated. Thus, the tobacco industry will avoid inefficient use of its resources for broad or unnecessary product testing.

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
280003: Increase compliance with tobacco product regulation by increasing the percentage of States and Territories with which FDA has developed a contract program to support the enforcement and public health goals of the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (formally known as the Re-Issued 1996 Rule) to assure that retailers refuse sales of cigarettes and smokeless tobacco products to adolescents under the age of 18. *(Outcome)*	FY 2010: 27% (Target Met)	25%	95%	+70%

Tobacco Product Health Communications and Education - Center Activities
Base Amount: $45,380,000 (All UF)

Public Health Focus
In addition to regulatory and enforcement programs, FDA is engaging in public health education and outreach activities to inform Americans about the ingredients and constituents of tobacco products and the risks associated with tobacco product use, and to promote awareness of and compliance with the Tobacco Control Act.

Public Health Outcome
Specific accomplishments during FY 2011 include the continuation of the public education program directed toward tobacco product retailers and the general public, especially youth, to assure compliance with regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents. Additionally in FY 2011, FDA continued its public education campaign to inform the public about the new graphic health warning labels for cigarettes.

Also in FY 2011, FDA continued its Stakeholder Discussion Series to fully explore ideas about the implementation of the Tobacco Control Act and to develop effective communication between and among various stakeholder groups.

More generally, as FDA develops knowledge and information about tobacco products and their ingredients and constituents, it will work to communicate that information to all segments of the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

Promoting Efficiency
The Tobacco Control Act requires FDA to educate the public about tobacco products and their dangers. The public health education that will accompany FDA's new

cigarette warning labels and graphic depiction of the negative health effects of tobacco use as well as education about the actual harmful and potentially harmful ingredients of tobacco product will create facts where myths currently exist and contribute to both the economic and health well-being of the nation.

Effective use of FDA health education and communications targeted to prevent youth initiation along with increased tobacco use cessation among current users will result in enormous public health benefits to society. In enacting the Tobacco Control Act, Congress found that in 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.[6]

In addition, FDA will continue to engage stakeholders, including large and small tobacco manufacturers and tobacco product retailers, about how to implement the Tobacco Control Act and comply with its requirements. Specifically, FDA is providing "Break the Chain of Addiction" educational and display materials at no charge to retailers, that were developed with input from retail establishments. These materials include posters, flyers, widgets and syndicated content for retailer websites.

FDA also is launching an "FDA 101" education campaign for various segments of industry to help promote understanding of how regulations are issued, identify opportunities for industry involvement in the regulatory process, and provide information about public dockets, notice and comment rulemaking activities, etc. Providing this basic information is particularly important because tobacco products have generally not been regulated by FDA prior to the Tobacco Control Act.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	FY 2010: Announced the Stakeholder Discussion Series (Target Met) FY 2010: Launched the "Break the Chain of Tobacco Addiction" campaign to educate retailers and the public about new tobacco regulations (Target Met)	Develop education program directed to retailers and the general public, especially youth.	Continue to implement and improve programs designed to educate the public and industry.	Maintain

[6] Section 2(16) of the Family Smoking Prevention and Tobacco Control Act (PL 111-31).

Information Technology Investments –**Tobacco Program Activities** (Base Amount displayed as a non-add item: $2,363,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance and future scientific computing capabilities.

The Tobacco Control Act granted FDA the authority to regulate tobacco products and impacted more than the infrastructure and enterprise investments described above. It also resulted in a need to leverage existing IT systems supporting FDA Foods and Medical Device programs to provide an electronic solution to regulate the marketing, sale, and content of tobacco products. Two specific examples include the implementation of the Tobacco module in the FDA Unified Registration and Listing System (FURLS) that will allow tobacco facilities to register themselves and their products with the FDA and the e-Submitter/e-Loader which will create a customized form for collecting, processing and loading the data into an internal FDA document management system. CTP also plans, assigns, and tracks regulatory activities, including domestic inspections, investigations, and compliance/enforcement actions using the Tobacco Inspection Management System (TIMS). With such information management technologies, the FDA will be able to regulate the tobacco products with transparency, collaboration, knowledge management, agility and improved efficiency.

The CTP Social Media/ Knowledge Management investment will create a networking site with capabilities that enable groups to more effectively collaborate on work products, that provide enhanced communication platforms, and capabilities that allow users to manage and their online identity and experience. With such information management technologies, 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 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2007 Actual	N/A	N/A	N/A	N/A
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 Continuing Resolution	$216,523,000	$0	$216,523,000	90

Summary of the Budget Request

The FY 2012 budget request for the FDA Tobacco Act Program is $454,751,000, which is an increase of $238,228,000 from the FY 2010 Enacted Level. The Center for Tobacco Products amount is $448,501,000 supporting 366 FTE. The Field amount is $6,250,000, supporting 26 FTE.

The amount requested in the FY 2012 budget is authorized by the Tobacco Control Act and is made up entirely of industry user fees. The Tobacco Control Act stipulates that these user fees may only be spent for FDA tobacco regulation activities. Conversely, the law provides that no funds, other than these user fees, may be spent on FDA tobacco regulation activities.

CTP oversees the implementation of the Tobacco Control Act on behalf of FDA. The Agency's FY 2010 tobacco control and population-based public health and prevention goals include:

- preventing youth from using tobacco and helping all those who use tobacco to quit
- promoting public understanding of the harmful and potentially harmful constituents of tobacco products
- developing a science base for tobacco regulation, and
- regulating tobacco products in order to reduce the toll of tobacco-related disease, disability, and death.

The Tobacco Control Act provides FDA with several new authorities. In addition to enforcement authorities enabling FDA to act quickly and effectively to remove products that are in violation of the statute, these authorities also include:

- restricting the marketing of tobacco products to minors
- requiring new warning labels for cigarettes and smokeless tobacco products

- prohibiting marketing techniques that are misleading to consumers
- establishing tobacco product standards
- requiring Good Manufacturing Practice standards for tobacco product manufacturing facilities
- requiring industry reporting of tobacco product ingredient and constituent data, including a description of the nicotine content and delivery mechanisms

Protecting the Public Health from the Harmful Effects of Tobacco Use

Center Activities (Base Amount: $38,225,000)
FY 2012 increase for current law user fees: +$50,615,496; 18 FTE

FDA will continue to protect the public health in FY 2012 by conducting research on how to assess the public health impact of product standards and modified risk tobacco products. Among other things, this research will analyze the public's perception of whether or not modified risk tobacco products are less dangerous than cigarettes.

In FY 2012, FDA will continue to pursue the goals of limiting the appeal and access of tobacco products to children and adolescents. As a step towards accomplishing these goals, FDA will issue regulations concerning the marketing and advertising of tobacco products that are sold by means other than a face-to-face transaction between a retailer and customer.

To meet its public health mandate in FY 2012, FDA also will continue to conduct behavioral research on the effects of regulatory actions on users and non-users of tobacco products, and will study the impact of the new graphic health warning statements on cigarettes and in advertisements on cessation and non-initiation.

Tobacco Scientific Product Standard-Setting and Tobacco Product Review

Center Activities (Base Amount: $64,100,000)
FY 2012 increase for current law user fees: +$92,355,773; 127 FTE

In FY 2012, FDA will continue its efforts to develop a scientific base to better understand and reduce the harmful effects of tobacco products. FDA intends to issue a proposed rule or draft guidance that establishes requirements or contains recommendations regarding the scientific evidence required for assessment and ongoing review of modified risk products. FDA will work to establish validated biomarkers and intermediate clinical endpoints, as well as institute post-market surveillance that will be required from industry in order to effectively assess modified risk tobacco products, and determine their risk to the public health.

Also in FY 2012, FDA will establish a list of harmful and potentially harmful constituents in tobacco products and cigarette smoke and seek public comment on that list. Once

this list is established, FDA will be able to educate the public and may consider establishing tobacco product standards to control certain harmful constituents.

In FY 2012, based on a required TPSAC report, FDA will consider the nature and impact of the use of dissolvable tobacco products on the public health, which will involve a request to industry for documents related to dissolvables.

Other FDA goals in FY 2012 include reviewing substantial equivalence, new products, and modified risk applications in a timely manner. FDA will also evaluate the report and recommendations from TPSAC on the impact of the use of menthol in cigarettes on public health to develop appropriate product standards.

Compliance and Regulatory Activities

Center Activities (Base Amount: $64,118,000)
FY 2012 increase for current law user fees: +$33,836,376; 20 FTE

FDA will continue to issue regulations in accordance with the timetables set forth in the Tobacco Control Act. This will include issuing regulations permitting a tobacco manufacturing company to file a single application for a new tobacco product that is intended to be marketed as a modified risk tobacco product. The Tobacco Control Act defines a new tobacco product as any product that was not commercially marketed or any modification to a product sold after February 15, 2007. During FY 2012, FDA intends to establish a list of harmful and potentially harmful constituents in tobacco products and smoke, publish a public notice requesting information about that list, and issue regulations addressing the promotion and marketing of tobacco products through means other than direct exchange.

FDA also will expand its small business assistance program in FY 2012 to assist small tobacco manufacturers, distributors and retailers comply with the Tobacco Control Act.

Field Activities (Base Amount: $4,700,000)
FY 2012 increase for current law user fees: +$1,550,000; 6 FTE

FDA will continue to develop and award State and Territorial government contracts to enforce the provisions of the new law that are applicable to retailers including the new regulation that restricts the sale of cigarettes and smokeless tobacco to minors and also restricts the advertising, marketing, and promotion of these products. The FY 2012 goal for this initiative is to contract with all U.S. States and Territories that elect to assist with inspections and enforcement.

Tobacco Product Health Communications and Education

Center Activities (Base Amount: $45,380,000)
FY 2012 increase for current law user fees: +$59,870,355; 27 FTE

In order to ensure that the public is educated and informed about the Tobacco Control Act, FDA will continue to develop methods to effectively communicate information to the public concerning scientific findings about tobacco products. FDA also will focus on public education activities aimed at decreasing initiation of tobacco products use, especially among youth and adolescents, and increasing cessation among all tobacco users.

In FY 2012, FDA will continue to implement public education programs designed to inform retailers and the general public about the regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to persons under the age of eighteen and develop a public education campaign with respect to harmful and potentially harmful constituents in tobacco products and smoke. Also, FDA will continue its efforts to educate the public about the new graphic health warning statements on cigarette packages and in advertisements, and continue the Stakeholder Discussion Series which was announced in FY 2010.

CTP Performance Activity Data (PAD)

The following table lists the CTP Program Activity Data (PAD) over a four year fiscal period.

CTP Workload and Outputs	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Administrative/Management Support			
Workload			
Compliance checks conducted by States and territories under contract	0	14,000	127,000
Number of Advisory Committee Meetings	6	8	9

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HEADQUARTERS AND OFFICE OF THE COMMISSIONER

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

FDA Program Resources Table

(Dollars in Thousand)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$196,306**	**$178,300**	**$202,926**	**$288,638**	**92,332**
Program Level FTE	**861**	**947**	**947**	**1,047**	**186**
Budget Authority	**$140,848**	**$141,321**	**$140,848**	**$197,686**	**$56,838**
Center	$140,848	$141,321	$140,848	$197,686	$56,838
Pay Increase (non add)				*$329*	*$329*
Transforming Food Safety and Nutrition (non-add)				*$15,505*	*$15,505*
Protecting Patients (non-add)				*$3,518*	*$3,518*
Advancing Medical Countermeasures (non-add)				*$33,463*	*$33,463*
FDA Regulatory Science and Facilities (non-add)				*$9,557*	*$9,557*
Administrative and Contract Savings (non-add)				*-$5,534*	*-$5,534*
Budget Authority FTE	**644**	**722**	**722**	**742**	**98**
User Fees	**$55,458**	**$36,979**	**$62,078**	**$90,952**	**$35,494**
PDUFA	$34,073	$28,953	$40,693	$52,222	$18,149
FTE	172	172	172	201	29
MDUFMA	$5,914	$3,592	$5,914	$6,962	$1,048
FTE	22	23	23	24	2
ADUFA	$693	$631	$693	$873	$180
FTE	4	4	4	4	0
AGDUFA	$204	$158	$204	$228	$24
FTE	1	1	1	1	0
MQSA	$238	$270	$238	$238	$0
FTE	2	2	2	2	0
Tobacco	14,336	3,375	14,336	15,196	860
FTE	16	23	23	34	18
Voluntary Qualified Importer Program (VQIP) User Fee				3,674	3,674
FTE				14	14
Recall User Fee				661	661
FTE				2	2
Generic Drugs				$1,325	$1,325
FTE				5	5
Food Reinspection				$3,395	$3,395
FTE				7	7
Medical Product Reinspection				$5,902	$5,902
FTE				10	10
International Courier User Fee				276	276
FTE				1	1
User Fees FTE	**217**	**225**	**225**	**305**	**88**

Following is a list of the Headquarters and Office of the Commissioner Statutory Authority:

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)

* 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.

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*
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 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*

Allocation Method: Direct Federal/Intramural

* 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.

Program Description and Accomplishments

The Headquarters and Office of the Commissioner Program 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. The Office of the Commissioner consists of seven subordinate offices that provide: policy making, program direction, coordination and liaison, and expert advice to FDA leadership and programs.

1. **Office of the Chief Counsel** — Provides expert legal advice and review on statutory and regulatory interpretations affecting FDA enforcement and administrative actions.

2. **Office of Policy, Planning and Budget**
   - 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
   - Plans, organizes and carries out annual and multi-year budgeting in support of FDA's public health mission and programs.

3. **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.

4. **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.

5. **Office of International Programs**
   - Serves as FDA's primary lead and clearing authority for all international programs, activities and interactions, including negotiating and managing bilateral agreements
   - Manages all aspects of FDA's foreign locations, information sharing, and capacity

- Builds, coordinates and participates in international harmonization activities
- Coordinates and supports interactions with international organizations.

6. **Office of Administration**
   - 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
   - Provides administrative and program support services
   - Assures strategic and operational management of information technology, financial management, and administrative programs.

7. **Office of the Commissioner-Additional Offices** — Provide policy making, 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.

FDA intends to establish the Office of Minority Health consistent with the requirements of 42 U.S.C. 300u-6, Office of Minority Health.

Office of the Chief Counsel (OCC)
Base Amount: $21,649,715 (BA: $13,730,324 / UF: $7,919,391)

The Office of the Chief Counsel (OCC) provides legal advice and policy guidance and acts as liaison to the Department of Justice and other Federal agencies and programs.

Public Health Focus

In upcoming years, OCC will continue to provide a broad range of critical 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 (HHS) on:

- draft and final regulations
- draft and final guidance documents
- responses to citizen petitions
- draft legislation
- congressional testimony
- press materials
- 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
- medical product approvals and safety issues
- food safety and nutrition issues
- animal health issues
- public health emergencies.

OCC completed review of over 6,100 requests for legal services in FY 2010. In addition, OCC 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 successfully defended FDA's actions in:

- Commonwealth Brands and BBK cases — tobacco companies challenging TCA
- Allergan and Lannett Co. — challenges to drug approval process
- Null — H1N1 vaccine
- Comed — himerisol in vaccines
- Del Monte — imported foods— cases.

OCC played significant roles in the successful criminal prosecutions for violations of the Federal Food, Drug, and Cosmetic Act. The prosecutions include:

- Sarcona — misbranded food
- Guidant — devices
- Novartis — off-label promotion of drugs
- College Pharmacy and Vitality — drug compounding
- Ortho-McNeil Pharmaceutical and Allergan — off-label promotion
- Reuben — falsification of research study data.

OCC defended the integrity of FDA's generic drug approval decisions in numerous cases such as Teva (losartin), Enoxaparin, and Actavis NCE exclusivity.

OCC also gave substantial support to FDA's enforcement actions initiated to ensure the safety of the food, drugs and devices in numerous cases including, among others:

- Peregrina and Quesos Mi Pueblito — cheese
- Oraganic Pastures — raw milk
- Quality Formulation Labs — insanitary conditions and unsafe color additive
- Franck's Pharmacy — facility that compounded the new animal drug that killed 21 polo ponies
- Caraco — drug CGMP
- Steris, Sybaritic, and 45 Units...Ozone Generator — maintain the integrity of the device manufacturing and clearance and approval processes

Promoting Efficiency: The FDA Transparency Initiative is an agency-wide effort to open the doors of the Agency and promote innovation and efficiency, in a manner compatible with FDA's responsibility to protect confidential information. As FDA moves to enhance the transparency of its activities, OCC provides essential legal analysis and review to support FDA transparency efforts.

Office of Policy, Planning, and Budget (OPPB)
Base Amount: $16,976,783 (BA: $10,561,431 / UF: $6,415,352)

Public Health Focus

The Office of Policy, Planning and Budget (OPPB) 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 evaluation, and budget formulation and presentation.

OPPB is comprised of the Office of Policy, Office of Planning and the Office of Budget. OPPB:

- manages FDA's annual and multi-year budgeting for FDA public health programs
- coordinates the publication of FDA rules and notices in the Federal Register
- serves as the FDA focal point for policy development
- ensures 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.

Public Health Outcome

OPPB achieves its public health outcome through its mission of providing strategic policy direction, planning, and data-driven analysis to more effectively and efficiently protect and promote the public health. OPPB reaches its public health outcome by implementing FDA's responsibilities associated with the Government Performance and

Results 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: OPPB has a leadership role in the FDA-TRACK initiative. FDA-TRACK is the new FDA-wide performance management system. When fully implemented, FDA-TRACK will monitor more than 90 FDA programs through key performance measures and data that are gathered on a monthly basis. Each quarter, the FDA-TRACK team analyzes the monthly performance data, and senior managers present this data to the FDA senior leadership. The public can track FDA's progress through the FDA-TRACK website.

Consistent with the principles of open government, FDA-TRACK adheres to values that comprise its name – **T**ransparency, **R**esults, **A**ccountability, **C**redibility and **K**nowledge-sharing.

Office of the Chief Scientist (OCS)

Base Amount: $19,368,386 (BA: $17,069,375 / UF: $2,299,011)

Public Health Focus

The Office of the Chief Scientist (OCS) 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.

Support of regulatory science, both within FDA and externally, is critical to expanding this vital field, which informs product development and FDA's review and approval processes. 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. In FY 2010, OCS awarded approximately $4 million in support of comparative effectiveness research through a contract with Johns Hopkins University.

OCS aims to support 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 (NIH), National Institute of Standards and Technology (NIST), Center for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), and the Defense Advanced Research Projects Agency (DARPA) 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 is participating in efforts and initiated pilot projects to begin 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.

Public Health Outcome

The Office of Counterterrorism and Emerging Threats (OCET) protects the public health by developing and implementing policies to safeguard medical products from adulteration or disruption of supplies due to terrorist activities or emerging threats. OCET facilitates the development, evaluation and availability of safe and effective public health emergency medical countermeasures. OCET also participates in national counterterrorism and emerging threats preparedness and response activities and coordinates FDA's participation in the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Governance Board. During FY 2010, OCET collaborated with U.S. government partners (e.g., HHS/Office of Assistant Secretary for Preparedness and Response (ASPR), HHS/Biomedical Advanced Research and

[1] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM222536.pdf

Development Authority (BARDA), NIH, CDC, the Department of Defense (DOD)) to conduct an in-depth review of the Medical Countermeasures (MCM) Enterprise. As a result, FDA developed an Action Plan designed to address some of the challenges confronting medical countermeasure development and availability.

OCET plays a critical role in making available MCMs (i.e., vaccines, drugs, personal protective equipment, and diagnostic tests), as it did during the government's response to the 2009 H1N1 influenza pandemic. OCET coordinates the provision of FDA technical assistance and regulatory expertise to product developers, the scientific community, and government partners (local, State, federal, and international) regarding MCMs.

In addition to OCET's ongoing collaborations with PHEMCE partners, OCET supports the Enterprise through participation and coordination of FDA subject matter experts in various PHEMCE partner committees and working groups. For example, FDA participates in working groups that help set requirements for MCMs against chemical, biological, radiological and nuclear threats, including broad spectrum therapeutics and diagnostics for specific threats (e.g., anthrax, botulinum, smallpox, and other emerging threats).

OCET works with other federal and state agencies that are developing approaches to expedite deployment of countermeasures in emergencies and protocols to monitor adverse event reporting during and after an emergency.

The Office of Science and Innovation (OSINN) builds new programs aimed at supporting regulatory science innovation within FDA and through external partnerships. OSINN fosters high quality, mission-targeted FDA collaborative and extramural research to enhance product evaluation tools. OSINN expands FDA's efforts in providing clear pathways to industry for development of novel products; advances major scientific initiatives such as personalized medicine, innovative clinical trial design strategies, scientific computing approaches for assessment of data, and enables partnerships and consortia to promote transformation in product development and to advance regulatory science as a hub for various partnerships. OSINN also enhances and supports consistent and collaborative approaches to science and innovation across the entire FDA.

The Office of Scientific Integrity (OSI) 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 Critical Path Programs (OCPP) supports the Critical Path Initiative (CPI), FDA's science-based effort to drive innovation and modernize the scientific tools used in developing, evaluating, and manufacturing FDA-regulated medical products. CPI

programs are underway across FDA, with internal and external collaboration forming the cornerstone of the Initiative. By collaborating with stakeholders to achieve breakthroughs in emerging scientific and technological areas, CPI is facilitating the development of innovative medical products to prevent, diagnose, and treat Alzheimer's, diabetes, cancer, tuberculosis, and rare and neglected diseases. CPI efforts include helping strengthen the U.S. clinical trial enterprise, improving healthcare quality and patient safety, and expanding the use of personalized therapies. CPI is supporting and expanding the following areas to improve public health, promote innovation, and advance regulatory science:

- **Biomarkers:** develop and qualify diagnostic biomarkers, prognostic biomarkers, toxicity biomarkers, surrogate endpoints for clinical trials, and biomarkers to facilitate personalized medicine
- **Models and modeling:** develop new animal models to evaluate efficacy and toxicity; develop in vitro toxicity models to evaluate toxicity and efficacy; and expand the use of silico models (computer-based models) for predicting safety and efficacy
- **Trial design and strategy:** explore and implement new ways to acquire data and standardize data acquisition during clinical testing; identify new electronic and technologic tools that can help streamline trial performance while optimizing the type and quality of data needed to ensure product safety; support current and develop new strategies to facilitate product development for rare and neglected diseases
- **Bioinformatics:** harness appropriate computer technologies to facilitate conduct of trials, electronic case report forms, and electronic informed consent
- **Training and communication:** develop and expand electronic and other outreach programs to ensure transparency and facilitate implementation of new tools; and continue and expand FDA training programs for clinical investigators and others as identified
- **Manufacturing:** promote process improvement in manufacturing; encourage the use of quality by design and other new testing approaches, and incorporate new technologies in the manufacturing process

OCPP, in leading the initiative, supports center projects as requested and manages numerous projects centrally.

Promoting Efficiency: OCS's vision for science and innovation across FDA will ultimately lead to breakthroughs and development of new scientific and technical tools that will help inform the product development process and streamline the product review processes. Clinical trials will be streamlined, thereby reducing costs to industry and, in turn, to consumers. As advancements occur in science and technology, FDA must make sure it remains up-to-date in areas such as personalized medicine, so that the public does not spend its money inefficiently on treatments that may not work.

As the world's pre-eminent regulatory agency, FDA houses the largest known repository of clinical data. Harnessing this data to identify and reduce redundancies in the drug development enterprise will lead to savings for all parties and better products for

consumers. By investing in science and innovation within FDA, leveraging the expertise, and ensuring FDA's expertise about the latest scientific trends and emerging technologies, public health will ultimately be the benefactor. New and innovative products will reach the market faster and will remain safe for patients and consumers. As FDA's responsibilities and workload increase, the best way FDA to ensure that the public's health is not compromised is to invest in science and innovation to become more efficient, proactive, and scientifically sound.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	Pilot evaluation of the Fellowship program developed. (Target Met)	Develop pilot evaluation of program	Implement changes to achieve target identified in the 2011 review	N/A
293206: Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)*	N/A	N/A	Continue regulatory science studies on evaluating nanomaterials from 2011.	N/A

Office of Foods (OF)

Base Amount: $4,849,410 (BA: $4,756,808 / UF: $92,602)

Public Health Focus

The Office of Foods (OF) provides leadership, guidance, and support to the FDA Foods Program to achieve the FDA's public health goals. The FDA Foods Program protects and promotes the health of humans and animals by ensuring the safety of food for humans, including dietary supplements; ensuring the safety of animal feed and the safety effectiveness of animal drugs; setting science-based standards for preventing foodborne illness and ensuring compliance with these standards; protecting the food and feed supply from intentional contamination; and ensuring that food labels contain reliable information.

Public Health Outcome

OF is charged with ensuring that FDA has the strategies, scientific and regulatory capacities, programs, and will to protect our citizens from unsafe foods. OF is responsible for coordinating all elements of FDA's food program to ensure they not only

have the tools they need, but are working in a closely integrated fashion to prevent foodborne illness and improve the nutritional quality and labeling of the food supply.

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.

Office of International Programs (OIP)
Base Amount: $7,041,529 (BA: $5,397,449 / UF: $1,644,080)

The Office of International Programs (OIP) serves as the FDA's focal point for all international matters. The Food, Drug & Cosmetic Act mandates as part of FDA's mission (Section 903 of the FFDCA) 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; to enhance and maximize the impact of FDA's communications and interactions globally; to help assure they reflect the FDA's policies and best scientific, legal, and policy thinking; to help assure that FDA international communications and interactions are consistent with HHS and administration public health objectives; to leverage more effectively the human, financial, and informational resources of trusted foreign counterpart agencies and to collaborate with U.S. Government counterpart agencies with complementary missions in meeting FDA's public health mission. OIP accomplishes these tasks through offices that are structured geographically to lead and manage these activities. In addition, FDA currently established a permanent in-country presence and has staff located overseas in China, India, Europe, Latin America, and in 2011, the Middle East/North Africa.

Collaboration (Bilateral and Multilateral) – OIP carries out and manages daily interactions with a myriad of countries, both 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 our 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 still 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, Pan American Health Organization, Food and Agriculture Organization (FAO), Organization for Economic Co-Operation and Development (OECD), World Organisation 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 help 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 to increase interactions with regulatory counterparts, exporting industry, in-country United States Government counterparts, and third party certifiers. These interactions increase the quality information FDA has to make regulatory decisions at home, especially decisions on the admission of products to the U.S. market. These efforts help better safeguard the public health in the U.S. by helping to better ensure that products exported to the U.S. meet health and safety requirements. These 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 to better ensure that safety is built into the products from the beginning and that FDA has better information about the safety and quality of imports to make decisions to protect consumers from harmful products, e.g. identifying a product that has been produced in violation of FDA's requirements.

Public Health Focus

The primary purpose of the 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 enabled the FDA to increase the number and quality of inspections of foreign manufacturing facilities; 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 quality of 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 imported products 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 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 will 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 help to improve the regulatory capabilities of specific foreign counterpart regulatory authorities and industry. This helps better assure that FDA-regulated products that are 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 decision 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 that are 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
291301: The number of FDA foreign posts to increase collaboration with foreign counterparts. *(Outcome)*	FY 2010: 12 (Target Not Met)	15	16	+1
291302: The number of agencies who participate in the Regulators Forum of the International Conference on Harmonization. *(Outcome)*	FY 2010: 12 (Target Met)	12	16	+4

Office of Administration (OA)
Base Amount: $59,012,222 (BA: $32,466,881 / UF: $26,545,341)

The Office of Administration (OA) provides executive direction, leadership, coordination, and guidance for the overall day-to-day operations of FDA, assuring timely and effective implementation of operations and high quality delivery of services across FDA and its Centers. OA supports the mission of FDA by providing financial management services and IT services across FDA.

The Office of Management (OM) 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 to include administering the FDA Ethics and Integrity program ensuring that all FDA employees are free from conflicts of interest and do not hold prohibited interests; and oversight of FDA-wide Commissioned Corps activities.

The Office Shared Services (OSS) administers shared administrative services to support facilities operations across the country for more than 350 laboratories and buildings; provides oversight of the FDA administrative records through the Dockets management program and the FDA History Office; provides oversight of the FDA's Freedom of Information and privacy act programs as well as serving as the central resource for our scientific staff through the FDA Biosciences Library; and manages the Employee Resource Information Center Call Center.

The Office of White Oak Services (OWOS) in coordination with the General Services Administration and the FDA Centers, leads the consolidation of nearly 8,000 FDA employees to a unique state-of-the-art campus. OWOS also provides the logistics and operations services to create a highly productive environment for all employees and visitors – sharing resources and technology, fostering collaboration, and enhancing scientific performance across FDA. The FDA campus serves as the nucleus for establishing health standards for the country and an anchor for community and scientific partnerships.

The Office of Financial Management (OFM) supports the mission of FDA by providing financial management services, budget execution and controls, financial policy and compliance, and financial systems support. OFM expanded its scope for the Office of Management and Budget's A-123 Appendix A- Internal Controls Over Financial Reporting by utilizing a methodology of Control Rationalization to bring about a more robust risk-based internal control assessment and to identify opportunities for improvement of all of the FDA user fees. OFM will document the processes and procedures performed in the Division of User Fee for each unique User Fee, complete a gap analysis and provide recommendations.

Since FY 2005, the Unified Financial Management System (UFMS) has been fully implemented in FDA by OFM. As UFMS is an integrated system, and all HHS Operating Divisions (OPDIVs) share it, FDA remains involved and participates in all other OPDIVs phased implementations. FDA continued its efforts to stabilize the UFMS environment now that all OPDIVs have gone live, and to explore and analyze the effects of moving to a later version of ORACLE Federal Financials, bringing HHS one step closer to Federal Managers Financial Integrity Act compliance. In FY 2009, FDA began migrating to version 11.5.10 of ORACLE Federal Financials. This version of Federal Financials will eliminate multiple manual processes, and will enhance reporting capabilities. In FY 2012, FDA plans to continue its business intelligence reporting development of UFMS 2012 initiatives towards economies of scale, improve AS-IS UFMS processes to gain transparency, agility and efficiency and in the process address deficiencies in the areas of Segregation of Duties and access controls.

OA oversees administrative programs and management initiatives related to addressing Presidential, Departmental, and FDA priorities related to:

- human capital management programs that include performance management, 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.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)*	OBI Beta Implementation (Target Met), UFMS 2010 initiatives 1. Performance Assessment and Business Availability (Target Met). 2. OCI Tactical and Strategic Enhancements (Target Met). 3. Improve CAN Realignment (Target Met) 4. Improve YE CAN Management (Target Met). 5. e2e Process Documentation (Target Met) 6. Training Redesign Pilot Program (Target Met). 7. Transition to a Role Based Access in UFMS (Target Met). 8. During FY2010 there were 4 Point Releases to deploy enhancements and bug fixes. (Target Met)	Continue OBI dev., UFMS 2010 initiatives (To be defined), improve AS-IS UFMS processes to gain transparency, agility and efficiency and in the process address deficiencies in the areas of SOD violations and other control deficiencies.	Continue to enhance training opportunities for all FDA stakeholders and continue to improve on Oracle Business Intelligence Enterprise Edition (OBIEE) reporting solution for management reports. Continue improvements on the Financial Business Processes.	N/A

The Office of Information Management (OIM) manages information technology (IT) and other related services including technical oversight of system development processes, policies, and methodologies and management of IT infrastructure to ensure FDA has a robust IT foundation that enables interoperability across the FDA and allows the development of enterprise wide systems necessary to meet FDA's 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 continues its IT Modernization effort to enhance IT infrastructure and to create a robust foundation to enable interoperability across FDA and allow the FDA to develop enterprise wide systems necessary to transform nearly every aspect of FDA operations; from bioinformatics and scientific computing to adverse event detection, and provide global leadership in protecting and promoting public health. With FDA's increased focus on safety inspections for food, drugs, and medical devices, FDA's IT goals for FY 2012 align with and support this direction. FDA's IT goals also support FDA's public health goals and specifically focus on:

- Transforming the Food Safety and Nutrition Initiative

- Advancing Medical Countermeasure Initiative
- Protecting Patients Initiative
- FDA Regulatory Science and Facilities Initiative

OIM is committed to working 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 will focus on strategic investment in information technology to 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 the 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 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 to target 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 2012 by:

- delivering major program releases in 3 to 6 month increments to provide healthcare stakeholders with early insight into 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 process for drug applications and biologic product
    - submissions,
    - electronic workflows with digital signatures to speed regulation of drugs
    - devices and food additives given to animals,
    - integrated information and knowledge management systems,
    - faster and far reaching public communications via conventional, online and social media
    - secure computing and communications
    - green computing environment through acquisition of Energy Star designated products; implementing an environmentally friendly disposition;
    - server virtualization to minimize the number of physical servers required to support FDA operations; require all contract requests for proposals to reference appropriate “green” requirements

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
291404: Percentage of servers that are high efficiency energy star compliant. *(Output)*	FY 2010: 89.2% (Target Exceeded)	50%	95%	+45%
291405: Percentage of application availability during non-scheduled, emergency outages. *(Output)*	FY 2010: 98.3% (Target Exceeded)	98%	99.9%	+1.9%

Office of the Commissioner - Additional Offices
Base Amount: $67,407,955 (BA: $56,865,732 / UF: $10,542,223)

Office of Legislation (OL)

Public Health Focus

The Office of Legislation (OL) 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. For example, OL will work with FDA experts and Congressional staff to ensure reauthorization of several critical programs, including the Prescription Drug User Fee Act and the Medical Device User Fee Act. 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.

Office of the Counselor to the Commissioner (OCtC)

Public Health Focus

The Office of the Counselor to the Commissioner (OCtC) 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, and provides leadership in the development and management of emergency and crisis management policies and programs in the FDA.

Office of Crisis Management (OCM)

The FDA Office of Crisis Management (OCM) provides coordination and strategic management of FDA's response to incidents involving or impacting FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health.

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 or impact FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Framework, National Incident Management System (NIMS) and Homeland Security Presidential Directives.

Public Health Outcome

OCM designed, developed, and implemented the Reportable Food Registry component of the Emergency Operations Network Incident Management System (EON IMS), a web-based portal for regulated industry and state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007. In FY 2011, OCM will implement electronic notifications of Reportable Food Registry Reports to Federal and State Counterparts.

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 will expand the geospatial capabilities of EON IMS to increase usage during incident response and recovery by 25%. EON IMS is used to support preparedness exercises that have included international, federal, state and local partners as well as manage data related to FDA's response to incidents involving FDA regulated products.

In FY 2010, OCM completed the update of the FDA Emergency Operations Plan and its incident specific annexes and designed training for FDA staff on implementation of the plan to be conducted in early FY 2011. OCM developed an FDA-wide National Incident Management System implementation plan to enhance response operations through the use of the Incident Command System (ICS) and the application of standardized procedures and preparedness measures which promote cross-jurisdictional agency, statewide, and interstate mechanisms for coordinating response. In 2010 OCM developed FDA specific versions of NIMS/ICS training and assessed the training needs of appropriate staff within FDA.

OCM enhanced FDA's Incident Command System structure and its ability to respond to food-related events in FY 2010 by improving response capabilities with incorporation of subject matter expertise into strategic planning and day-to-day operations. OCM improved FDA preparedness by conducting exercises/after action reviews to assess response capabilities to foodborne illness and outbreaks or other threats to public health and will further integrate emergency policy and planning into FDA emergency operations.

Promoting Efficiency – OCM: OCM established 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 infrastructure provided a vehicle to receive, triage and manage reports submitted through the Reportable Food Registry mandated by the Food and Drug Administration Amendments Act of 2007 (FDAAA). By leveraging existing technologies the Agency is able to efficiently manage the influx of reports received during a major incident protecting the public from human and animal food products that pose a risk to public health.

The Geographic Information Systems (GIS) component of EON IMS proved essential in providing critical data analysis used by the Agency officials to determine safe federal and state water re-openings for fish and shellfish during the Deepwater Horizon Oil Spill.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	FY 2010: Piloted a mechanism to use EON IMS to share data with Federal and State counterparts. Enhanced surveillance and detection capabilities within the Office of Emergency Operations through the further expansion of GIS. Revised and exercised FDA's Emergency Operations Plan and designed and scheduled training on the plan and annexes. Coordinated participation in inter-agency work-groups, and implemented an Agency-wide National Incident Management System (NIMS) plan. (Target Met)	Pilot EON IMS data sharing with Federal and State counterparts. Enhance surveillance and detection capabilities within the Office of Emergency Operations. Revise and exercise FDA's Emergency Operations Plan and provide training on the plan and annexes. Implement an Agency-wide National Incident Management System (NIMS) plan.	Enhance FDA's preparedness and planning 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.	N/A

Office of the Chief of Staff (OCoS)

Public Health Focus

The Office of the Chief of Staff advises and provides integrated policy analysis and strategic consultation to the Commissioner, Deputy Commissioners, Associate Commissioners, Center Directors and other FDA officials on activities and issues that affect significant FDA programs, projects and initiatives, including complex and difficult issues.

Public Health Outcome

OCoS provides leadership, coordination and management of the Commissioner's priority policies across the Office of the Commissioner and FDA-wide. OCoS serves as

liaison to HHS and includes the Executive Secretariat staff, which provides direct support to the Commissioner and Deputy Commissioners; maintains official FDA correspondence; coordinates review and clearance of various documents and reports; and serves as the FDA liaison to the Government Accountability Office and the HHS Office of the Inspector General, coordinating activities across the FDA.

Office of Women's Health (OWH)

Public Health Focus

The Office of Women's Health (OWH) 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 (IND) submission and New Drug Application (NDA) clinical data must be broken out by age, race, and sex. FDA also requires that NDAs should include summaries of effectiveness and safety data for important demographic subgroups, again--age, race and sex.

Promoting Efficiency: OWH utilizes educational consumer health information and focus group tested materials to communicate important public health messages on a variety of health topics. Collaboration, which is 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research.	FY 2010: 5 (Target Met)	5	9	+4

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
(Output)				
291303: The number of collaborations and partnerships to maximize Outreach activities. *(Output)*	FY 2010: 300 (Target Met)	300	400	+100

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 42 U.S.C. 300u-6, Office of Minority Health.

The Office of Minority Health will be charged with guiding FDA's policies and programs that will address current persistent gaps between the health status of minorities and non-minorities (health disparities) in the United States. OMH is also charged with addressing increasing needs to have cultural and linguistic services that are appropriate for increasingly diverse populations from various racial and ethnic minority communities in the United States.

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 committee conflicts of interest, and good clinical practice.

Public Health Outcome

OSMP leads the Advisory Committee Oversight and Management Staff (ACOMS), which is responsible for ensuring that FDA's advisory committees comply with relevant statutory requirements, including the Federal Advisory Committee Act, 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 the Office of the Commissioner. 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, recruits and screens candidates to fill committee vacancies, and reviews advisory committee members' financial reports for potential financial conflicts of interest. There currently are 49 advisory committees with 608 authorized positions.

Promoting Efficiency: OSMP coordinates important cross-cutting FDA public health initiatives, such as human subjects 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. By leveraging the state-of-the-art expertise of over 500 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.

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. These activities are intended to 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 ORA, 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:

- protect the rights, safety, and welfare of subjects involved in FDA-regulated clinical trials
- determine the accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications
- assess 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 is, those 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. The Agency worked 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; 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 guidance documents and participating in domestic and foreign outreach activities in support of this important effort.

Specifically, in coordination with the Centers and ORA, the OGCP issued documents aimed at improving the overall conduct of clinical investigator site inspections, including the development of criteria for enforcement actions, and handling of clinical investigator disqualification actions. In recognition of the globalization of clinical trials, OGCP issued guidance to clarify the requirements for inspections of clinical investigators conducting studies overseas, participated in international GCP capacity building activities, such as training of non-US regulators, and is developing a proposed rule to define good clinical practice for studies of medical devices conducted outside the US.

As the agency focal point for HSP/BIMO issues, the OGCP regularly conducts training for Center review staff as well as field investigators. The Office develops and conducts training programs for FDA reviewers on HSP/BIMO issues, such as informed consent for studies involving tissue specimens, clinical investigator financial disclosure, etc. 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/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: The OGCP works with various federal agencies whose missions are inter-related with that of FDA's (e.g., OHRP, National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS) as well as various professional societies (e.g., American Medical Association) on documents for which we have a mutual interest (e.g., improving the informed consent process, ensuring equivalent human subject protections for international clinical trials). 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 International Working Group, OGCP provides expert advice on FDA's regulations and policies on specialized topics. Topics of interest include research involving biological specimens, alternative Institutional Review Board models, and exception to the informed consent requirements for research conducted in emergency settings.

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.

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 to assign 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. Therefore, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), enacted on October 26, 2002, authorized FDA to create the Office of Combination Products (OCP). MDUFMA established broad

responsibilities for OCP that cover the regulatory life cycle of drug-device, drug-biologic, and device-biologic combination products. Specifically, the statute (503(g)(4)(B-F)) requires OCP to:

- Promptly assign a Center with primary jurisdiction for a combination product
- Ensure the timely and effective premarket review of combination products by overseeing the timeliness of and coordinating reviews involving more than one Center
- Ensure the consistency and appropriateness of postmarket regulation of combination products
- Resolve disputes regarding the timeliness of premarket review of combination products
- Review and update agreements, guidance documents or practices specific to the assignment of combination products.

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 Request 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 combination products. For this reason, one of the primary functions of OCP to develop guidance documents and regulations to ensure combination products are regulated consistently by the Agency. To this end, OCP is currently working on two regulations (shown below) that will help clarify the premarket and post-market requirements for 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 Postmarketing Safety Reporting for Combination Products.** OCP is working with the Centers to amend the combination product regulations to set forth postmarketing safety reporting requirements for combination products. Specifically, the rule will clarify the postmarketing safety reporting requirements that

apply when regulated articles (drugs, devices, and biological products) are combined to create a combination product. This final rule is intended to clarify requirements for postmarketing safety reporting for combination products.

Another primary function of OCP is to make formal determinations on Request 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 post-market 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 (shown below) which will clarify our decision making process.

- **Guidance Document For Classifying A Product As a Drug or a Medical Device.** To date, the Agency 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.

- **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). How FDA interprets this term can affect whether the Agency 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.

- **Guidance Document on How To Write an RFD.** This guidance document provides the companies with specific information and data that they should include in an RFD in order for FDA to file the RFD adequately and make an appropriate decision within the statutory timeframe.

In addition, OCP also resolves disputes regarding the timeliness of premarket review of combination products; serves as a focal point for combination product and other cross-cutting regulatory issues for internal and external stakeholders; and facilitates the intra-center consultative review process for combination products and other medical products. OCP also met with international counterparts from Canada, the European Union (EU), Australia, and Japan to exchange information about regulation of combination products and to develop areas of potential harmonization. These activities have the potential to improve knowledge about regulation of combination products and streamline product review.

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. Having this understanding early in the product development cycle will help companies better prepare for meeting the regulatory and data requirement 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 is hoping to reduce the number of inquiries that are submitted to the office every year. With a small staff, this 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 is also committed to make 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 will enable 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. As such, each product will be 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	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
293205: Percentage of requests for Designations processed within the 60 day statutory requirement. *(Output)*	FY 2010: 100% (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

As of September 30, 2010, 353 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 device programs under the Food Drug and Cosmetic Act; 50 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: 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, and outreach activities.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
293201: The total number of decisions on applications for promising orphan drug and humanitarian use device designations. *(Output)*	FY 2010: 301 (Target Exceeded)	246	335	+89
293202: The number of medical devices facilitated in development by the new Pediatric Device Consortia Grant Program. (O*utput)*	FY 2010: 80 (Target Exceeded)	1	100	+99

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. This is accomplished through collaborations with external partners such as NIH, Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Critical Path Institute CPI, Academic Hospitals, American Academy of Pediatrics (AAP), CDC, external scientific experts, the World Health Organization and the European Medicines Agency, in addition to pediatric advocacy groups.

Public Health Outcome

OPT is accomplishing its mission through the following 4 programs:

Pediatric Safety Program: coordinates the mandated pediatric focused safety reviews of drug and biologic products recently studied in the pediatric population to be presented to the Pediatric Advisory Committee (PAC). Annually, OPT brings from 20 to 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.

Pediatric Advisory Committee (PAC) Coordination Program: coordinates the meetings that are mandated for pediatric postmarket safety reviews. OPT manages the PAC membership, renewal, and meeting logistics (e.g., travel arrangements, meeting registration and hotel accommodations, payments). OPT assures there is adequate representation and pediatric expertise needed to handle the wide array of product safety reviews and prepares full conflict of interest paperwork and justification for each PAC and special government employee (SGE) for their participation in each meeting.

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 on ethical issues in pediatric product development to CDER, CBER and CDRH. It has been increasingly apparent that many FDA reviewers simply are not familiar with the additional pediatric protections found in 21 CFR 50, Subpart D, as illustrated by a number of common conceptual errors or omissions that are encountered. As a result, studies presenting an unreasonable risk of harm to children may not be recognized in a timely manner, or may not be recognized at all. Clinical studies that could have been more easily redesigned in the planning stages often are delayed. In addition, enrolled children are potentially exposed to unethical and significant risks of harm. Thus, in addition to making each consultation an opportunity for case-based education of the involved FDA staff, the OPT Ethics Program is integrating ethics education into the initial and continuing education training for FDA reviewers within all three Centers. The pediatric ethicist is a required member of the internal cross-center committee that reviews all protocols being proposed for pediatric studies. The program also provides internal and external training in ethical issues in pediatric clinical trials, building on the dozens of consultations on ethical issues directed to OPT annually to bring difficult pediatric ethical trial issues to some form of public forum such as the PAC, other advisory committees and/or FDA-sponsored public workshops.

Science & Communication Program: 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. FDA is the repository for over 1,000 pediatric studies and has a moral obligation to learn from these studies to better inform future pediatric trials. OPT provided analysis of pediatric trials across classes of products,,across failed trials, and safety issues and published the results in two to five scientific journals each year. The Office works with sister Agencies such as the National Institute of Child Health and Human Development (NICHD) in the NIH, AHRQ and HRSA to identify and advance the science of pediatric therapeutics. OPT staff also speak at numerous forums in an effort to "get the information out".

Pediatric International Program: 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 Union's regulatory body where information on proposed pediatric trials is exchanged. In the 3.5 years since initiation of this collaboration, information was exchanged on over 450 products with discussions on 221 products. Although we reached consensus on many issues, we continue ongoing discussions related to a number of pediatric scientific and ethical concerns related to products and product classes. Due to the continued expansion of our global pediatric collaborations, this international initiative will experience exponential growth for the years to come.

Promoting Efficiency – OPT: FDA developed an efficient centralized approach to enhancing the information needed to instruct how best to utilize products that are being given to children to treat their illness or condition. This includes post market reviews of the safety of drugs studied in children. Realizing it is critical to educate caregivers on pediatric therapies, OPT participates in conferences with professional societies, publishes findings in academic journals and provides a monthly column in the AAP monthly newsletter.

Through coordinated efforts by OPT across the Agency and through the collaborations described above, significant progress is being made in ensuring that necessary information is available to prescribe and use therapies for children properly. For example, pediatric trials that are "negative" or do not demonstrate efficacy have that information put in the label. This is particularly important since so few pediatric trials are conducted. Through June 2010, there have been 385 labeling changes with new pediatric information in the label to assist in properly prescribing a pediatric appropriate dose or identify products not effective in children.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
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 and through collaboration with Latin America. *(Output)*	FY 2010: 62 (Target Exceeded)	10	36	+26
293204: Number of new medical products studied in children with labeling changes and safety reviews completed. *(Output)*	FY 2010: 36 (Target Exceeded)	25	30	+5

The Office of External Affairs (OEA)

Public Health Focus

The Office of External Affairs (OEA) 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 External Relations (OER)

Public Health Focus

The Office of External Relations (OER) manages FDA's contacts with a broad range of stakeholder groups to advance FDA's public health goals. The staff maintains close working relationships with consumers, minorities, older Americans, youth, small business and trade groups, public health officials, academia, and Native American tribes. OER also creates and distributes public health information in several formats that consumers and patients can use to improve their well being and avoid risky products.

Public Health Outcome

OER creates and distributes *Consumer Updates* articles, videos and photo slide shows that provide timely information about public health and safety topics. During FY 2009, approximately 100 updates were published and distributed to nearly 60,000 e-mail subscribers. *Consumer Updates* are also syndicated throughout the Internet and receive some 2.5 million page views every month making them the most viewed consumer content on the FDA Web site. In seeking additional ways to reach consumers and patients, in FY 2009 OER launched a series of innovative partnerships.

OER's relationship with WebMD ensured that FDA information is not only available to those who visit www.fda.gov but also to tens of millions of Web visitors who are seeking information through WebMD. During FY 2010, FDA launched similar partnerships with Everyday Health and Drugs.com, and several additional partnerships are in development.

When FDA announces a major policy initiative or action designed to promote and protect the public health, OER communicates with key target stakeholder audiences via email, the FDA Web site, through informal conversations and networks, or by arranging for stakeholders to participate in teleconferences. These communications reach thousands of organizations and individuals with FDA's public health messages.

OER also manages meetings and policy briefings between FDA executives and external stakeholders representing tens of thousands of individual constituents, enabling FDA to convey its public health information on topics that range from the judicious use of antibiotics to the risk of tainted dietary supplements.

OER manages the process of creating and establishing Memoranda of Understanding (MOU) between FDA and constituents in government, academe, and the private sector. During FY 2009, OER processed approximately 14 MOUs and cooperative agreements. These agreements foster collaboration and information exchanged designed to promote and protect the public health.

Promoting Efficiency – OER: OER is extending the reach and effectiveness of FDA's public health messages through partnerships with other trusted providers of health information and by capitalizing on new media channels to reach audiences.

Office of Public Affairs (OPA)

Public Health Focus

The Office of Public Affairs (OPA) is the principal point of contact for the FDA with the news media. OPA is responsible for providing the public, through the news media, with timely, factual and accurate information about FDA actions that protect and promote the health of Americans by ensuring the safety of foods, cosmetics, and medical products.

Public Health Outcome

OPA is charged with the following responsibilities in support of FDA's mission:

- Conducting media relations for FDA, which includes the timely release of information to the media about FDA's public health goals as well as staffing advisory committee meetings;
- Establishing media relations policies and priorities;
- Coordinating media activities with FDA centers, offices, the Office of the Commissioner, and all other operating units as needed;
- Ensuring that public information products are well written and in line with media principles, practices and expectations.

- Coordinating FDA press announcements, activities, events and materials with HHS; and
- Coordinating and reviews the performance of all media relations activities.

Promoting Efficiency: OPA acts as the liaison between FDA and the press, managing and coordinating press conferences, public statements and other agency announcements.

Office of Special Health Issues (OSHI)

Public Health Focus

The Office of Special Health Issues (OSHI) coordinates and integrates FDA policy, scientific, and public health programs and initiatives for patient, patient advocate, health professional, special and minority population stakeholders. Operationally, OSHI divides its functions by stakeholder category into the Patient Liaison Program and the Health Professional Liaison Program. In addition to being FDA lead for those stakeholder populations, OSHI provides agency-wide coordination and expertise on issues related to AIDS, cancer, neurological disorders, expanded access to investigational medical products, clinical trials, MedWatch safety information and other special health issues. OSHI conducts liaison services for FDA by engaging, collaborating, and communicating with its stakeholders about FDA regulatory decisions and policies to address public health issues related to the safety of marketed human medical products and the review of new medical products. In practice, this includes managing the Patient Representative Program, organizing patient and health professional stakeholder telephone briefings/meetings and initiating major projects of interest to OSHI stakeholders. These activities help ensure FDA's decisions are based upon a full range of perspectives and that important safety and regulatory information is communicated, both of which support open government and transparency by the FDA. In additionto its advocacy and liaison activities, OSHI manages several informational resources, including websites and email lists and a public email box and telephone number to take inquiries from stakeholders on a variety of patient focused issues, primarily dealing with clinical trials and access to investigational drugs.

Public Health Outcome

Above and beyond many of the day-to-day liaison, advocacy, and outreach activities OSHI conducts, selected recent accomplishments include:

- OSHI's collaboration with HRSA and three member academic institutions of the American Association of Colleges of Pharmacy to evaluate the integration of the "Science of Safety" into the curriculum of the Doctor of Pharmacy degree at accredited colleges and schools of pharmacy. Based on the findings, the AACP research team proposed ten recommendations for its over 100 member pharmacy schools to enhance the teaching of the science of safety towards improving the healthcare delivery system.

- OSHI piloted the project with CDER and conducted six telephone briefings on recently approved new molecular entity (NME) or a new drug approval with

associated safety concerns. The briefings provide opportunities for the societies to ask questions about review issues that are relevant to clinical practice. OSHI also moderated over 10 stakeholder calls with health professional and/or patient groups on various human medical product safety issues.

- OSHI staff hosted numerous training sessions including 12 webinars to prepare patient representatives for serving on FDA advisory committees. In September the staff hosted its annual workshop "Patient Representatives Making a Difference". These efforts allowed patients and health professional organizations to take an active role in and become knowledgeable about the public health impact of FDA decision-making.

- OSHI staff moderated several live listening sessions, public meetings, and stakeholder meetings with patient and health professional groups to gather their input on various important FDA initiatives and processes (for example, the unapproved drugs initiative, public meeting on lab developed tests, MDUFA and PDUFA public and stakeholder meetings).

- The HIV/AIDS and Hepatitis email lists, with over 38,000 subscribers combined, provide HHS and FDA-wide announcements of interest to patients, health professionals, and other stakeholders interested in those disease areas.

- The "FDA Updates for Health Care Professionals" email list, with over 35,000 subscribers, provides recent announcements particularly related to human medical product safety, human medical product approvals, opportunities to comment on proposed rules, upcoming public meetings, and other information of interest to health professionals. In FY 2010, subscribers to this elist increased by 10%. OSHI's health professional webpage serves as a portal for FDA information, particularly safety-related information, of interest to health professionals.

- The MedWatch website **Error! Hyperlink reference not valid.**is a major outreach tool for FDA medical product safety information. MedWatch pages rank among the top ten most accessed pages on the FDA site. The "MedWatch Safety Alerts" email list, with almost 173,000 subscribers, broadcasts timely new safety information to healthcare professionals and their patients. Subscribers to the elist increased by 10% in FY 2010. The safety alerts are also delivered via the website, Really Simple Syndication (RSS) feeds, and Twitter.
- This important safety information is further distributed to health professionals and patients through MedWatch Partners and other commercial and non-commercial medical information providers. Each of these information resources for the public provide safety information that can impact healthcare decision-making related to use of human medical products, which ultimately improves health care quality and promotes patient safety.

Through OSHI, FDA is increasing the engagement of patients and health professionals in FDA activities and decision-making processes. This goal, as well as the OSHI

mission and core responsibilities, is consistent with Presidential, HHS, and FDA priorities, namely:

- Administration and HHS priorities for transforming health care: reducing long-term growth of health care costs, investing in prevention and wellness, improving patient safety and quality of care, and providing quality health care for the American public
- Administration initiative as described in President Obama's January 21, 2009, Memoranda on Transparency and Open Government
- HHS Open Government plan for greater transparency of our data and operations, expansion of opportunities for citizens to participate in government, and improved collaboration across government
- FDA's key performance measures described in FDA-Transparency, Results, Accountability, Credibility, Knowledge Sharing, the performance management system that monitors over 100 FDA program offices.

Promoting Efficiency: The MedWatch staff issued 179 safety alerts and 167 safety updates to over 160,000 MedWatch e-list subscribers during FY 2010. Additionally, as a result of implementing streamlined processes, the staff posted over 300 drug labeling changes in FY 2010. The goal of disseminating the monthly labeling changes within 15 calendars days following the end of the month was achieved over 80% of the time.

In response to stakeholder requests for streamlined FDA information, OSHI piloted a program with several health professional organizations to explore the feasibility of targeting MedWatch Safety Alerts to health professional organizations based on pre-defined medical specialty terms. This was an OSHI Key Project in FDA Track. Although the sample of participants was small, those who responded identified satisfaction with targeted messaging.

Performance Measures

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

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	FY 2010: 1 (Target Not Met)	3	3	Maintain

Other Headquarters Offices

Office of Shared Services (OSS)

Public Health Focus

The Office of Shared Services (OSS) centrally manages overall administrative and support services across the FDA Centers, the Office of Regulatory Affairs and the Office of the Commissioner. OSS provides program direction, leadership, coordination and overall guidance for the FDA's administrative programs including facilities management, information centers, library services and the Employee Resource and Information Center (ERIC). By managing administrative services centrally, OSS has the opportunity to develop business services according to best practices currently performed across the Federal government as well as to develop the operational experience needed to be both efficient and responsive to its internal and external client base.

OSS is composed of six offices, each focused on providing specific administrative services, across the FDA:

- Employee Resource and Information Center (ERIC): ERIC provides central request management support via web, email and phone tickets for FDA employees and contractors seeking help with services such as information technology issues, human resources needs, buildings and facilities services, and other core administrative functions.

- Office of Acquisitions and Grants Services (OAGS): OAGS strives to improve its services by continuously analyzing the 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.

- Equal Employment Opportunity and Diversity Management (OEEODM): OEEODM develops and implements programs related to equal employment opportunity and diversity management to ensure consistent adherence to Federal mandates and regulations.

- Office of Financial Management: (OFS): OFS manages the processes related to generating payments to all employees, vendors and contractors.

- Office of Public Information and Library Services (OPILS): OPILS is responsible for planning and guiding FDA's information and library programs, including the development of policies and procedures for information services to the FDA and the public. OPILS also manages the FDA's Freedom of Information and Dockets Management programs, which are funded by the Office of the Commissioner and are not included in the OSS budget.

- Office of Real Property Services (ORPS): ORPS provides an efficient and effective program of nationwide support across the FDA in the areas of real property management, engineering services, environmental management, occupational safety and health, and long range planning for FDA's current and future facilities needs.

Public Health Outcome

OSS provides a full portfolio of administrative and support services across all components of the FDA. OSS provides tremendous value to the FDA as a customer service support organization by pooling and streamlining FDA's administrative functions so as to effectively and efficiently deliver the necessary services across FDA. As a result, FDA Centers, the Office of Regulatory Affairs and the Office of the Commissioner can focus on their business mission, knowing that their administrative needs are managed responsively, based on needs and urgency.

Promoting Efficiency: OSS provided the FDA with remarkable successes in the overall management of agency-wide administrative and support services, in particular:

- In FY 2010, OSS met or exceeded over 95% of its Service Level Agreement objectives, and is on target to do the same in FY 2011. OSS, through its OAGS office, continues to lead HHS in its socio-economic and competitive contracting efforts, and has experienced tremendous progress in utilizing performance-based acquisition procedures.

- OSS increased the FDA Biosciences Library's portfolio of research titles available online and is expanding its Integrated Library System as the primary tool for its FDA client base to access critically-needed research support.

- OSS' OFS component strives towards efficiency in the management of all payment requests, having achieved over 99 percent on-time Accounts Payable record and over 97 percent usage of Electronic Funds Transfer. Also, through active management of FDA's travel program, OFS continues to maintain very low travel payment delinquency rates, supporting the needs of individuals traveling in support of the FDA mission.

- OSS efficiently manages FDA's real property assets, including over 350 government-owned or leased facilities nationwide, and focuses attention on increasing utilization rates and improving facility conditions. The Real Property Management System, currently being implemented, promises to further improve facility utilization and condition by providing FDA the ability to use extensive knowledge about its facilities when planning property acquisition, allocation and maintenance. OSS is currently developing investment plans that should yield upgrades to several of its laboratory and other facilities, needed to support current and future FDA operations and to meet Federal guidelines related to energy saving initiatives.

- OSS operates a cost-effective consolidated call center, known as "ERIC", in support of FDA administrative and IT services, which centrally manages FDA clients' requests for support.

- Finally, OSS continues its ongoing efforts to meet the goals associated with Executive Order 13423, *Strengthening Federal Environmental, Energy and Transportation Management* to improve environmental quality, reduce energy

and water consumption, increase renewable energy use, increase green procurement, improve transportation management and implement sustainable building practices, across the FDA.

Office of IT Shared Services (OITSS)

The Office of IT Shared Services continues to consolidate and modernize FDA's IT infrastructure and provide FDA customers with a single point of contact for the identification, consolidation, testing, evaluation, integration, deployment, and decommissioning of all IT infrastructure services and equipment.

Information Technology Investments –**Office Activities** (Base Amount displayed as a non-add item: $ 40,908,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across FDA program areas. This allows the FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, modernizing and enhancing IT will ensure that FDA operations are effectively managed within FDA's regulatory framework and that available resources are put to the most efficient use in support of FDA's science-based regulatory work. In addition to the ongoing operations and maintenance of existing IT systems that support FDA operations, projects such as Automated Employee Process (AEP) will use a universal system to streamline and standardize the entry process throughout FDA for each new FDA and contractor employee.

Establishing foreign offices in China, India, the Middle East, Europe, and Latin America will foster closer collaboration with regulatory counterparts in these countries, and help FDA promote food and medical product safety and quality, and greatly expand FDA's oversight of imported food and medical products through efficient IT systems. Additionally, IT systems and infrastructure will support and improve efficiency of critical FDA functions and enhance existing operational capabilities to ensure continuity of operations during an emergency outbreak, such as a pandemic influenza outbreak, food and drug recalls, and other national emergency response initiatives that may affect the public health.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	$111,425,000	$91,813,000	$19,612,000	671
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 Continuing Resolution (CR)	$202,926,000	$140,848,000	$62,078,000	947

Summary of the Budget Request

The FY 2012 Budget Request for Headquarters and Office of the Commissioner is $288,638,000 supporting 1,047 FTEs. This amount is an increase of $92,332,000 above the FY 2010 Enacted.

Headquarters and Office of the Commissioner provides a broad range of critically important services to support FDA's public health mission.

The base funding for Headquarters and the Office of the Commissioner is $196,306,000. BA: $140,848,000 / User Fees: $55,458,000

FY 2012 User Fees Increases

FY 2012 increase for current law user fees:

- PDUFA: +$18,149,000 / 54 FTE
- MDUFMA: +$1,048,000 / 2 FTE
- ADUFA: +$180,000 / 0 FTE
- AGDUFA: +$24,000 / 0 FTE
- Tobacco: +$860,000 / 18 FTE

FY 2012 increase for Food Safety Modernization Act user fees:

- Food Re-inspection User Fee: +$3,395,000 / 7 FTE
- Voluntary Qualified Importer Program (VQIP): +3,674,000 / 14 FTE
- Recall User Fee: +$661,000 / 2 FTE

FY 2012 increase for proposed user fees:

- Generic Drug User Fee: +$1,325,000 / 5 FTE
- Medical Products Re-inspection User Fee: +$5,902,000 / 10 FTE
- International Courier User Fee: +276,000 / 1 FTE

BA Initiatives

Advancing Medical Countermeasures Initiative: (29,708,000 / 28 FTE)

The Office of Counterterrorism and Emerging Threats will lead, implement, coordinate, manage, track and report on the activities and outcomes associated with 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.

Program Support for Advancing Medical Countermeasures: (+$3,755,000 / 9 FTE)

The MCM Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their MCM outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communications, ethics, headquarters coordination and related support functions.

Transforming Food Safety and Nutrition Initiative: (+$3,814,000 / 7 FTE)

The Office of Foods and other components of OC/HQ will coordinate and lead in the development of a strong, reliable food safety system for American consumers and a commitment to improving the health of Americans through better nutrition.

Program Support for Transforming Food Safety and Nutrition: (+$11,691,000 / 29 FTE)

The TFS Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communications, ethics, headquarters coordination and related support functions.

Protecting Patients Initiative (+$1,831,000 / 7 FTE)

The Office of Chief Counsel and Office of Policy in the Office of the Commissioner will work with CDER and CBER to develop the regulatory and policy framework to establish a pathway for the approval of follow-on biologics. These offices will develop policy, guidance, and regulations to implement the new ACA provision on follow-on biologics. In addition, Office of the Chief Counsel will provide legal advice to CDER and CBER, including facilitating response to industry inquiries.

Program Support for Protecting Patients: (+$1,687,000 / 5 FTE)

The PP Initiative includes resources to ensure that the programs that participate in this initiative receive the support necessary to achieve their outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communications, ethics, headquarters coordination and related support functions.

FDA Regulatory Science and Facilities (+$8,829,000 / 10 FTE)

The Office of the Chief Scientist (OCS) provides strategic leadership, coordination, and expertise to support scientific excellence, innovation and infrastructure in FDA science that will advance the agency's ability to protect and promote the health of the public.

With the funds requested, FDA will be able to strengthen FDA's nanotechnology product evaluation capabilities by increasing FDA laboratory capacity at the White Oak and NCTR/ORA campuses, enhancing professional development programs and developing research project plans as evidenced by developing and conducting nanotechnology studies in partnership with external laboratories and establishing standard operating procedures in research protocols for detecting nanoscale materials in FDA-regulated products.

The proposed resources will allow FDA to launch new scientific priorities within the Critical Path Initiative. The scientific priorities will include projects to develop and qualify new biomarkers, enable personalized medicine, modernize and increase the efficiency of the clinical trial enterprise, improve tools to predict safety and effectiveness of medical products, modernize the methods used in toxicology studies, and more effectively apply information technologies to evaluate product safety and effectiveness.

Program Support for FDA Regulatory Science and Facilities Initiative (+$728,000 / 3 FTE)

To ensure the successful implementation of the FDA Regulatory Science and Facilities Initiative, the requested funds will be use to bolster the program support. The program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communications, ethics, headquarters coordination and related support functions.

BA Increase for Pay Costs: +$329,000

Contract and Administrative Savings: (-$5,534,000)

Headquarters and the Office of the Commissioner will achieve contract savings by:

- Reducing the OC contribution to enterprise contracts related to financial services, recruitment and workforce management, and information technology, including $4.0 million in savings related to the MedWatch Plus IT System

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INFRASTRUCTURE
GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

The following table displays funding levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$301,424**	**$301,913**	**$306,434**	**$406,611**	**$105,187**
GSA Rent	$175,840	$177,709	$173,417	$214,302	$38,462
Other Rent	$84,088	$85,668	$91,066	$123,788	$39,700
White Oak	$41,496	$38,536	$41,951	$68,521	$27,025
Budget Authority	**$248,656**	**$248,658**	**$248,656**	**$318,176**	**$69,520**
GSA Rent	$145,260	$145,261	$145,260	$167,826	$22,566
Other Rent	$64,860	$64,861	$64,860	$86,212	$21,352
White Oak	$38,536	$38,536	$38,536	$64,138	$25,602
User Fees	**$52,768**	**$53,255**	**$57,778**	**$88,435**	**$35,667**
GSA Rent	**$30,580**	**$32,448**	**$28,157**	**$46,476**	**$15,896**
PDUFA	$22,328	$25,632	$19,905	$25,544	$3,216
MDUFMA	$4,264	$2,361	$4,264	$5,019	$755
ADUFA	$885	$659	$885	$1,115	$230
AGDUFA	$305	$105	$305	$340	$35
Tobacco	$2,798	$3,691	$2,798	$5,503	$2,705
Voluntary Qualified Importer Program (VQIP) User Fee				$3,920	$3,920
Food Reinspection				$1,338	$1,338
Generic Drugs				$1,943	$1,943
Medical Product Reinspection				$1,026	$1,026
Recall User fee				$434	$434
International Courier User Fee				$294	$294
Other Rent	**$19,228**	**$20,807**	**$26,206**	**$37,576**	**$18,348**
PDUFA	$16,275	$18,991	$23,253	$29,841	$13,566
MDUFMA	$1,376	$1,087	$1,376	$1,620	$244
ADUFA	$162	$121	$162	$204	$42
AGDUFA	$72	$105	$72	$80	$8
Tobacco	$1,343	$503	$1,343	$1,550	$207
Voluntary Qualified Importer Program (VQIP) User Fee				$2,240	$2,240
Food Reinspection				$592	$592
Generic Drugs				$578	$578
Medical Product Reinspection				$455	$455
Recall User fee				$248	$248
International Courier User Fee				$168	$168
White Oak	**$2,960**	**$0**	**$3,415**	**$4,383**	**$1,423**
PDUFA	$2,960	$0	$3,415	$4,383	$1,423

The FDA Infrastructure Program operates under the following legal authorities and executive orders.

The following are 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 authorities establish the consolidation of FDA Headquarters 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 Centers and ORA with secure and cost-effective office and laboratory space in which to perform mission critical work. The Infrastructure Program includes three areas:

- GSA Rental Payments
- Other Rent and Rent-Related Activities
- The FDA White Oak Consolidation.

GSA Rental Payments
Base Amount: $175,840,000 (BA: $145,260,000 / UF: $30,580,000)

The GSA Rental account includes FDA rental payments to the General Services Administration (GSA) covering FDA's office and laboratory facilities and to the Department of Homeland Security (DHS) for standard level security services at these facilities.

FDA currently occupies over 5.6 million square feet of GSA-owned or -leased office, laboratory, and warehouse space. More than two-thirds of the GSA and DHS 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 OC, CDER, and CDRH. In total, FDA-occupied GSA space comprises approximately 282 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 2010, with the OC and ORA migration to the FDA White Oak campus, FDA vacated space in five Headquarters locations but immediately backfilled four of these locations with newly hired OC staff and with staff vacating the Parklawn Building. In total, FDA reduced its space in the Parklawn Building by 279,000 rentable square feet (RSF). The remaining 124,000 RSF occupied by FDA will be vacated by January 31, 2011. In addition to two new buildings on the White Oak campus, FDA acquired expansion space for CFSAN at University Station in College Park. FDA's Office of Criminal Investigations (OCI) opened two new field offices and expanded one field office. ORA opened two new Resident Posts, acquired expansion space for four Resident Posts and one Border Station, relocated 11 Resident Posts and two Border Stations, and closed one Resident Post. ORA also acquired expansion space for one District Office.

FDA is working with 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, energy efficient and to acquire the necessary space to meet the mission and nationally recognized standards.

Other Rent and Rent-Related Activities
Base Amount: $84,088,000 (BA: $64,860,000 / UF: 19,228,000)

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 working on the implementation of numerous energy savings efforts that will decrease long term utility usage and costs, increase the life span and efficiency of operating and maintaining facilities, and save on overall energy usage. These changes will help FDA realize a significant savings in Other Rent and Rent Related. The implementation of these types of projects supports and meets the requirements set forth in Executive Order 13423 Strengthening Federal Environmental, Energy, and Transportation Management. These projects contribute to meeting the requirements of the Department of Health and Human Services (DHHS) Efficient Energy Management Assessments, the Energy Policy Act of 2005, and the DHHS Sustainable and High Performance Buildings Policy, High Performance Buildings Implementation Plan and the

2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

FDA continues to issue Utility Energy Service Contracts (UESC) for FDA owned facilities. These contracts are based on the implementation of specific energy and water conservation measures (ECMs) including:

- replacing chillers and cooling towers
- converting laboratory air handling units to new variable air volume controls
- upgrading and enhancing laboratory electrical systems.

These ECMs are estimated to save almost $2.0 million annually in water, sewer, electricity and fuel costs, representing a 35 percent utility cost savings. In addition, FDA installed advanced meters during FY 2010 which were linked to the Building Automation System which generates monthly reports documenting the energy savings. FDA will use this information to identify areas using excess energy and upgrade to more efficient, cost effective items.

Washington Gas and FDA conducted a second preliminary audit in March 2010 to investigate and survey ten more potential ECM's such as:

- a boiler stack economizer
- chiller replacement
- boiler blow-down/heat recovery
- water conservation measurements
- lighting upgrades.

These measures will provide approximately $400,000 of projected annual energy savings costs. This proposed UESC also includes one facility improvement measure (FIM), which consists of electrical upgrades\replacement of the aged switchgear system. The replacement of this equipment provides the facility reliable power and improves the facility condition index of the asset. FDA is reviewing the preliminary audit and will determine whether to proceed with an investment grade audit that will provide more detailed analyses of the cost savings and a more accurate construction cost.

FDA is also considering an energy saving contract for the ORA District Laboratory and Office in Irvine, CA with the Southern California Edison Electric (SCE) Power Company. If determined to be cost effective and economically feasible, FDA will proceed with awarding the contract. SCE surveyed the facility and determined that there were several opportunities to be pursued, including but not limited to:

- on- and off-site renewables
- roof mounted solar panels
- a solar screen wall
- lighting controls such as dimmers and sensors
- high efficiency motors
- advanced meters
- replacement of first generation T8 lighting
- upgrades to the HVAC-DDC controls.

Actual project cost and cost savings are not known at this time but appear to have great potential as viable energy conservation measures. FDA anticipates the submission of a formal-preliminary audit before the end of the fiscal year.

Awarding additional UESCs and procuring renewable energy will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2012 activities related to UESCs and renewable energy will help reduce Scope 1 and 3 greenhouse gas emissions.

White Oak Consolidation
Base Amount: $41,496,000 (BA: $38,536,000 / UF: $2,960,000)

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 fit-out and move costs. FDA initiated relocation activities to White Oak in FY 2002.

During FY 2010 approximately 1,026 employees moved to the White Oak Campus. The total number of employees currently working on the White Oak Campus is 5,496. A Child Care Center will be completed in 2011. If adequate GSA construction funds are appropriated in FY 2012 and 2013, during FY 2014 and 2015, FDA plans to relocate another 3,393 employees to the White Oak Campus, for a total on Campus of 8,889, and the current phase of the consolidation will conclude in FY 2015.

Completed design plans include:

- The Southeast Parking Garage — plans completed in May 2009 — will be built pending appropriation of GSA construction funding and completed by FY 2014.
- Buildings 52 and 72 — the Life Sciences-Biodefense Laboratories II and III and the vivarium — plans are complete; construction began fourth quarter FY 2010.
- Buildings 71 and 75 — construction is scheduled to begin in mid-FY 2011.

Buildings 25, 45 (Distribution Facility) and the Communications Facility are scheduled to be designed in FY 2011.

Based on FY 2010 funding and the FY 2009 Master Plan, GSA considers the 130-acre White Oak Campus project to be 70 percent complete. FDA is working with the GSA to secure GSA construction funding for the remaining facilities included in the current White Oak Campus Master Plan design.

However, FDA is experiencing an unprecedented and dramatic surge in staffing and facility needs that will cause FDA facility requirements to exceed the scope of the 2009 Master Plan. This staffing surge is based on FY 2008 and FY 2009 appropriation increases, budgeted increases for FY 2010, and growth associated with the Center for

Tobacco Products. On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act, giving FDA the authority to regulate the manufacturing, marketing and sale of tobacco products. Implementing this legislation will require FDA to hire as many as 700 additional professionals to support the new Center for Tobacco Products.

FDA is working with GSA to secure funding for environmental planning, design, and construction for facilities to support our growth. Where necessary, FDA will acquire temporary leased office space to accommodate program growth until the facilities are available.

FDA White Oak funding will be used for:

- furniture
- information technology and telecommunications equipment and infrastructure
- AV Equipment
- security equipment and cabling for Office Building 75.

White Oak will also fund security equipment and communications networks for Office Building 25 and the Auxiliary Support Facilities, such as Visitor Center Screening and Communications Facility. Security screening equipment for the Southeast Garage will also be installed.

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, in the 2013 to 2015 timeframe, the Campus will grow by another 60 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 our human capital. The Campus is being built with centrally shared functional spaces such as document rooms and conference areas to make the most effective use of resources and eliminate redundant activities across FDA Centers. 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 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2007 Actual	$138,896,000	$126,871,000	$12,025,000
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 Continuing Resolution	$173,417,000	$145,260,000	$28,157,000

FIVE YEAR FUNDING TABLE – OTHER RENT AND RENT-RELATED ACTIVITIES

The following table displays funding levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2007 Actual	$49,906,000	$42,000,000	$7,906,000
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 Continuing Resolution	$91,066,000	$64,860,000	$26,206,000

FIVE YEAR FUNDING TABLE – WHITE OAK

The following table displays funding levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2007 Actual	$35,657,000	$25,552,000	$10,105,000
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 Continuing Resolution	$41,951,000	$38,536,000	$3,415,000

Budget Request

The FY 2012 budget request for the Infrastructure program is $406,611,000. The request includes $318,176,000 in Budget Authority and $88,435,000 in User Fees. This amount is an increase of $69,520,000 in Budget Authority and $35,667,000 in User Fees for a total of $105,187,000 above the FY 2010 Enacted Level.

The base funding for FDA's Infrastructure Program is $301,424,000 including $248,656,000 in Budget Authority and $52,768,000 in User Fees.

GSA Rental Payments (Base: $175,840,000)

FDA requests $214,302,000 for GSA Rental Payments which is an increase of $38,462,000 over the base. The increase includes $22,566,000 in Budget Authority and $15,896,000 in User Fees. The total request includes $167,826,000 in Budget Authority and $46,476,000 in User Fees.

The rental properties that provide office and laboratory space for FDA's 12,000 employees are essential facilities that allow FDA to perform its vital public health mission. Base funding for GSA Rental Payments covers the cost of rental payments to GSA for FDA's five 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 (Base: $84,088,000)

FDA requests $123,788,000 for Other Rent and Rent Related which is an increase of $39,700,000 over the base. The increase includes $21,352,000 in Budget Authority and $18,348,000 in User Fees. The total request includes $86,212,000 in Budget Authority and $37,576,000 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 (Base: $41,496,000)

FDA requests $68,521,000 for the White Oak Consolidation which is an increase of $27,025,000 over the base. The increase includes $25,602,000 in Budget Authority and $1,423,000 in User Fees. The total request includes $64,138,000 in Budget Authority and $4,383,000 in User Fees.

The remaining construction on the White Oak Campus includes the two largest laboratories – the Life Sciences-Bioterrorism Laboratories II and III – and facilities to support the White Oak laboratories. These laboratories and related campus improvements include nearly 1.2 million square feet of specialized scientific and support facilities.

In August 2010 GSA awarded a contract for construction of the Life Sciences-Biodefense laboratories and other remaining White Oak facilities. This budget request allows FDA to pay their share of the costs to make the laboratory operational. FDA will invest in security, communications network, outfitting, commissioning and providing the essential equipment and infrastructure for the Life Sciences-Biodefense Laboratories II and III, as well as supporting facilities in the Southeast Quadrant to ensure that they are safe, certified and operational.

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BUILDINGS AND FACILITIES

The following table displays funding levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	**$15,930**	**$22,111**	**$15,930**	**$13,055**	**-$2,875**
Budget Authority	**$15,930**	**$22,111**	**$15,930**	**$13,055**	**-$2,875**
Building and Facilities	$12,433	$15,117	$12,433	$13,055	$622
Natural Products Center	$3,497	$6,994	$3,497	$0	-$3,497

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.*)
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)

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. The B&F Program provides direct support that allows FDA to accomplish its public health mission.

B&F supports FDA's strategic goal of transforming administrative systems and infrastructure to support FDA operations. The B&F program funding is provided to construct mission critical laboratory, office and support space, and for renovations, repairs and improvements to 85 FDA-owned facilities located at six sites in the U.S. and Puerto Rico where FDA conducts operations that are critical to FDA's public health mission.

FDA uses the majority of its B&F funds for renovation, repair and improvement projects. Those projects can take multiple years to complete, based on the project size and

* 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.

complexity. For example, designing the project, procuring construction services and completing the actual renovations, repairs and improvements usually take more than 18 months.

The Department of Health and Human Services (HHS) developed a Real Property Asset Management Plan (AMP). AMP outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets. 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-owned assets, which includes a substantial amount of laboratory facilities and site infrastructure, is critically important. 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 facility use and operating costs.

An important component of FDA real property asset management is conducting facility condition assessments on a three-year cycle. Facility condition assessments evaluate:

- site infrastructure such as utility distribution systems, roads, and sidewalks
- buildings, including the associated physical systems such as architectural, civil, mechanical, and electrical issues, as well as code compliance, life and other safety conditions, and finishes and aesthetics.

These periodic assessments of FDA facilities 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. The BMAR includes 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 2010, FDA's total BMAR, which includes building deficiencies, site infrastructure deficiencies and required renewals, for its six owned sites was approximately $100,500,000. 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 63 percent of FDA-owned assets have an FCI score below the HHS established goal and require significant repairs and improvements.

FDA used B&F Program funding provided in FY 2010 and FY 2011 and plans to use the FY 2012 funds to accomplish several mission critical and BMAR driven projects at each of its six owned sites. The FY 2012 B&F projects will improve the condition of these assets and ensure that the assets can successfully support FDA's mission. The list below is representational and not comprehensive. Severe weather and other natural events can alter the list and its priorities.

FDA's Gulf Coast Seafood Laboratory site, located in Dauphin Island, Alabama, 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 2010, FDA completed numerous projects to ensure the continued functionality of this facility. These projects include:

- resurfacing the parking lot and roads
- replacing the boiler and windows
- installing crawl space insulation to improve the energy efficiency and ensure a comfortable work environment.

FDA also plans to replace the switchgear and parallel conductors in the main laboratory building.

The FDA Muirkirk Road Complex (MRC) located in Laurel, Maryland is a campus which is shared by CFSAN and the Center for Veterinary Medicine (CVM). At MRC, FDA conducts research programs related to food and animal drug safety, toxicology, microbiology, and molecular biology. In addition, FDA uses the laboratories at this site for the Laboratory and Food Emergency Response Networks.

At MRC, recent B&F projects include:

- designs to replace the aged and non-compliant fire alarm systems and exit signs
- a study for replacing two chillers for the aquaculture facility
- installing and updating ground fault circuit interrupter protection
- installing emergency and egress lighting
- retubing boilers
- overhauling cooling towers and chillers
- designing a replacement laboratory nitrogen manifold system
- replacing variable frequency drives for laboratory air handling units and exhaust fans
- replacing reheat coils
- repaving a bridge and repairing associated sinkholes.

These projects support FDA's ability to establish science-based regulatory standards and rapid responses to outbreaks.

FDA also plans to renovate the mission critical laboratory space for CVM in MOD2 to support program mission requirements. These renovations include:

- installing a new nitrogen gas delivery system for essential laboratory equipment in MOD2
- renovating the BRF Support Building for the Office of Regulatory Affairs (ORA)
- replacing the MRC MOD 1 Fire Alarm System.

FDA will initiate additional projects to address other facility deficiencies, including the essential replacement or repair of motor controls, HVAC controls and compressors in MOD1, which will improve the reliability of building systems to support essential animal research and laboratory operations.

Finally, FDA is evaluating whether to enter into a second utility energy service contract (UESC) at MRC and is considering an investment grade audit to provide a more accurate cost estimate and annual savings from the preliminary audit report performed earlier in the year. In addition to projects that will result in energy conservation, FDA is considering including facility improvement projects, such as the replacement of the aged switchgear at MOD1, as part of this UESC. UESCs provide an opportunity to finance projects over time through a contract with a local utility provider, which allows FDA to use its B&F funds to make other needed repairs and improvements in support of the mission at this site. FDA also plans to develop a Master Plan for this site.

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, investigating toxicity, and studying the extrapolation of data from animal studies to humans, all of which informs FDA regulatory policies. The ARL provides analytical laboratory support to ORA's regulatory mission in the Southwest Region.

At JLC, FDA recently funded the following projects:

- fit-out of one floor of Building 50, a key administrative building
- renovating existing space for critical research and neurotoxicology laboratories in Building 62
- replacing a boiler and its associated equipment and controls in Building 7 with one that is more energy efficient and reliable
- replacing a chiller in Building 26 with a larger more energy efficient chiller
- replacing HVAC equipment in Building 5 that supports critical research support areas with more energy efficient equipment.

FDA has designed projects such as repairs of critical campus wide electrical distribution infrastructure and future laboratory repairs in Building 14A and 14B. Repair and improvement projects include:

- replacing fire alarm systems and reworking the electrical distribution system at campus substation #3
- renovating research support rooms and dressing rooms in Building 5
- renovating laboratory space in Building 14.

Other key site and building infrastructure projects involve repairing processing area equipment in Building 5A that supports animal research and replacing emergency generators and associated controls, air handling units and electrical distribution systems. Designs for critical laboratory, conference room, and administrative space renovations, a water recycling project, natural gas and hot water piping repairs and HVAC system replacement projects will also be completed and actual repair and improvement work associated with some of these designs will begin. FDA also initiated a project to develop a Master Plan for the site.

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 completed the projects to replace the rooftop central air conditioning units and direct expansion units, as well as the conference room carpet and ceiling. FDA also funded projects to complete additional HVAC repairs, clean ductwork, replace the Hazmat/Chemical Storage Building, make improvements to ensure ADA compliance, and paint exterior doors identified as facility deficiencies. Additional projects for various electrical repairs throughout the site are scheduled.

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 base in the Los Angeles area.

During FY 2010, FDA completed a mission-required office renovation at the Irvine facility as well as projects that included repainting exterior metal surfaces, repairing wall cracks and installing expansion control joints. FDA also plans to fund a UESC Investment Grade Audit, which will include energy, water and other sustainable design measures, such as the design and construction of solar screens to improve energy efficiency, ensure a comfortable work environment, and generate solar power for portions of the building.

The Winchester Engineering and Analytical Center 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 has substantially completed a project to upgrade the laboratory HVAC, plumbing, and electrical systems, and replace the domestic water heater, three fume hoods and the acoustical ceiling. FDA also funded a project to upgrade additional HVAC equipment and to correct emergency generator deficiencies. FDA plans to continue work on miscellaneous HVAC, electrical and structural repairs.

FDA completed feasibility studies that identified program needs and required facility modifications to develop core scientific research facilities for nanotechnology, flow cytometry and imaging programs at the MRC, JLC and White Oak Campus. FDA plans to fund facility condition and sustainability assessments for its owned assets that are less than 5,000 square feet, which is consistent with HHS policy.

Promoting Efficiency

FDA laboratories and the site infrastructure that supports laboratories are essential for FDA to achieve its mission. Many laboratory upgrades funded through the B&F account permit FDA to improve and repair building and site infrastructure deficiencies to ensure laboratories are operating as efficiently as possible in support of FDA science, which in turn leads to improved public health.

FDA also uses B&F funds to install more modern equipment to analyze and address food, drug and cosmetic safety and toxicity concerns and concerns about the other products that FDA regulates. Updated equipment produces more rapid, accurate and sophisticated results, allowing FDA to respond to threats to public health and prevent injury, illness or death. Faster and more accurate results give FDA the ability to identify which firms within an industry sector are responsible for contamination – and which are not – allowing firms to resume business operations more quickly.

Five Year Funding Table

The following table displays funding levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority
FY 2007 Actual	$10,382,000	$10,382,000
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 Continuing Resolution[3]	$15,930,000	$15,930,000

[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.
2FY 2010 includes $6,994,000 to the National Center for Natural Products Research for construction and renovation.
[3]FY 2011 C.R. level estimates $3,497,000 to the National Center for Natural Products Research for construction and renovation.

Summary of the Budget Request

The FY 2012 budget request for the Buildings and Facilities Program is $13,055,000. This amount includes a $622,000 increase above the FY 2010 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 initially 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 2012 funding to complete these priority projects. Conditions and mission needs at FDA sites may change after this prioritization process that may require FDA to modify its planned projects for FY 2012, 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 2012 B&F funding at its Jefferson Labs Complex (JLC) site to:

- repair the electrical distribution system at campus substations #1 and #2
- renovate critical laboratory and support space
- replace a second boiler with a new energy efficient low, nitrogen oxide emitting boiler
- replace HVAC and reheat piping systems in multiple buildings.

These projects are critical to ensure adequate, reliable site infrastructure and building operations in support of the FDA 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 2012 at the Muirkirk Road Complex (MRC) include:

- replacing pneumatic mechanical system controls with direct digital controls in multiple buildings and tying them to a single building system
- replacing the atrium glass in MOD1 that chronically leaks, repairing large portions of the asphalt roads and parking lots
- installing more efficient control valves in laboratory research areas to improve safety
- correcting various structural, life safety, lighting, HVAC and electrical deficiencies in multiple buildings.

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 public health. Repairs to the facility enable 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 2012 for site infrastructure improvements to include:

- repairing a cracked walkway
- modifying the site security entrance
- resealing the parking lot
- modifying the slope at the loading dock to ensure water drains away from the building.

This 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. Existing microbiological media preparation capabilities severely restrict timely FDA public health response in regulatory and analytical testing operations. B&F projects at this site will recommission the building to ensure that major systems are functioning as designed.

Improvements planned for the main laboratory at the Winchester, MA site include:

- upgrading the fire alarm and emergency lighting systems
- replacing exit signs, replacing HVAC equipment and controls
- painting, cleaning ductwork and testing and balancing the building
- upgrading the building management system,
- installing a fire suppression system in the ashing room.

FDA also plans to upgrade exterior lighting at the site. This site 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 the main laboratory at the San Juan, PR site by replacing chemical fume hoods and modifying or replacing entrance ramps. Improvements to various other buildings on the site include installing new handrails for Americans with Disabilities Act compliance, replacing exterior doors, and repairing various electrical deficiencies. 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 renovations are essential to the infrastructure of this mission critical laboratory and necessary to ensure continued optimal laboratory functionality.

FDA will complete critical site infrastructure improvements at the Dauphin Island, AL site in FY 2012 including:

- installing an emergency domestic water storage tank and pumps
- improving electrical distribution from the site transformer to existing buildings

- replacing the hazardous waste storage building.

Projects planned for the main laboratory building include replacing worn fuel feed pumps and improving the HVAC system to support IT equipment. 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. B&F projects planned at this facility support 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 2012 funds.

FY 2012 Buildings and Facilities Allocation Plan

Site/Initiative	*Total*
Jefferson Laboratories Complex (NCTR & ARL) - Jefferson, AR	$6,900,000
Muirkirk Road Complex (MOD I, MOD II, BRF) – Laurel, MD	$4,982,000
ORA Pacific Regional Laboratory SW – Irvine, CA	$150,000
Winchester Engineering and Analytical Center – Winchester, MA	$446,000
San Juan District Office – San Juan, PR	$272,000
CFSAN Gulf Coast Seafood Laboratory	$305,000
B&F PROJECT TOTAL	**$13,055,000**

FDA's B&F Program funding for FY 2012 will continue to make meeting mission requirements and 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 Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2012 projects to replace aged, inefficient HVAC and electrical equipment at several locations; to replace a boiler that services the entire Jefferson Laboratories Complex; and to replace windows and atrium glass at the MOD I facility will help reduce Scope 1 and 3 greenhouse gas emissions.

Buildings and Facilities Program Activity Data[1]

Facility	Average FCI Score		
	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Gulf Coast Seafood Laboratory[2]	92	95	97
Jefferson Laboratory Complex[3]	81	83	84
Muirkirk Road Complex[4]	86	89	90
Pacific Regional Laboratory Southwest[5]	100	100	100
San Juan District Office and Laboratories[6]	83	84	85
Winchester Engineering and Analytic Center[7]	70	73	76

[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.

[2]Based on funding levels in FY2011 and FY2012, the remaining BMAR for this site, approximately $80K, will be eliminated. Surplus of approximately $296K will be used for sustainment improvements and other mission related projects.

[3]Based on funding levels in FY2011 and FY2012 the BMAR for this site will decrease by approximately $8.4M. Remaining BMAR total will be approximately $57.5M.

[4]Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately $4.9M. Remaining BMAR total will be approximately $10.6M.

[5]Based on funding levels in FY2011 and FY2012, the remaining BMAR for this site, approximately $66K, will be eliminated. Surplus of approximately $564K will be used for sustainment improvements and other mission related projects as well as to subsidize a Utility Energy Service Contract (UESC) to help meet presidential mandates, executive orders and energy efficiency statutes.

[6]Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately $268K. Remaining BMAR total will be approximately $2.5M.

[7]Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately $853K. Remaining BMAR total will be approximately $3.4M.

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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]			
2012	4,256,673,000[45]			

* 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 $2,730,910,000 (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), $14,700,000 for Food Reinspection 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, $2,700,000 in Export Certification, $1,267,000 in Food Export Certification and $7,700,000 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			
2012	13,055,000			

[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

	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Increase or Decrease
Personnel compensation:				
Full-time permanent (11.1)	$699,741	$742,719	$796,876	$54,158
Other than full-time permanent (11.3)	$106,813	$113,411	$121,681	$8,270
Other personnel compensation (11.5)	$54,567	$57,932	$62,156	$4,224
Military personnel (11.7)	$56,254	$60,153	$64,539	$4,386
Special personnel services payments (11.8)	$1,167	$1,285	$1,378	$94
Subtotal personnel compensation	**$918,542**	**$975,499**	**$1,046,631**	**$71,132**
Civilian benefits (12.1)	$238,032	$252,634	$271,056	$18,422
Military benefits (12.2)	$29,763	$31,824	$34,145	$2,321
Benefits to former personnel (13.0)				
Total Pay Costs	**$1,186,337**	**$1,259,957**	**$1,351,831**	**$91,968**
Travel and transportation of persons (21.0)	$48,810	$41,357	$50,527	$9,170
Transportation of things (22.0)	$5,473	$4,781	$6,061	$1,280
Rental payments to GSA (23.1)	$145,261	$145,561	$167,826	$22,265
Rent payments to others (23.2)	$4,757	$52,983	$86,212	$33,229
Communication, utilities, and misc. charges (23.3)	$70,051	$71,172	$84,025	$12,853
Printing and reproduction (24.0)	$2,755	$2,503	$3,053	$550
Other Contractual Services:				
Advisory and assistance services (25.1)	$53,731	$68,851	$67,859	-$992
Other services (25.2)	$320,709	$244,395	$378,506	$134,111
Purchase of goods and svcs from Govt Acts. (25.3)……	$158,157	$129,406	$136,250	$6,844
Operation and maintenance of facilities (25.4)	$93,069	$94,558	$119,534	$24,976
Research and Development Contracts (25.5)	$46,517	$36,325	$39,517	$3,192
Medical care (25.6)	$0	$0	$0	$0
Operation and maintenance of equipment (25.7)	$15,061	$15,302	$19,434	$4,132
Subsistence and support of persons (25.8)	$0	$0	$0	$0
Subtotal Other Contractual Services	**$687,244**	**$588,837**	**$761,100**	**$32,300**
Supplies and materials (26.0)	$46,450	$46,450	$55,538	$9,088
Equipment (31.0)	$97,583	$87,743	$110,091	$22,348
Land and Structures (32.0)	$14,092	$6,619	$6,619	$0
Investments and Loans (33.0)	$0	$0	$0	$0
Grants, subsidies, and contributions (41.0)	$60,066	$51,908	$59,566	$7,658
Insurance claims and indemnities (42.0)	$1,842	$1,915	$1,515	-$400
Interest and dividends (43.0)	$0	$0	$0	$0
Receivables Collected (61.7)	$0	$0	$0	$0
Total Non-Pay Costs	**$1,184,384**	**$1,101,829**	**$1,392,134**	**$150,342**
Total Budget Authority by Object Class	**$2,370,721**	**$2,361,786**	**$2,743,965**	**$242,310**

Food and Drug Administration
User Fee by Object
Dollars in thousands

	2010 Actual	FY 2011 Estimate	2012 Estimate	Increase or Decrease
Personnel compensation:				
Full-time permanent (11.1)	$268,773	301,477	$517,172	$215,695
Other than full-time permanent (11.3)	$39,202	51,046	$79,509	$28,463
Other personnel compensation (11.5)	$19,676	31,915	$40,086	$8,171
Military personnel (11.7)	$20,391	33,611	$43,091	$9,480
Special personnel services payments (11.8)	$417	451	$471	$20
Subtotal personnel compensation	**$348,459**	**$418,499**	**$680,329**	**$261,830**
Civilian benefits (12.1)	$88,560	90,463	$178,423	$87,960
Military benefits (12.2)	$10,752	17,450	$23,522	$6,072
Benefits to former personnel (13.0)	$0			
Total Pay Costs	**$447,771**	**$526,412**	**$882,274**	**$355,862**
Travel and transportation of persons (21.0)	$8,610	14,536	$10,488	-$4,048
Transportation of things (22.0)	$488	614	$982	$368
Rental payments to GSA (23.1)	$32,448	**33,157**	$46,476	$13,319
Rent payments to others (23.2)	$1,308	34,206	$37,576	$3,370
Communication, utilities, and misc. charges (23.3)	$6,045	14,598	$16,160	$1,562
Printing and reproduction (24.0)	$665	752	$1,204	$451
Other Contractual Services:				
Advisory and assistance services (25.1)	$28,051	37,527	$75,404	$37,877
Other services (25.2)	$129,238	134,542	$231,511	$96,969
Purchase of goods and svcs from Govt Acts. (25.3)……	$52,615	59,597	$101,650	$42,053
Operation and maintenance of facilities (25.4)	$53,269	78,510	$103,412	$24,902
Research and Development Contracts (25.5)	$4,317	11,299	$8,499	-$2,800
Medical care (25.6)	$0	$0	$0	$0
Operation and maintenance of equipment (25.7)	$22,419	30,562	$43,515	$12,953
Subsistence and support of persons (25.8)	$0	$0	$0	$0
Subtotal Other Contractual Services	**$289,909**	**$352,037**	**$563,992**	**$274,083**
Supplies and materials (26.0)	$12,882	$13,541	$25,167	$11,626
Equipment (31.0)	$15,175	$20,002	$29,425	$9,423
Land and Structures (32.0)	$0	$0	$0	$0
Investments and Loans (33.0)	$0	$0	$0	$0
Grants, subsidies, and contributions (41.0)	$525	$562	$1,450	$888
Insurance claims and indemnities (42.0)	$649	$755	$1,120	$365
Interest and dividends (43.0)	$0	$2	$2	$0
Refunds (44.0)	$0	$0	$0	$0
Total Non-Pay Costs	**$368,702**	**$484,763**	**$734,042**	**$311,407**
Total User Fee by Object Class	**$816,472**	**$1,011,175**	**$1,616,316**	**$667,269**

Food and Drug Administration
Total Program by Object
Dollars in thousands

	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Increase or Decrease
Personnel compensation:				
Full-time permanent (11.1)	$968,514	$1,044,195	$1,314,048	$269,853
Other than full-time permanent (11.3)	$146,015	$164,457	$201,190	$36,733
Other personnel compensation (11.5)	$74,243	$89,847	$102,242	$12,396
Military personnel (11.7)	$76,645	$93,764	$107,630	$13,866
Special personnel services payments (11.8)	$1,584	$1,736	$1,850	$114
Subtotal personnel compensation	**$1,267,001**	**$1,393,998**	**$1,726,960**	**$1,726,960**
Civilian benefits (12.1)	$326,592	$343,097	$449,479	$106,381
Military benefits (12.2)	$40,515	$49,274	$57,666	$8,393
Benefits to former personnel (13.0)	$0	$0	$0	$0
Total Pay Costs	**$1,634,108**	**$1,786,369**	**$2,234,105**	**$2,234,105**
Travel and transportation of persons (21.0)	$57,420	$55,893	$61,015	$5,122
Transportation of things (22.0)	$5,961	$5,395	$7,044	$1,649
Rental payments to GSA (23.1)	$177,709	$178,718	$214,302	$35,584
Rental payments to others (23.2)	$6,065	$87,189	$123,788	$36,599
Communication, utilities, and misc. charges (23.3)	$76,096	$85,770	$100,185	$14,415
Printing and reproduction (24.0)	$3,420	$3,255	$4,256	$1,001
		$0		$0
Other Contractual Services:		$0		$0
Advisory and assistance services (25.1)	$81,782	$106,378	$143,263	$36,885
Other services (25.2)	$449,947	$378,937	$610,018	$231,081
Purchase of goods and svcs from Govt Acts. (25.3)	$210,772	$189,003	$237,900	$48,897
Operation and maintenance of facilities (25.4)	$146,338	$173,068	$222,946	$49,878
Research and Development Contracts (25.5)	$50,834	$47,624	$48,016	$392
Medical care (25.6)	$0	$0	$0	$0
Operation and maintenance of equipment (25.7)	$37,480	$45,864	$62,949	$17,085
Subsistence and support of persons (25.8)	$0	$0	$0	$0
Subtotal Other Contractual Services	**$977,153**	**$940,874**	**$1,325,092**	**$384,218**
Supplies and materials (26.0)	$59,332	$59,991	$80,705	$20,714
Equipment (31.0)	$112,758	$107,745	$139,516	$31,771
Land and Structures (32.0)	$14,092	$6,619	$6,619	$0
Investments and Loans (33.0)	$0	$0	$0	$0
Grants, subsidies, and contributions (41.0)	$60,591	$52,470	$61,016	$8,546
Insurance claims and indemnities (42.0)	$2,491	$2,670	$2,635	-$35
Interest and dividends (43.0)	$0	$2	$2	$0
Refunds (44.0)		$0		$0
Total Non-Pay Costs	**$1,553,086**	**$1,586,592**	**$2,126,176**	**$539,584**
				$0
Total Program by Object Class	**$3,187,193**	**$3,372,961**	**$4,360,281**	**$2,773,689**

Food and Drug Administration
Salaries and Expenses

	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate	Increase or Decrease
Personnel compensation:				
Full-time permanent (11.1)	$699,741	$742,719	$796,876	$97,135
Other than full-time permanent (11.3)	$106,813	$113,411	$121,681	$14,867
Other personnel compensation (11.5)	$54,567	$57,932	$62,156	$7,589
Military personnel (11.7)	$56,254	$60,153	$64,539	$8,285
Special personnel services payments (11.8)	$1,167	$1,285	$1,378	$212
Subtotal personnel compensation	**$918,542**	**$975,499**	**$1,046,631**	**$128,089**
Civilian benefits (12.1)	$238,032	$252,634	$271,056	$33,024
Military benefits (12.2)	$29,763	$31,824	$34,145	$4,382
Benefits to former personnel (13.0)				
Total Pay Costs	**$1,186,337**	**$1,259,957**	**$1,351,831**	**$165,494**
Travel and transportation of persons (21.0)	$48,810	$41,357	$50,527	$1,718
Transportation of things (22.0)	$5,473	$4,781	$6,061	$588
Rental payments to Others (23.2)	$4,757	$52,983	$86,212	$81,455
Communication, utilities, and misc. charges (23.3)	$70,051	$71,172	$84,025	$13,974
Printing and reproduction (24.0)	$2,755	$2,503	$3,053	$297
Other Contractual Services:				$0
Advisory and assistance services (25.1)	$53,731	$68,851	$67,859	$14,128
Other services (25.2)	$320,709	$244,395	$378,506	$57,798
Purchase of goods and svcs from Govt Acts. (25.3)……..	$158,157	$129,406	$136,250	-$21,907
Operation and maintenance of facilities (25.4)	$93,069	$94,558	$119,534	$26,466
Research and Development Contracts (25.5)	$46,517	$36,325	$39,517	-$7,000
Medical care (25.6)	$0	$0	$0	$0
Operation and maintenance of equipment (25.7)	$15,061	$15,302	$19,434	$4,372
Subsistence and support of persons (25.8)	$0	$0	$0	$0
Subtotal Other Contractual Services	**$687,244**	**$588,837**	**$761,100**	**$73,857**
Supplies and materials (26.0)	$46,450	$46,450	$55,538	$9,088
Total Non-Pay Costs	**$865,541**	**$808,083**	**$1,046,517**	**$180,977**
Total Salary and Expense	**$2,051,878**	**$2,068,040**	**$2,398,348**	**$346,471**
Rental Payments to GSA (23.1)	$145,261	$145,561	$167,826	$22,565
Grand Total, Salaries & Expenses and Rent	**$2,197,138**	**$2,213,601**	**$2,566,174**	**$369,036**
Direct FTE	$9,368	$9,853	$10,135	$767

Food and Drug Administration
Detail of Full-Time Equivalent (FTE) Employment
Program Level

Project[1]	FY 2010 Actual			FY 2011 CR			FY 2012 Estimate		
	Civilian	Military	Total FY 2010 Actual	Civilian	Military	Total FY 2011 CR	Civilian	Military	Total FY 2012 President's Request
Center for Food Safety and Applied Nutrition	836	35	871	836	35	871	1,112	35	1,147
Center for Drug Evaluation and Research	2,739	358	3,097	2,739	358	3,097	3,354	358	3,712
Center for Biologics Evaluation and Research	962	61	1,023	962	61	1,023	1,070	61	1,131
Center for Veterinary Medicine	481	7	488	481	7	488	480	7	487
Center for Devices and Radiological Health	1,236	96	1,332	1,236	96	1,332	1,277	96	1,373
National Center for Toxological Research	246	-	246	246	-	246	215	-	215
Office of Regulatory Affairs	3,936	299	4,235	3,936	299	4,235	4,601	299	4,900
Headquarters and Office of the Commissioner	897	50	947	897	50	947	997	50	1,047
Export Certification	20	-	20	20	-	20	18	-	18
Color Certification	38	-	38	38	-	38	40	-	40
Family Smoking Prevention and Tabacco Control Act	78	6	84	78	6	84	360	6	366
TOTAL	**11,469**	**912**	**12,381**	**11,469**	**912**	**12,381**	**13,524**	**912**	**14,436**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2007	12.3
FY 2008	12.3
FY 2009	12.3
FY 2010	12.2
FY 2011	12.2

[1] *FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE.*

FOOD AND DRUG ADMINISTRATION

DISTRIBUTION OF FTE BY GRADE[1]

	FY 2010 Actuals	FY 2011 CR	FY 2012 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	58	58	75
Total ES			
GS-15	1,102	1,102	1,351
GS-14	2,168	2,168	2,525
GS-13	3,213	3,213	3,437
GS-12	1,703	1,703	2,198
GS-11	668	668	815
GS-10	31	31	67
GS-9	812	812	905
GS-8	136	136	182
GS-7	616	616	734
GS-6	80	80	122
GS-5	140	140	217
GS-4	11	11	32
GS-3	1	1	25
GS-2	-	-	-
GS-1	-	-	-
Subtotal, GS	10,681	10,681	12,610
AL			-
ST/SL			-
RS	15	15	20
CC - 08/07/06	202	202	202
CC - Other	710	710	710
Subtotal, CC	912	912	912
AD (includes Title 42)	476	476	551
Wage Grade	33	33	37
Consultants	205	205	230
Total FTE (End of Year)	12,381	12,381	14,436
Average ES Level	-		-
Average ES Salary	169,300	169,300	174,200
Average GS grade	12	12	12
Average GS salary	132,141	132,141	152,973

[1] *FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPFAR, 6 HCFAC and 11 IDDA FTE.*

PROGRAMS PROPOSED FOR ELIMINATION

FDA has no programs proposed for elimination.

FY 2012 HHS Enterprise Information Technology and Government-Wide E-Gov Initiatives

OPDIV Allocation Statement:

The **FDA** will use **$4,108,238.00** of its **FY 2012** 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, **$590,471.00** is allocated to developmental government-wide E-Government initiatives for **FY 2012**. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Developmental E-Gov Initiatives*	
Line of Business - Human Resources	$22,694.00
Line of Business - Grants Management	$1,351.00
Line of Business - Financial	$18,063.00
Line of Business - Budget Formulation and Execution	$13,263.00
Disaster Assistance Improvement Plan	$0.00
Federal Health Architecture	$535,100.00
Line of Business - Geospatial	$0.00
FY 2012 Developmental E-Gov Initiatives Total	**$590,471.00**

* 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, **$422,387.00** is allocated to ongoing government-wide E-Government initiatives for **FY 2012**. This amount supports these government-wide E-Government initiatives as follows:

FY 2012 Ongoing E-Gov Initiatives*	
E-Rule Making	$313,849.00
GovBenefits	$00.00
Integrated Acquisition Environment	$77,779.00
Grants.gov	$30,759.00
FY 2012 Ongoing E-Gov Initiatives Total	**$422,387.00**

* Specific levels presented here are subject to change, as redistributions to meet changes in resource demands are assessed.

FDA FY 2012 Exhibit 300: Capital Asset and Business Case Summaries can be found at http://itdashboard.gov/.

Food and Drug Administration
FY 2012 Congressional Budget Request
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FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

	PREMARKET													
FY 2010 Actual					OUTREACH COORDINATION				INSPECTIONS					
	REVIEW		APPLIED RESEARCH		DOMESTIC		FOREIGN		DOMESTIC		FOREIGN		TOTAL	
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS														
Center for Food Safety & Applied Nutrition	17,824	102	9,094	27	13,984	80	4,395	31					45,297	240
Field Activities													-	-
FOODS TOTAL	**17,824**	**102**	**9,094**	**27**	**13,984**	**80**	**4,395**	**31**	**-**	**-**	**-**	**-**	**45,297**	**240**
HUMAN DRUGS														
Center for Drug Evaluation & Research	433,984	1,978	40,997	78	27,171	116	9,330	38	8,848	42	8,908	43	529,238	2,295
Field Activities									*22,277*	*132*	*17,333*	*94*	39,610	226
PDUFA (non-add): Center	*275,330*	*1,303*	*15,781*	*46*	*16,936*	*78*	*6,630*	*27*	*6,137*	*30*	*4,934*	*24*	325,748	1,508
Field									*3,539*	*32*	*2,800*	*17*	6,339	49
HUMAN DRUGS TOTAL	**433,984**	**1,978**	**40,997**	**78**	**27,171**	**116**	**9,330**	**38**	**31,125**	**174**	**26,241**	**137**	**568,848**	**2,521**
BIOLOGICS														
Center for Biologics Evaluation & Research	161,215	639	22,346	145	25,856	99	701	2	2,261	8			*212,379*	*893*
Field Activities									2,139	19	204	1	*2,343*	*20*
PDUFA (non-add): Center	*64,058*	*284*			*10,184*	*45*	-	-	*704*	*3*			*74,946*	*332*
Field									*1,685*	*5*	-	-	*1,685*	*5*
MDUFMA (non-add): Center	*6,098*	*26*			*777*	*3*	*12*	-					*6,887*	*29*
Field									*383*	-	-	-	*383*	-
BIOLOGICS TOTAL	**161,215**	**639**	**22,346**	**145**	**25,856**	**99**	**701**	**2**	**4,400**	**27**	**204**	**1**	**214,722**	**913**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	53,269	256	3,022	18	684	4							*56,975*	*278*
Field Activities									2,027	9	822	4	*2,849*	*13*
ADUFA (non-add): Center	*14,644*	*65*								-			*14,644*	*65*
Field									*546*	*2*	-	-	*546*	*2*
AGDUFA (non-add): Center	4,225	22											*4,225*	*22*
Field									*144*	*1*	-	-	*144*	*1*
ANIMAL DRUGS & FEEDS TOTAL	**53,269**	**256**	**3,022**	**18**	**684**	**4**	**-**	**-**	**2,027**	**9**	**822**	**4**	**59,824**	**291**
DEVICES AND RADIOLOGICAL HEALTH													-	-
Center for Devices & Radiological Health	138,409	713	15,905	58	8,338	45	1,958	11					*164,610*	*827*
Field Activities									8,317	46	543	2	*8,860*	*48*
MQSA (non-add): Center													-	-
Field									-				-	-
MDUFMA (non-add): Center	29,047	174	2,154	9	1,725	11	403	2					*33,329*	*196*
Field									1,442	13			*1,442*	*13*
DEVICES TOTAL	**138,409**	**713**	**15,905**	**58**	**8,338**	**45**	**1,958**	**11**	**8,317**	**46**	**543**	**2**	**173,470**	**875**
CENTER FOR TOBACCO PRODUCTS													-	-
Center for Tobacco Products	50	-			1	-	6	-					*57*	-
Field Activities													-	-
CENTER FOR TOBACCO PRODUCTS TOTAL	**50**	**-**	**-**	**-**	**1**	**-**	**6**	**-**	**-**	**-**	**-**	**-**	**57**	**-**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**36,874**	**157**									***36,874***	***157***
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**47,987**	**287**	**11,039**	**220**	**5,224**	**42**	**1,118**	**5**	**3,490**	**15**	**2,012**	**9**	**70,870**	**578**
USER FEES (non-add): PDUFA	*18,570*	*124*	*675*	*4*	*1,631*	*9*	*400*	*2*	*1,060*	*5*	*571*	*3*	*22,907*	*147*
MQSA	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
MDUFMA	*1,901*	*17*	*240*	*1*	*354*	*1*	*49*	*0*	*200*	*1*	*0*	*0*	*2,744*	*20*
ADUFA	*618*	*4*	*0*	*0*	*0*	*0*	*0*	*0*	*11*	*0*	*0*	*0*	*629*	*4*
AGDUFA	*152*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*6*	*0*	*0*	*0*	*158*	*1*
Center of Tobacco Product	*2,321*	*15*	-	-	-	-	-	-	-	-	-	-	**2,321**	**15**
HEADQUARTERS / OC TOTAL	**47,987**	**287**	**11,039**	**220**	**5,224**	**42**	**1,118**	**5**	**3,490**	**15**	**2,012**	**9**	**70,870**	**578**
SUB-TOTAL:	**852,738**	**3,975**	**102,403**	**546**	**81,258**	**386**	**17,508**	**87**	**49,359**	**271**	**29,822**	**153**	**1,133,031**	**5,418**
Total Center	852,738	3,975	102,403	546	81,258	386	17,508	87	14,599	65	10,920	52	1,079,426	5,111
Total Field	-	-	-	-	-	-	-	-	34,760	206	18,902	101	53,662	307
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA	*414,643*	*2,020*	*18,850*	*60*	*31,607*	*147*	*7,494*	*31*	*15,857*	*92*	*8,305*	*44*	496,756	2,394
User Fees - non add)														
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
Other Rent and Rent Related PDUFA (non-add)														
Other Rent and Rent Related MDUFMA (non-add)														
Other Rent and Rent Related ADUFA (non-add)														
Other Rent and Rent Related AGDUFA (non-add)														
Other Rent and Rent Related Tobacco (non-add)														
GSA Rent														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
GSA Rent AGDUFA (non-add)														
GSA Rent Tobacco (non-add)														
Export certification User Fee														
Color Certification User Fee														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

	POSTMARKET																	
FY 2010 Actual	**COORDINATION**				**LABORATORY ANALYSIS**				**INSPECTIONS**									
	COMPLIANCE		**APPLIED RESEARCH**		**DOMESTIC**		**IMPORTS**		**DOMESTIC**		**FOREIGN**		**IMPORTS**		**TOTAL**		**FDA**	
	$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	101,087	390	53,940	138	13,085	31	10,988	27	3,866	15	5,094	24	2,997	6	191,057	631	236,354	871
Field Activities	128,001	551	1,099	5	84,084	321	81,285	387	110,401	607	20,819	87	121,135	558	546,824	2,516	546,824	2,516
FOODS TOTAL	**229,088**	**941**	**55,039**	**143**	**97,169**	**352**	**92,273**	**414**	**114,267**	**622**	**25,913**	**111**	**124,132**	**564**	**737,881**	**3,147**	**783,178**	**3,387**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	177,131	616	18,275	68	3,999	18	747	3	10,483	51	7,295	36	2,032	10	219,962	802	749,200	3,097
Field Activities	29,883	166			14,631	71	3,801	21	30,335	166	8,363	54	7,636	34	94,649	512	134,259	738
PDUFA (non-add): Center	*89,129*	*341*													89,129	341	414,877	1,849
Field															-	-	6,339	49
HUMAN DRUGS TOTAL	**207,014**	**782**	**18,275**	**68**	**18,630**	**89**	**4,548**	**24**	**40,818**	**217**	**15,658**	**90**	**9,668**	**44**	**314,611**	**1,314**	**883,459**	**3,835**
BIOLOGICS																		
Center for Biologics Evaluation & Research	34,759	121	226	1					2,052	8					37,037	130	249,416	1,023
Field Activities	7,928	43							28,177	149	2,157	8	1,409	7	39,671	207	42,014	227
PDUFA (non-add): Center	*1,835*	*9*													1,835	9	76,781	341
Field															-	-	*1,685*	*5*
MDUFMA (non-add): Center	*152*	*1*													152	1	7,039	30
Field															-	-	*383*	*0*
BIOLOGICS TOTAL	**42,687**	**164**	**226**	**1**	**-**	**-**	**-**	**-**	**30,229**	**157**	**2,157**	**8**	**1,409**	**7**	**76,708**	**337**	**291,430**	**1,250**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	35,685	161	8,127	49											43,812	210	*100,787*	*488*
Field Activities	17,042	73			6,098	33	1,302	7	17,337	111	1,276	16	7,228	26	50,283	266	53,132	279
ADUFA (non-add): Center															-	-	*14,644*	*65*
Field															-	-	546	*2*
AGDUFA (non-add): Center															-	-	*4,225*	*22*
Field															-	-	144	*1*
ANIMAL DRUGS & FEEDS TOTAL	**52,727**	**234**	**8,127**	**49**	**6,098**	**33**	**1,302**	**7**	**17,337**	**111**	**1,276**	**16**	**7,228**	**26**	**94,095**	**476**	**153,919**	**767**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	98,116	439	1,893	10	14,532	56									114,541	505	279,151	1,332
Field Activities	22,194	129			4,634	18	2,821	14	37,880	176	7,356	31	7,075	53	81,960	421	90,820	469
MQSA (non-add): Center	*4,284*	*23*													4,284	23	4,284	23
Field	*5,253*	*5*							*4,257*	*3*					9,510	8	*9,510*	*8*
MDUFMA (non-add): Center	*7,280*	*32*	*21*	*0*	*652*	*4*									7,953	36	41,282	232
Field															-	-	*1,442*	*13*
DEVICES TOTAL	**120,310**	**568**	**1,893**	**10**	**19,166**	**74**	**2,821**	**14**	**37,880**	**176**	**7,356**	**31**	**7,075**	**53**	**196,501**	**926**	**369,971**	**1,801**
CENTER FOR TOBACCO PRODUCTS																		
Center for Tobacco Products	45,870	62	13,908	19	2,520	3			-						62,298	84	62,355	84
Field Activities	767	3					753	1	-	0			543	2	2,063	6	2,063	6
CENTER FOR TOBACCO PRODUCTS TOTAL	**46,637**	**65**	**13,908**	**19**	**2,520**	**3**	**753**	**1**	**-**	**-**	**-**	**-**	**543**	**2**	**64,361**	**90**	**64,418**	**90**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			21,657	89											21,657	89	58,531	246
															21,657	**89**	**58,531**	**246**
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**46,459**	**161**	**11,823**	**16**	**10,263**	**33**	**7,174**	**27**	**17,351**	**76**	**3,705**	**15**	**10,655**	**41**	**107,430**	**369**	**178,300**	**947**
USER FEES (non-add): PDUFA	*6,046*	*25*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*6,046*	*25*	*28,953*	*172*
MQSA	*197*	*2*	*0*	*0*	*0*	*0*	*0*	*0*	*73*	*0*	*0*	*0*	*0*	*0*	*270*	*2*	*270*	*2*
MDUFMA	*777*	*3*	*0*	*0*	*64*	*0*	*0*	*0*	*7*	*0*	*0*	*0*	*0*	*0*	*848*	*3*	*3,592*	*23*
ADUFA	*0*	*0*	*2*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*2*	*0*	*631*	*4*
AGDUFA	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*158*	*1*
Center of Tobacco Product	-	-	*1,054*	*8*	-	-	-	-	-	-	-	-	-	-	*1,054*	*8*	*3,375*	*23*
HEADQUARTERS / OC TOTAL	**46,459**	**161**	**11,823**	**16**	**10,263**	**33**	**7,174**	**27**	**17,351**	**76**	**3,705**	**15**	**10,655**	**41**	**107,430**	**369**	**178,300**	**947**
SUB-TOTAL:	**744,922**	**2,915**	**109,291**	**306**	**153,846**	**584**	**108,871**	**487**	**257,882**	**1,359**	**56,065**	**271**	**160,710**	**737**	**1,548,883**	**6,658**	**2,783,206**	**12,323**
Total Center	539,107	1,950	108,192	301	44,399	141	18,909	57	33,752	150	16,094	75	15,684	57	776,137	2,731	1,914,094	8,088
Total Field	205,048	962	1,099	5	109,447	443	89,209	429	224,130	1,209	39,971	196	145,026	680	813,930	3,924	869,112	4,235
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA	*114,953*	*441*	*23*	-	*716*	*4*	-	-	*4,337*	*3*	-	-	-	-	120,029	448	748,265	3,013
User Fees - non add)																		
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocation)																	**124,204**	0
Other Rent and Rent Related PDUFA (non-add)																	*18,991*	*0*
Other Rent and Rent Related MDUFMA (non-add)																	*1,087*	*0*
Other Rent and Rent Related ADUFA (non-add)																	*121*	*0*
Other Rent and Rent Related AGDUFA (non-add)																	*105*	*0*
Other Rent and Rent Related Tobacco (non-add)																	*503*	
GSA Rent																	**177,709**	**0**
GSA Rent PDUFA (non-add)																	*25,632*	*0*
GSA Rent MDUFMA (non-add)																	*2,361*	*0*
GSA Rent ADUFA (non-add)																	*659*	*0*
GSA Rent AGDUFA (non-add)																	*105*	*0*
GSA Rent Tobacco (non-add)																	*3,691*	
Export certification User Fee																	*3,663*	*20*
Color Certification User Fee																	6,768	38
Buildings and Facilities																	**22,111**	0
TOTAL S&E PROGRAM:																	**3,117,661**	**12,381**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2011 Continuing Resolution	PREMARKET													
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION				INSPECTIONS				TOTAL	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN			
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS														
Center for Food Safety & Applied Nutrition	12,893	102	7,504	27	9,811	80	8,327	31					38,535	240
Field Activities													-	-
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	**12,893**	**102**	**7,504**	**27**	**9,811**	**80**	**8,327**	**31**	**-**	**-**	**-**	**-**	**38,535**	**240**
HUMAN DRUGS														
Center for Drug Evaluation & Research	472,654	1,978	42,176	78	29,453	116	10,135	38	9,618	42	9,524	43	573,560	2,295
Field Activities									25,063	132	17,791	94	42,854	226
PDUFA (non-add): Center	*314,077*	*1,303*	*16,963*	*46*	*19,222*	*78*	*7,437*	*27*	*6,908*	*30*	*5,551*	*24*	370,158	1,508
Field									*6,325*	*32*	*3,258*	*17*	9,583	49
Proposed GDUFA (non-add): Center	*0*												0	-
Field	*0*												0	-
Proposed Reinspection user fee (non-add): Field													-	-
Proposed International Courier User Fee (non-add): Center													-	-
HUMAN DRUGS TOTAL	**472,654**	**1,978**	**42,176**	**78**	**29,453**	**116**	**10,135**	**38**	**34,681**	**174**	**27,315**	**137**	**616,414**	**2,521**
BIOLOGICS														
Center for Biologics Evaluation & Research	184,479	639	22,346	145	28,602	99	770	2	2,496	8			238,693	893
Field Activities									4,913	19	204	1	5,117	20
PDUFA (non-add): Center	*80,611*	*284*			*12,816*	*45*			*887*	*3*			94,314	332
Field									*4,025*	*5*	-		4,025	5
MDUFMA (non-add): Center	*9,588*	*26*			*1,221*	*3*	*10*		*10*	-			10,829	29
Field									*507*	-	-		507	-
Proposed Reinspection user fee (non-add): Field													-	-
BIOLOGICS TOTAL	**184,479**	**639**	**22,346**	**145**	**28,602**	**99**	**770**	**2**	**7,409**	**27**	**204**	**1**	**243,810**	**913**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	54,098	256	3,024	18	685	4							57,807	278
Field Activities									1,730	9	822	4	2,552	13
ADUFA (non-add): Center	*15,290*	*65*											15,290	65
Field									*250*	*2*	-	-	250	2
AGDUFA (non-add): Center	*4,382*	*22*											4,382	22
Field									*143*	*1*	-	-	143	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	**54,098**	**256**	**3,024**	**18**	**685**	**4**	**-**	**-**	**1,730**	**9**	**822**	**4**	**60,359**	**291**
DEVICES AND RADIOLOGICAL HEALTH													-	-
Center for Devices & Radiological Health	132,629	713	15,487	58	7,995	45	1,875	11					*157,986*	*827*
Field Activities									7,943	46	543	2	*8,486*	*48*
MQSA (non-add): Center													-	-
Field													-	-
MDUFMA (non-add): Center	*23,102*	*174*	*1,713*	*9*	*1,372*	*11*	*322*	*2*					*26,509*	*196*
Field									*997*	*13*			*997*	*13*
Proposed Reinspection user fee (non-add): Field													-	-
Proposed International Courier User Fee (non-add): Center														
DEVICES TOTAL	**132,629**	**713**	**15,487**	**58**	**7,995**	**45**	**1,875**	**11**	**7,943**	**46**	**543**	**2**	**166,472**	**875**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**38,184**	**157**									***38,184***	***157***
Proposed Reinspection user fee (non-add): Center													-	-
CENTER FOR TOBACCO PRODUCTS													-	-
Center for Tobacco Products	29,655	-	10,591	-	7,414	-	1,058	-	3,707	-	530	-	*52,955*	-
Field													-	-
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**64,457**	**322**	**19,520**	**34**	**4,597**	**29**	**1,268**	**7**	**3,109**	**22**	**1,735**	**12**	**94,685**	**426**
USER FEES (non-add): PDUFA	*27,700*	*122*	*1,191*	*4*	*2,249*	*9*	*522*	*2*	*1,274*	*5*	*618*	*3*	**33,554**	**145**
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA	*4,253*	*17*	*223*	*1*	*337*	*1*	*43*	-	*197*	*1*	-	-	**5,053**	**20**
ADUFA	*682*	*4*	-	-	-	-	-	-	*11*	-	-	-	**693**	**4**
Proposed GDUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AGDUFA	*198*	*1*	-	-	-	-	-	-	*6*	-	-	-	**204**	**1**
TOBACC C	*2,007*	-	*717*	-	*502*	-	*72*	-	*251*	-	*36*	-	**3,585**	-
Food Reinspection user fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Recall User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed Reinspection User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed International Courier User Fee														
Proposed Food VQIP User Fee														
HEADQUARTERS / OC TOTAL	**64,457**	**322**	**19,520**	**34**	**4,597**	**29**	**1,268**	**7**	**3,109**	**22**	**1,735**	**12**	**5,053**	**20**
SUB-TOTAL:	**950,865**	**4,010**	**120,648**	**360**	**88,557**	**373**	**23,433**	**89**	**58,579**	**278**	**31,149**	**156**	**1,183,598**	**4,860**
Total Center	921,210	4,010	110,057	360	81,143	373	22,375	89	15,223	72	11,259	55	1,071,634	4,553
Total Field	-	-	-	-	-	-	-	-	39,649	206	19,360	101	59,009	307
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees	*447,050*	*1,874*	*18,676*	*55*	*34,631*	*137*	*7,769*	*29*	*20,052*	*86*	*8,809*	*41*	*536,987*	*2,222*
User Fees - non add)														
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
White Oak Relocation PDUFA (non-add)														
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)														
Other Rent and Rent Related PDUFA (non-add)														
Other Rent and Rent Related ADUFA (non-add)														
Other Rent and Rent Related for Proposed GDUFA (non-add)														
Other Rent and Rent Related AGDUFA (non-add)														
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)														
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														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
GSA Rent for Proposed GDUFA (non-add)														
GSA Rent AGDUFA (non-add)														
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)														
GSA Rent for Recall User Fee (non-add)														
GSA Rent for Proposed International Courier User Fee (non-add)														
Export Certification User Fee														
Colors Certification User Fee														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2011 Continuing Resolution	POSTMARKET																	
	OUTREACH COORDINATION		APPLIED RESEARCH		LABORATORY ANALYSIS				INSPECTIONS						TOTAL		FDA	
	COMPLIANCE				DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS					
	$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	121,586	390	45,932	138	10,581	31	10,511	27	2,712	15	3,574	24	2,569	6	197,465	631	236,000	871
Field Activities	127,159	551	1,100	5	84,187	321	81,385	387	109,489	607	20,845	87	121,284	558	545,449	2,516	545,449	2,516
Export Certification User Fee: (non-add):Center															-	-	*0*	*0*
Field															-	-	*0*	*0*
Reinspection User Fee (non-add)															-	-	*0*	*0*
Recall User Fee(non-add): Center																		
Field																		
Proposed International Courier User Fee (non-add): Center															-	-	*0*	*0*
Proposed Food VQIP user fee (non-add): Center															-	-	*0*	*0*
Field															-	-	*0*	*0*
FOODS TOTAL	**248,745**	**941**	**47,032**	**143**	**94,768**	**352**	**91,896**	**414**	**112,201**	**622**	**24,419**	**111**	**123,853**	**564**	**742,914**	**3,147**	**781,449**	**3,387**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	187,370	616	18,270	68	3,998	18	747	3	10,479	51	7,292	36	2,031	10	*230,187*	*802*	803,747	3,097
Field Activities	29,408	166			14,631	71	3,801	21	30,564	166	8,363	54	7,636	34	*94,403*	*512*	*137,257*	*738*
PDUFA (non-add): Center	*99,401*	*341*													*99,401*	*341*	*469,559*	*1,849*
Field															-	-	*9,583*	*49*
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	**216,778**	**782**	**18,270**	**68**	**18,629**	**89**	**4,548**	**24**	**41,043**	**217**	**15,655**	**90**	**9,667**	**44**	**324,590**	**1,314**	**941,004**	**3,835**
BIOLOGICS																		
Center for Biologics Evaluation & Research	32,015	121	226	1					2,248	8					34,489	130	273,182	1,023
Field Activities	7,781	43							28,141	149	2,157	8	1,409	7	39,488	207	*44,605*	*227*
PDUFA (non-add): Center	*2,310*	*9*													2,310	9	*96,624*	*341*
Field															-	-	*4,025*	*5*
MDUFMA (non-add): Center	*239*	*1*													239	1	*11,068*	*30*
Field															-	-	*507*	*0*
Proposed Reinspection user fee (non-add): Field															-	-	*0*	*0*
BIOLOGICS TOTAL	**39,796**	**164**	**226**	**1**	**-**	**-**	**-**	**-**	**30,389**	**157**	**2,157**	**8**	**1,409**	**7**	**73,977**	**337**	**317,787**	**1,250**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	35,710	161	8,135	49											43,845	210	101,652	488
Field Activities	17,033	73			6,098	33	1,302	7	17,722	111	1,276	16	7,228	26	50,659	266	53,211	279
ADUFA (non-add): Center															-	-	*15,290*	*65*
Field															-	-	*250*	*2*
AGDUFA (non-add): Center															-	-	*4,382*	*22*
Field															-	-	*143*	*1*
Reinspection user fee (non-add):															-	-	*0*	*0*
Recall User Fee(non-add): Center															-	-		
Field															-	-		
Proposed Food Inspection and Facility Registration user fee (non-add): Center															-	-	*0*	*0*
Field															-	-	*0*	*0*
Export Certification User Fee(non-add): Center															-	-	*0*	*0*
ANIMAL DRUGS & FEEDS TOTAL	**52,743**	**234**	**8,135**	**49**	**6,098**	**33**	**1,302**	**7**	**17,722**	**111**	**1,276**	**16**	**7,228**	**26**	**94,504**	**476**	**154,863**	**767**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	98,474	439	1,892	10	14,419	56									114,785	505	272,771	1,332
Field Activities	24,406	129			4,634	18	2,821	14	39,351	176	7,356	31	7,075	53	85,643	421	94,129	469
MQSA (non-add): Center	*6,003*	*23*													6,003	23	*6,003*	*23*
Field	*7,223*	*5*							*5,854*	*3*					13,077	8	*13,077*	*8*
MDUFMA (non-add): Center	*5,791*	*32*	*17*	-	*519*	*4*									6,327	36	*32,836*	*232*
Field									*52*	-					52	-	*1,049*	*13*
Proposed Reinspection user fee (non-add): Field															-	-	*0*	*0*
Proposed International Courier User Fee (non-add): Center															-	-	*0*	*0*
DEVICES TOTAL	**122,880**	**568**	**1,892**	**10**	**19,053**	**74**	**2,821**	**14**	**39,351**	**176**	**7,356**	**31**	**7,075**	**53**	**200,428**	**926**	**366,900**	**1,801**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**-**	**-**	**20,561**	**89**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	20,561	89	**58,745**	**246**
Proposed Reinspection user fee (non-add): Center		-			-	-	-	-	-	-	-	-	-	-	-	-	0	0
CENTER FOR TOBACCO PRODUCTS															**163,568**	**90**	**216,523**	**90**
Center for Tobacco Products	63,547	62	52,956	19	42,365	3									**158,868**	**84**	*211,823*	84
Field	**1,748**	**3**					**1,716**	**1**					**1,236**	**2**	**4,700**	**6**	4,700	6
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**40,895**	**229**	**26,512**	**17**	**8,321**	**47**	**6,040**	**39**	**14,456**	**109**	**3,055**	**22**	**8,962**	**59**	**108,241**	**521**	**202,926**	**947**
USER FEES (non-add): PDUFA	*7,139*	*27*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*7,139*	*27*	*40,693*	*172*
MQSA (HQ / OC)	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*784*	*3*	*2*	-	*68*	-	-	-	*7*	-	-	-	-	-	*861*	*3*	*5,914*	*23*
ADUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*693*	*4*
Proposed GDUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*0*	*0*
AGDUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*204*	*1*
TOBACC C	*4,301*	*17*	*3,584*	*5*	*2,867*	*1*	-	-	-	-	-	-	-	-	*10,752*	*23*	*14,336*	*23*
Food Reinspection user fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*0*	*0*
Recall User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*0*	*0*
Proposed Reinspection User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*0*	*0*
Proposed International Courier User Fee																		
Proposed Food VQIP User Fee																		
HEADQUARTERS / OC TOTAL	**40,895**	**229**	**26,512**	**17**	**8,321**	**47**	**6,040**	**39**	**14,456**	**109**	**3,055**	**22**	**8,962**	**59**	**108,241**	**521**	**202,926**	**947**
SUB-TOTAL:	**787,132**	**2,983**	**155,023**	**307**	**189,234**	**598**	**108,323**	**499**	**255,162**	**1,392**	**53,918**	**278**	**159,430**	**755**	**1,728,783**	**6,900**	**3,040,197**	**12,323**
Total Center	516,050	1,956	100,967	283	37,319	152	17,298	69	29,895	183	13,921	82	13,562	75	729,012	2,799	2,160,846	8,088
Total Field	205,787	962	1,100	5	109,550	443	89,309	429	225,267	1,209	39,997	196	144,632	678	815,642	3,922	879,351	*4,235*
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees	*122,715*	*414*	*17*	-	*519*	*4*	*1,716*	*1*	5,906	*3*	-	-	*1,236*	*2*	*132,109*	*424*	$1,011,175	3,013
User Fees - non add)																		
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocation)																	**133,017**	**-**
White Oak Relocation PDUFA (non-add)																	3,415	
White Oak Relocation Reinspection User Fee (non-add)																	0	
White Oak Relocation Proposed Reinspection User Fee (non-add)																	0	
Other Rent and Rent Related MDUFMA (non-add)																	1,376	-
Other Rent and Rent Related PDUFA (non-add)																	23,253	-
Other Rent and Rent Related ADUFA (non-add)																	165	-
Other Rent and Rent Related for Proposed GDUFA (non-add)																	0	-
Other Rent and Rent Related AGDUFA (non-add)																	72	-
Other Rent and Rent Related Food Reinspection User Fee (non-add)																	0	-
Other Rent and Rent Related Proposed Reinspection User Fee (non-add)																	0	
Other Rent and Rent Related for Center of Tobacco (non-add)																	1,343	
Other Rent and Rent Related for Recall User Fee (non-add)																	0	
Other Rent and Rent Related for Proposed International Courier User Fee (non-add)																	0	
Other Rent and Rent Related for Proposed Food VQIP User Fee (non-add)																	0	
GSA Rent																	**173,417**	**-**
GSA Rent PDUFA (non-add)																	19,905	-
GSA Rent MDUFMA (non-add)																	4,264	-
GSA Rent ADUFA (non-add)																	885	-
GSA Rent for Proposed GDUFA (non-add)																	0	-
GSA Rent AGDUFA (non-add)																	305	-
GSA Rent Food Reinspection User Fee (non-add)																	0	-
GSA Rent Proposed Reinspection User Fee (non-add)																	0	-
GSA Rent Proposed Food VQIP User Fee (non-add)																	0	-
GSA Rent for Center of Tobacco (non-add)																	2,798	
GSA Rent for Recall User Fee (non-add)																	0	
GSA Rent for Proposed International Courier User Fee (non-add)																	0	
Export Certification User Fee																	**2,700**	**20**
Colors Certification User Fee																	**7,700**	**38**
Buildings and Facilities																	**15,930**	
TOTAL S&E PROGRAM:																	**3,372,961**	**12,381**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2012 President's Budget	PREMARKET													
	REVIEW		APPLIED RESEARCH		OUTREACH COORDINATION				INSPECTIONS				TOTAL	
					DOMESTIC		FOREIGN		DOMESTIC		FOREIGN			
	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE
FOODS														
Center for Food Safety & Applied Nutrition	12,893	96	7,504	30	9,811	83	8,327	33	0	0	0	0	38,535	242
Field Activities													-	
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	**12,893**	**96**	**7,504**	**30**	**9,811**	**83**	**8,327**	**33**	**-**	**-**	**-**	**-**	**38,535**	**242**
HUMAN DRUGS														
Center for Drug Evaluation & Research	603,523	2,353	45,020	86	34,291	132	11,812	44	11,481	47	11,006	47	717,133	2,709
Field Activities									30,724	146	23,363	109	54,087	255
PDUFA (non-add): Center	*409,307*	*1,512*	*19,838*	*52*	*24,097*	*90*	*9,125*	*32*	*8,783*	*34*	*7,051*	*27*	478,201	1,747
Field									*8,144*	*38*	*4,154*	*20*	12,298	58
Proposed GDUFA (non-add): Center	*19,200*	*36*											19,200	36
Field									*3,368*	*6*	*3,369*	*6*	6,737	12
Proposed Reinspection user fee (non-add): Field													-	-
Proposed International Courier User Fee (non-add): Center													-	
HUMAN DRUGS TOTAL	**603,523**	**2,353**	**45,020**	**86**	**34,291**	**132**	**11,812**	**44**	**42,205**	**193**	**34,369**	**156**	**771,220**	**2,964**
BIOLOGICS														
Center for Biologics Evaluation & Research	215,355	698	27,753	163	33,395	108	883	3	2,901	10			280,287	982
Field Activities									6,579	24	422	2	7,001	26
PDUFA (non-add): Center	*103,449*	*332*			*16,447*	*53*	-	-	*1,138*	*4*			121,034	389
Field									5,165	*6*			5,165	6
MDUFMA (non-add): Center	*11,287*	*27*			*1,437*	*4*	*12*	-	*12*	-			12,748	31
Field									*597*	*4*			597	4
Proposed Reinspection user fee (non-add): Field													-	-
BIOLOGICS TOTAL	**215,355**	**698**	**27,753**	**163**	**33,395**	**108**	**883**	**3**	**9,480**	**34**	**422**	**2**	**287,288**	**1,008**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	60,330	248	3,148	16	678	4							64,156	268
Field Activities									1,815	9	824	4	2,639	13
ADUFA (non-add): Center	*19,261*	*66*											19,261	66
Field									*315*	*2*			315	2
AGDUFA (non-add): Center	*4,898*	*20*											4,898	20
Field									*160*	*1*			160	1
Reinspection user fee (non-add):													-	-
Recall User Fee(non-add): Center														
Field														
													-	-
Proposed Reinspection user fee (non-add): field													-	-
Field													-	-
Export Certification User Fee(non-add): Center													-	-
ANIMAL DRUGS & FEEDS TOTAL	**60,330**	**248**	**3,148**	**16**	**678**	**4**	**-**	**-**	**1,815**	**9**	**824**	**4**	**66,795**	**281**
DEVICES AND RADIOLOGICAL HEALTH													-	-
Center for Devices & Radiological Health	142,365	726	17,399	66	8,091	45	1,898	10					169,753	847
Field Activities									8,353	48	544	2	8,897	50
MQSA (non-add): Center													-	-
Field													-	-
MDUFMA (non-add): Center	*27,198*	*183*	*2,016*	*9*	*1,615*	*11*	*379*	*3*					31,208	206
Field									*1,174*	*14*			1,174	14
Proposed Reinspection user fee (non-add): Field													-	-
Proposed International Courier User Fee (non-add): Center													-	-
DEVICES TOTAL	**142,365**	**726**	**17,399**	**66**	**8,091**	**45**	**1,898**	**10**	**8,353**	**48**	**544**	**2**	**178,650**	**897**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**34,970**	**116**									**34,970**	**116**
Proposed Reinspection user fee (non-add): Center													-	-
CENTER FOR TOBACCO PRODUCTS													-	-
Center for Tobacco Products	61,670	51	22,025	18	23,418	13	2,203	2	7,709	6	1,101	1	*118,126*	*91*
Field													-	-
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**101,282**	**297**	**22,600**	**200**	**5,867**	**24**	**1,559**	**6**	**4,207**	**19**	**2,459**	**11**	**137,974**	**557**
USER FEES (non-add): PDUFA	*35,990*	*141*	*1,392*	*4*	*2,846*	*11*	*640*	*2*	*1,630*	*6*	*786*	*4*	**43,284**	**168**
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA	*5,005*	*18*	*262*	*1*	*397*	*1*	*51*	-	*232*	*1*	-	-	**5,947**	**21**
ADUFA	*859*	*4*	-	-	-	-	-	-	*14*	-	-	-	**873**	**4**
Proposed GDUFA	*701*	*3*	-	-	-	-	-	-	*123*	-	*123*	-	**947**	**3**
AGDUFA	*221*	*1*	-	-	-	-	-	-	*7*	-	-	-	**228**	**1**
TOBACCO	*2,089*	*5*	*746*	*2*	*793*	*1*	*75*	-	*261*	*1*	*37*	-	**4,001**	**9**
Food Reinspection user fee	*3,210*	*6*	-	-	-	-	-	-	-	-	-	-	**3,210**	**6**
Recall User Fee	*661*	*2*	-	-	-	-	-	-	-	-	-	-	**661**	**2**
Proposed Reinspection User Fee	*5,902*	*10*	-	-	-	-	-	-	-	-	-	-	**5,902**	**10**
Proposed International Courier User Fee	*276*	*1*	-	-	-	-	-	-	-	-	-	-	**276**	**1**
Proposed Food VQIP User Fee	*3,523*	*9*	*47*	-	-	*1*	*22*	-	*55*	*1*	*27*	-	**3,674**	**11**
HEADQUARTERS / OC TOTAL	**101,282**	**297**	**22,600**	**200**	**5,867**	**24**	**1,559**	**6**	**4,207**	**19**	**2,459**	**11**	**5,947**	**21**
SUB-TOTAL:	**1,197,418**	**4,469**	**145,449**	**579**	**115,551**	**409**	**26,682**	**98**	**73,769**	**309**	**39,719**	**176**	**1,466,561**	**5,504**
Total Center	1,135,748	4,418	123,424	561	92,133	396	24,479	96	18,589	76	13,465	58	1,275,811	5,069
Total Field	-	-	-	-	-	-	-	-	47,471	227	25,153	117	72,624	344
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees	*594,600*	*2,176*	*21,854*	*61*	*43,596*	*158*	*9,516*	*35*	*28,856*	*109*	*14,574*	*53*	*712,996*	*2,592*
User Fees - non add)														
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
White Oak Relocation PDUFA (non-add)														
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)														
Other Rent and Rent Related PDUFA (non-add)														
Other Rent and Rent Related ADUFA (non-add)														
Other Rent and Rent Related for Proposed GDUFA (non-add)														
Other Rent and Rent Related AGDUFA (non-add)														
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)														
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														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
GSA Rent for Proposed GDUFA (non-add)														
GSA Rent AGDUFA (non-add)														
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)														
GSA Rent for Recall User Fee (non-add)														
GSA Rent for Proposed International Courier User Fee (non-add)														
Export Certification User Fee														
Colors Certification User Fee														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2012 President's Budget	POSTMARKET																	
	OUTREACH COORDINATION				LABORATORY ANALYSIS				INSPECTIONS									
	COMPLIANCE		APPLIED RESEARCH		DOMESTIC		IMPORTS		DOMESTIC		FOREIGN		IMPORTS		TOTAL		FDA	
	$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	163,379	582	67,863	196	10,581	30	10,511	27	2,712	29	3,574	22	5,595	19	264,215	905	302,750	1,147
Field Activities	186,655	539	1,102	5	94,912	363	91,165	425	129,965	689	33,847	132	194,684	873	732,330	3,026	732,330	3,026
Export Certification User Fee: (non-add):Center	*1,185*	*7*													*1,185*	*7*	*1,185*	*7*
Field															-	-	*0*	*0*
Reinspection User Fee (non-add)									*6,825*	*48*					*6,825*	*48*	*6,825*	*48*
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): Center													*690*	*3*	*690*	*3*	*690*	*3*
Proposed Food VQIP user fee (non-add): Center	*232*	*1*													*232*	*1*	*232*	*1*
Field													*61,000*	*265*	*61,000*	*265*	*61,000*	*265*
FOODS TOTAL	**350,034**	**1,121**	**68,965**	**201**	**105,493**	**393**	**101,676**	**452**	**132,677**	**718**	**37,421**	**154**	**200,279**	**892**	**996,545**	**3,931**	**1,035,080**	**4,173**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	238,854	809	18,209	71	3,972	19	743	4	10,403	53	7,238	37	2,016	10	*281,435*	*1,003*	998,568	3,712
Field Activities	27,913	159			14,941	72	3,811	21	33,265	181	11,091	67	8,112	36	*99,133*	*536*	153,220	791
PDUFA (non-add): Center	*124,389*	*417*													*124,389*	*417*	*602,590*	*2,164*
Field															-	-	*12,298*	*58*
Proposed GDUFA (non-add): Center	*10,339*	*20*													*10,339*	*20*	*29,539*	*56*
Field									-	-					-	-	*6,737*	*12*
Proposed Reinspection user fee (non-add): Field									*2,630*	*18*					*2,630*	*18*	*2,630*	*18*
Proposed International Courier User Fee (non-add): Center													*460*	*2*	*460*	*2*	*460*	*2*
HUMAN DRUGS TOTAL	**266,767**	**968**	**18,209**	**71**	**18,913**	**91**	**4,554**	**25**	**43,668**	**234**	**18,329**	**104**	**10,128**	**46**	**380,568**	**1,539**	**1,151,788**	**4,503**
BIOLOGICS																		
Center for Biologics Evaluation & Research	*37,596*	137	*280*	*2*					2,640	10					40,516	149	320,803	1,131
Field Activities	7,309	41							29,296	156	2,439	9	1,412	7	40,456	213	47,457	239
PDUFA (non-add): Center	*2,964*	*10*													2,964	10	*123,998*	*399*
Field															-	-	*5,165*	*6*
MDUFMA (non-add): Center	*282*	*1*													282	1	*13,030*	*32*
Field															-	-	*597*	*4*
Proposed Reinspection user fee (non-add): Field									*537*	*3*					537	3	*537*	*3*
BIOLOGICS TOTAL	**44,905**	**178**	**280**	**2**	-	-	-	-	**31,936**	**166**	**2,439**	**9**	**1,412**	**7**	**80,972**	**362**	**368,260**	**1,370**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	43,192	172	9,661	47											*52,853*	*219*	117,009	487
Field Activities	18,443	75			6,122	33	1,305	7	21,952	135	1,516	17	7,472	27	*56,810*	*294*	59,449	307
ADUFA (non-add): Center															-	-	*19,261*	*66*
Field															-	-	*315*	*2*
AGDUFA (non-add): Center															-	-	*4,898*	*20*
Field															-	-	*160*	*1*
Reinspection user fee (non-add):									*2,550*	*18*					*2,550*	*18*	*2,550*	*18*
Recall User Fee(non-add): Center	*521*	*2*							-	-					*521*	*2*	*521*	*2*
Field									*639*	*2*					*639*	*2*	*639*	*2*
															-	-	*0*	*0*
Proposed Reinspection user fee (non-add): field									*134*	*1*					*134*	*1*	*134*	*1*
Field															-	-	*0*	*0*
Export Certification User Fee(non-add): Center	*82*	-													*82*	-	*82*	*0*
ANIMAL DRUGS & FEEDS TOTAL	**61,635**	**247**	**9,661**	**47**	**6,122**	**33**	**1,305**	**7**	**21,952**	**135**	**1,516**	**17**	**7,472**	**27**	**109,663**	**513**	**176,459**	**794**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	101,849	447	6,537	23	14,245	56									122,631	526	292,384	1,373
Field Activities	23,480	123			4,918	19	2,827	14	43,078	201	8,814	36	10,548	68	93,665	461	102,562	511
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	*6,817*	*34*	*20*	-	*610*	*4*									7,447	38	*38,655*	*244*
Field									*61*	-					61	-	*1,235*	*14*
Proposed Reinspection user fee (non-add): Field									*3,424*	*24*					*3,424*	*24*	*3,424*	*24*
Proposed International Courier User Fee (non-add): Center													*3,450*	*15*	*3,450*	*15*	*3,450*	*15*
DEVICES TOTAL	**125,329**	**570**	**6,537**	**23**	**19,163**	**75**	**2,827**	**14**	**43,078**	**201**	**8,814**	**36**	**10,548**	**68**	**216,296**	**987**	**394,946**	**1,884**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	-	-	**25,324**	**99**	-	-	-	-	-	-	-	-	-	-	25,324	99	**60,294**	**215**
Proposed Reinspection user fee (non-add): Center		-			-	-	-	-	-	-	-	-	-	-	-	-	0	0
CENTER FOR TOBACCO PRODUCTS															**336,625**	**301**	**454,751**	**392**
Center for Tobacco Products	132,150	154	110,125	48	88,100	73									**330,375**	**275**	*448,501*	366
Field	**2,062**	**9**					**2,090**	**8**					**2,098**	**9**	**6,250**	**26**	6,250	*26*
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**57,719**	**203**	**36,378**	**30**	**10,181**	**39**	**7,506**	**33**	**18,588**	**96**	**4,660**	**21**	**15,633**	**68**	**150,664**	**490**	**288,638**	**1,047**
USER FEES (non-add): PDUFA	*8,938*	*33*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*8,938*	*33*	*52,222*	*201*
MQSA (HQ / OC)	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*924*	*3*	*3*	-	*80*	-	-	-	*8*	-	-	-	-	-	*1,015*	*3*	*6,962*	*24*
ADUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*873*	*4*
Proposed GDUFA	*378*	*2*	-	-	-	-	-	-	-	-	-	-	-	-	*378*	*2*	*1,325*	*5*
AGDUFA						-	-	-	-	-	-	-	-	-	-	-	*228*	*1*
TOBACCO	*4,477*	*14*	*3,731*	*4*	*2,985*	*7*	-	-	-	-	-	-	-	-	*11,195*	*25*	*15,196*	*34*
Food Reinspection user fee	*70*	*1*	-	-	-	-	-	-	*115*	*1*	-	-	-	-	*185*	*1*	*3,395*	*7*
Recall User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*661*	*2*
Proposed Reinspection User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*5,902*	*10*
Proposed International Courier User Fee	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*276*	*1*
Proposed Food VQIP User Fee	*303*	*3*	-	-	-	-	-	-	-	-	-	-	-	-	-	*3*	*3,674*	*14*
HEADQUARTERS / OC TOTAL	**57,719**	**203**	**36,378**	**30**	**10,181**	**39**	**7,506**	**33**	**18,588**	**96**	**4,660**	**21**	**15,633**	**68**	**150,664**	**490**	**288,638**	**1,047**
SUB-TOTAL:	**1,040,601**	**3,450**	**250,155**	**422**	**247,972**	**704**	**119,958**	**539**	**291,899**	**1,550**	**73,179**	**341**	**247,570**	**1,117**	**2,296,657**	**8,222**	**3,930,216**	**14,378**
Total Center	642,589	2,350	138,928	369	38,979	144	18,760	64	34,343	188	15,472	80	23,244	97	912,314	3,292	2,828,947	9,478
Total Field	263,800	937	1,102	5	120,893	487	99,108	467	257,556	1,362	57,707	261	222,228	1,011	1,022,394	4,530	1,101,268	4,900
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, VQIP, proposed user fees	*160,161*	*522*	*20*	-	*610*	*4*	*2,090*	*8*	*15,190*	*67*	-	-	*2,098*	*9*	*180,169*	*610*	$1,616,316	4,301
User Fees - non add)																		
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocation)																	**192,309**	-
White Oak Relocation PDUFA (non-add)																	4,383	
White Oak Relocation Reinspection User Fee (non-add)																	0	
White Oak Relocation Proposed Reinspection User Fee (non-add)																	0	
Other Rent and Rent Related MDUFMA (non-add)																	1,620	-
Other Rent and Rent Related PDUFA (non-add)																	29,841	-
Other Rent and Rent Related ADUFA (non-add)																	204	-
Other Rent and Rent Related for Proposed GDUFA (non-add)																	578	-
Other Rent and Rent Related AGDUFA (non-add)																	80	-
Other Rent and Rent Related Food Reinspection User Fee (non-add)																	592	-
Other Rent and Rent Related Proposed Reinspection User Fee (non-add)																	455	
Other Rent and Rent Related for Center of Tobacco (non-add)																	1,550	
Other Rent and Rent Related for Recall User Fee (non-add)																	248	
Other Rent and Rent Related for Proposed International Courier User Fee (non-																	168	
Other Rent and Rent Related for Proposed Food VQIP User Fee (non-add)																	2,240	
GSA Rent																	**214,302**	-
GSA Rent PDUFA (non-add)																	25,544	-
GSA Rent MDUFMA (non-add)																	5,019	-
GSA Rent ADUFA (non-add)																	1,115	-
GSA Rent for Proposed GDUFA (non-add)																	1,943	-
GSA Rent AGDUFA (non-add)																	340	-
GSA Rent Food Reinspection User Fee (non-add)																	1,338	-
GSA Rent Proposed Reinspection User Fee (non-add)																	1,026	-
GSA Rent Proposed Food VQIP User Fee (non-add)																	3,920	-
GSA Rent for Center of Tobacco (non-add)																	5,503	
GSA Rent for Recall User Fee (non-add)																	434	
GSA Rent for Proposed International Courier User Fee (non-add)																	294	
Export Certification User Fee																	**2,700**	**18**
Colors Certification User Fee																	**7,700**	**40**
Buildings and Facilities																	**13,055**	
TOTAL S&E PROGRAM:																	**4,360,281**	**14,436**

Food and Drug Administration
HIV/AIDS
(Dollars in Thousands)

Program	FY 2008 Actual[1]	FY 2009 Actual	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Human Drugs	*$38,128*	*$36,643*	*$33,443*	*$33,443*	*$33,523*
Biologics	*$33,088*	*$32,045*	*$33,387*	*$33,387*	*$33,387*
Medical Devices	*$2,536*	*$2,506*	*$1,846*	*$1,769*	*$1,769*
Toxicological	*$95*	*$102*	*$235*	*$44*	*$0*
Other Activities	*$3,469*	*$3,355*	*$3,529*	*$3,560*	*$3,667*
Field Activity	*$17,825*	*$30,810*	*$36,256*	*$38,368*	*$40,480*
Total HIV/AIDS	**$ 95,141**	**$ 105,461**	**$ 108,696**	**$ 110,571**	**$ 112,826**

1 Includes 0.7% recission.

FOOD AND DRUG ADMINISTRATION
User Fee History
(Dollars in Thousands)

USER FEES: Appropriations

	FY 2006 Actual		FY 2007 Actual		FY 2008 Actual		FY 2009 Actual		FY 2010 Actual		FY 2011 Continuing Resolution		FY 2012 Estimate	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Definite Appropriations:														
PDUFA														
- Human Drugs	*1,110*	*$205,279*	*1,103*	*$223,476*	*1,252*	*$321,282*	*1,636*	*$358,434*	*1,849*	*$414,877*	*1,849*	*$469,559*	*2,164*	*$602,590*
- Biologics	*213*	*$52,014*	*242*	*$48,540*	*304*	*$70,890*	*326*	*$83,385*	*341*	*$76,781*	*341*	*$96,624*	*399*	*$123,998*
- Office of Regulatory Affairs	*44*	*$7,389*	*50*	*$6,266*	*40*	*$7,259*	*54*	*$8,447*	*54*	*$8,024*	*54*	*$13,608*	*64*	*$17,463*
- Headquarters and Office of the Commissioner	*114*	*$14,829*	*121*	*$16,042*	*166*	*$21,936*	*167*	*$24,800*	*172*	*$28,953*	*172*	*$40,693*	*201*	*$52,222*
- GSA Rent		*$14,100*		*$9,001*		*$11,821*		*$20,099*		*$25,632*		*$23,253*		*$25,544*
- Other Rent and Rent Related Activities		*$7,000*		*$7,000*		*$13,409*		*$14,226*		*$18,991*		*$19,905*		*$29,841*
- FDA Consolidation at White Oak		*$5,033*		*$10,105*		*$4,190*		*$2,660*		*$0*		*$3,415*		*$4,383*
Subtotal, PDUFA	**1,481**	**$305,644**	**1,516**	**$320,430**	**1,762**	**$450,787**	**2,183**	**$512,051**	**2,416**	**$573,258**	**2,416**	**$667,057**	**2,828**	**$856,041**
MDUFMA														
- Medical Devices and Radiological Health	*130*	*$19,838*	*151*	*$22,329*	*164*	*$23,289*	*175*	*$32,256*	*232*	*$41,283*	*232*	*$32,836*	*244*	*$38,655*
- Biologics	*26*	*$5,452*	*28*	*$5,731*	*28*	*$6,005*	*30*	*$7,455*	*30*	*$7,039*	*30*	*$11,068*	*32*	*$13,030*
- Office of Regulatory Affairs	*8*	*$1,123*	*8*	*$1,182*	*8*	*$1,230*	*9*	*$1,330*	*13*	*$1,825*	*13*	*$1,556*	*18*	*$1,832*
- Headquarters and Office of the Commissioner	*20*	*$2,654*	*21*	*$2,808*	*21*	*$2,967*	*22*	*$3,389*	*23*	*$3,592*	*23*	*$5,914*	*24*	*$6,962*
- GSA Rent		*$2,237*		*$2,349*		*$2,081*		*$1,982*		*$2,361*		*$4,264*		*$5,019*
- Other Rent and Rent Related Activities		*$765*		*$803*		*$850*		*$892*		*$1,087*		*$1,376*		*$1,620*
Subtotal, MDUFMA	**184**	**$32,069**	**208**	**$35,202**	**221**	**$36,422**	**236**	**$47,304**	**298**	**$57,187**	**298**	**$57,014**	**318**	**$67,118**
ADUFA														
- Animal Drugs and Feeds	*54*	*$8,264*	*51*	*$10,969*	*59*	*$12,260*	*64*	*$11,792*	*65*	*$14,644*	*65*	*$15,290*	*66*	*$19,261*
- Office of Regulatory Affairs							*2*	*$250*	*2*	*$546*	*2*	*$250*	*2*	*$315*
- Headquarters and Office of the Commissioner	*4*	*$493*	*4*	*$522*	*4*	*$563*	*4*	*$594*	*4*	*$631*	*4*	*$693*	*4*	*$873*
- GSA Rent		*$628*		*$675*		*$598*		*$628*		*$659*		*$885*		*$1,115*
- Other Rent and Rent Related Activities		*$291*		*$103*		*$109*		*$115*		*$121*		*$162*		*$204*
Subtotal, ADUFA	**58**	**$9,676**	**55**	**$12,269**	**63**	**$13,530**	**70**	**$13,379**	**71**	**$16,601**	**71**	**$17,280**	**72**	**$21,768**
AGDUFA														
- Animal Drugs and Feeds							*11*	*$1,495*	*22*	*$4,225*	*22*	*$4,382*	*20*	*$4,898*
- Office of Regulatory Affairs							*2*	*$303*	*1*	*$144*	*1*	*$143*	*1*	*$160*
- Headquarters and Office of the Commissioner							*1*	*$127*	*1*	*$158*	*1*	*$204*	*1*	*$228*
- GSA Rent								*$100*		*$105*		*$305*		*$340*
- Other Rent and Rent Related Activities								*$100*		*$105*		*$72*		*$80*
Subtotal, AGDUFA							**14**	**$2,125**	**24**	**$4,737**	**24**	**$5,106**	**22**	**$5,706**
TOBACCO														
- Tobacco Products							**0**	**$0**	84	$62,355	84	$211,823	366	$448,501
- Office of Regulatory Affairs							**0**	**$0**	6	$2,063	6	$4,700	26	$6,250
- Headquarters and Office of the Commissioner							**0**	**$0**	23	$3,375	23	$14,336	34	$15,196
- GSA Rent								**$0**		$3,691		$2,798		$1,550
- Other Rent and Rent Related Activities								**$0**		$503		$1,343		$5,503
Subtotal, TOBACCO							**0**	**$0**	**113**	**$71,987**	**113**	**$235,000**	**426**	**$477,000**
VOLUNTARY QUALIFIED IMPORTER PROGRAM (VQIP)														
- Foods													1	$232
- Office of Regulatory Affairs													265	$61,000
- Headquarters and Office of the Commissioner													14	$3,674
- GSA Rent														$3,920
- Other Rent and Rent Related Activities														$2,240
Subtotal, VQIP													**280**	**$71,066**
REINSPECTION:														
- Office of Regulatory Affairs													***66***	***9,375***
Foods Program Estimate													*48*	*$6,825*
Human Drugs Program Estimate													*18*	*$2,550*
- Headquarters and Office of the Commissioner													*7*	*$3,395*
- GSA Rent														*$1,338*
- Other Rent and Rent Related Activities														*$592*
Subtotal, Reinspection User Fee													***73***	***14,700***
RECALL														
- Foods													*2*	*$464*
- Animal Drugs and Feeds													*2*	*$521*
- Office of Regulatory Affairs													*25*	*$10,036*
- Headquarters and Office of the Commissioner													*2*	*$661*
- GSA Rent														*$434*
- Other Rent and Rent Related Activities														*$248*
Subtotal, Recall													**31**	**$12,364**
Proposed Definite Appropriations:														
Generic Prescription Drug User Fee (GDUFA):														
- Human Drugs													*56*	*$29,539*
- Office of Regulatory Affairs													*12*	*$6,737*
- Headquarters and Office of the Commissioner													*5*	*$1,325*
- GSA Rent														*$1,943*
- Other Rent and Rent Related Activities														*$578*
Subtotal, Generic Prescription Drug													***73***	***$40,122***
Medical Products Reinspection User Fee:														
- Office of Regulatory Affairs													***46***	***6,725***
-Human Drug Program													*18*	*2,630*
- Biologics Program													***3***	***537***
-Animal Drugs Program													*1*	*$134*
-Devices and Radiological Health Program													*24*	*$3,424*
- Headquarters and Office of the Commissioner													*10*	*$5,902*
- GSA Rent														*$1,026*
- Other Rent and Rent Related Activities														*$455*
Subtotal, Medical Products Reinspection													***56***	***14,108***
International Courier User Fee:														
- Office of Regulatory Affairs													***20***	***4,600***
-Foods Program													*3*	*690*
- Human Drugs Program													***2***	***460***
-Devices and Radiological Health Program													*15*	*$3,450*
- Headquarters and Office of the Commissioner													*1*	*$276*
- GSA Rent														*$294*
- Other Rent and Rent Related Activities														*$168*
Subtotal, Medical Products Reinspection													***21***	***5,338***
Indefininate Appropriations:														
MQSA														
- Devices and Radiological Health	*26*	*$4,784*	*21*	*$4,141*	*21*	*$4,047*	*21*	*$4,144*	*23*	*$4,284*	*23*	*$6,003*	*26*	*$6,003*
- Office of Regulatory Affairs	*8*	*$8,980*	*8*	*$9,457*	*8*	*$9,242*	*8*	*$9,324*	*8*	*$9,510*	*8*	*$13,077*	*8*	*$13,077*
- Headquarters and Office of the Commissioner	*2*	*$234*	*2*	*$240*	*2*	*$248*	*2*	*$263*	*2*	*$270*	*2*	*$238*	*2*	*$238*
Subtotal, MQSA	**36**	**$13,998**	**31**	**$13,838**	**31**	**$13,537**	**31**	**$13,731**	**33**	**$14,064**	**33**	**$19,318**	**36**	**$19,318**
Export Certification	**13**	**$2,033**	**18**	**$2,732**	**17**	**$2,707**	**10**	**$1,651**	**20**	**$3,663**	**20**	**$2,700**	**18**	**$2,700**
FOOD EXPORT CERTIFICATION:														
- Foods													*7*	*$1,185*
- Animal Drugs and Feeds														*$82*
Subtotal, Food Export Certification User Fee													***7***	***$1,267***
Certification Fund	**33**	**$5,694**	**36**	**$6,954**	**39**	**$7,379**	**38**	**$7,407**	**38**	**$6,768**	**38**	**$7,700**	**40**	**$7,700**
Total, User Fees	**1,805**	**$369,114**	**1,864**	**$391,425**	**2,133**	**$524,362**	**2,582**	**597,648**	**3,013**	**748,265**	**3,013**	**1,011,175**	**4,301**	**1,616,316**

FOOD AND DRUG ADMINISTRATION
User Fee History
(Dollars in Thousands)

USER FEES: Obligations

	FY 2004 Actual		FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2008 Actual		FY 2009 Actual		FY 2010 Actual	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
PDUFA:														
- Human Drugs	*972*	*$162,653*	*1,049*	*$185,555*	*1,110*	*$205,279*	*1,103*	*$223,476*	*1,252*	*$321,282*	*1,636*	*$351,021*	*1,849*	*$409,029*
- Biologics	*217*	*$40,170*	*243*	*$41,175*	*213*	*$52,014*	*242*	*$48,540*	*304*	*$70,890*	*326*	*$79,122*	*341*	*$80,664*
- Office of Regulatory Affairs	*41*	*$5,808*	*39*	*$6,138*	*44*	*$7,389*	*50*	*$6,266*	*40*	*$7,259*	*55*	*$9,905*	*54*	*$9,988*
- Headquarters and Office of the Commissioner	*122*	*$13,535*	*124*	*$14,020*	*114*	*$14,829*	*121*	*$16,042*	*166*	*$21,936*	*166*	*$35,018*	*172*	*$28,954*
- GSA Rent		*$6,146*		*$11,212*		*$14,100*		*$9,001*		*$11,821*		*$16,886*		*$25,632*
- Other Rent and Rent Related Activities		*$3,770*		*$8,334*		*$7,000*		*$7,000*		*$13,409*		*$20,099*		*$18,991*
- White Oak		*$0*		*$3,000*		*$5,033*		*$10,105*		*$4,190*		*$0*		*$0*
Subtotal, PDUFA	**1,352**	**$232,082**	**1,455**	**$269,434**	**1,481**	**$305,644**	**1,516**	**$320,430**	**1,762**	**$450,787**	**2,183**	**$512,051**	**2,416**	**$573,258**
MDUFMA														
- Medical Devices and Radiological Health	*100*	*$17,253*	*108*	*$15,492*	*130*	*$19,838*	*151*	*$22,329*	*164*	*$23,289*	*176*	*$32,462*	*232*	*$41,256*
- Biologics	*21*	*$3,437*	*22*	*$5,260*	*26*	*$5,452*	*28*	*$5,731*	*28*	*$6,005*	*29*	*$7,227*	*30*	*$6,990*
- Office of Regulatory Affairs	*6*	*$676*	*8*	*$966*	*8*	*$1,123*	*8*	*$1,182*	*8*	*$1,230*	*9*	*$1,352*	*13*	*$1,901*
- Headquarters and Office of the Commissioner	*10*	*$1,142*	*15*	*$2,644*	*20*	*$2,654*	*21*	*$2,808*	*21*	*$2,967*	*22*	*$3,389*	*23*	*$3,592*
- GSA Rent		*$1,080*		*$2,237*		*$2,237*		*$2,349*		*$2,081*		*$1,982*		*$2,361*
- Other Rent and Rent Related Activities		*$287*		*$562*		*$765*		*$803*		*$850*		*$892*		*$1,087*
Subtotal, MDUFMA	**137**	**$23,875**	**153**	**$27,161**	**184**	**$32,069**	**208**	**$35,202**	**221**	**$36,422**	**236**	**$47,304**	**298**	**$57,187**
ADUFA														
- Animal Drugs and Feeds	*3*	*$983*	*39*	*$7,538*	*54*	*$8,264*	*51*	*$10,969*	*59*	*$12,260*	*64*	*$11,792*	*65*	*$14,926*
- Office of Regulatory Affairs	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*2*	*$250*	*2*	*$264*
- Headquarters and Office of the Commissioner	*0*	*$0*	*3*	*$384*	*4*	*$493*	*4*	*$522*	*4*	*$563*	*4*	*$594*	*4*	*$631*
- GSA Rent		*$100*		*$567*		*$628*		*$675*		*$598*		*$628*		*$659*
- Other Rent and Rent Related Activities		*$0*		*$0*		*$291*		*$103*		*$109*		*$115*		*$121*
Subtotal, ADUFA		**$1,083**	**42**	**$8,489**	**58**	**$9,676**	**55**	**$12,269**	**63**	**$13,530**	**70**	**$13,379**	**71**	**$16,601**
AGDUFA														
- Animal Drugs and Feeds											*11*	*$1,854*	*22*	*$4,225*
- Office of Regulatory Affairs											*2*	*$54*	*1*	*$144*
- Headquarters and Office of the Commissioner											*1*	*$17*	*1*	*$158*
- GSA Rent												*$100*		*$105*
- Other Rent and Rent Related Activities												*$100*		*$105*
Subtotal, AGDUFA											**14**	**$2,125**	**24**	**$4,737**
TOBACCO														
- Tobacco Products													*84*	*$62,355*
- Office of Regulatory Affairs													*6*	*$2,063*
- Headquarters and Office of the Commissioner													*23*	*$3,375*
- GSA Rent														*$3,691*
- Other Rent and Rent Related Activities														*$503*
Subtotal, TOBACCO													**113**	**$71,987**
MQSA	36	$12,716	36	$13,185	36	$13,998	31	$13,838	31	$13,537	31	$13,731	33	$14,064
Export Certification	11	$1,806	8	$1,425	13	$2,033	18	$2,732	17	$2,707	10	$1,651	20	$3,663
Certification Fund	35	$6,128	35	$5,506	33	$5,694	36	$6,954	39	$7,379	38	$7,407	38	$6,768
Subtotal	**82**	$20,650	**79**	$20,116	**82**	$21,725	**85**	$23,524	**87**	$23,623	**79**	$22,789	**91**	$24,495
Total, FDA	**1,571**	**$277,690**	**1,729**	**$325,200**	**1,805**	**$369,114**	**1,864**	**$391,425**	**2,133**	**$524,362**	**2,582**	**$597,648**	**3,013**	**$748,265**

USER FEES: Collections

	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Actual	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 Estimate
	$	$	$	$	$	$	$
PDUFA Collections	$313,660	$370,935	$480,286	$513,236	$572,614	$667,057	$856,041
MDUFMA Collections	$35,063	$28,726	$49,158	$62,012	$64,865	$57,014	$67,118
ADUFA Collections	$11,018	$13,472	$11,420	$12,904	$15,441	$17,280	$21,768
AGDUFA Collections	$0	$0	$0	$4,588	$4,521	$5,106	$5,706
Tobacco Collections 1/	$0	$0	$0	$22,673	$193,114	$235,000	$477,000
MQSA Collections	$13,485	$13,600	$16,347	$21,580	$15,485	$16,104	$16,749
Export Certification	$2,164	$2,780	$2,885	$2,911	$3,225	$3,354	$3,488
Certification Fund	$6,633	$6,640	$7,606	$6,614	$7,811	$8,123	$8,448
Total, User Fees Collections	**$382,023**	**$436,153**	**$567,702**	**$646,518**	**$877,076**	**$1,009,039**	**$1,456,318**

1/ The Family Smoking Prevention and Tobacco Control Act authorizes quarterly collection of industry user fees. Tobacco user fees are billed and collected 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 2010- FY 2012 Cross-cutting Information

(Program Level in Thousands)

	FY 2010 Actual	FY 2011 CR	FY 2012 Estimate
Antimicrobial Resistance	**30,153**	**30,112**	**29,673**
Budget Authority (non-add)	*27,321*	*27,027*	*26,249*
Bioterrorism	**316,401**	**396,845**	**374,437**
Food Defense (non-add)	*217,490*	*217,490*	*217,489*
Medical Countermeasures (non-add)	*91,940*	*172,384*	*149,977*
Physical Security (non-add)	*6,971*	*6,971*	*6,971*
Budget Authority (non-add)	*306,637*	*386,708*	*364,179*
Blood Safety	**108,168**	**116,916**	**130,472**
Budget Authority (non-add)	*85,531*	*85,493*	*91,374*
BSE (Prion Disease)	**29,704**	**26,111**	**26,413**
Budget Authority (non-add)	*28,134*	*24,108*	*23,880*
Dietary Supplements	**15,233**	**17,709**	**16,104**
Budget Authority (non-add)	*15,233*	*17,709*	*16,104*
Drug Marketing, Advertising, and Communication Activities	**18,007**	**18,148**	**18,403**
Budget Authority (non-add)	*15,486*	*15,516*	*15,521*
Drug Safety	**861,812**	**935,740**	**1,111,687**
Pre-market (non-add)	*502,416*	*561,886*	*680,621*
Post-market (non-add)	*359,396*	*373,854*	*431,066*
Office of Surveillance &Epidemiology (non-add)	*74,630*	*77,268*	*89,052*
Budget Authority (non-add)	*525,324*	*537,018*	*577,347*
Food Labeling	**10,218**	**9,885**	**14,121**
Budget Authority (non-add)	*10,218*	*9,885*	*14,121*
Food Safety	**1,051,364**	**1,049,364**	**1,375,335**
Food Defense (non-add)	*217,490*	*217,490*	*217,489*
Budget Authority (non-add)	*1,051,364*	*1,049,364*	*1,275,182*
Human Generic Drugs Program	**95,561**	**95,278**	**133,668**
Office of Generic Drugs (non-add)	*51,868*	*51,868*	*72,762*
Field Drug Program (for Generic Drugs (non-add)	*7,519*	*7,236*	*14,608*
Budget Authority (non-add)	*95,561*	*95,278*	*97,392*
Immunization	**22,392**	**24,935**	**29,080**
Budget Authority (non-add)	*15,619*	*15,610*	*16,788*
Medical Device Surveillance	**27,499**	**26,196**	**25,681**
Budget Authority (non-add)	*22,252*	*20,881*	*20,323*
Over-the-Counter Drugs	**16,437**	**16,860**	**17,166**
Budget Authority (non-add)	*7,757*	*8,069*	*7,977*
Pandemic Influenza	**46,730**	**44,193**	**51,014**
Budget Authority (non-add)	*36,310*	*33,922*	*40,622*
Pre-Market Human Drug Review	**787,910**	**866,876**	**1,061,724**
Budget Authority (non-add)	*373,990*	*381,992*	*411,506*
Tissues	**16,623**	**17,272**	**19,131**
Budget Authority (non-add)	*16,149*	*16,145*	*17,685*
Women's Health	**56,451**	**62,193**	**66,832**
Budget Authority (non-add)	*24,497*	*25,318*	*25,648*
Office of Women's Health (non-add)	*6,040*	*6,040*	*6,378*
Breast Cancer (MQSA) (non-add)	*20,545*	*24,098*	*25,985*
White Oak	**38,536**	**41,951**	**68,521**

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.

FDA Central Budget*

(Dollars in Thousands)

	FY 2010 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	7,009		1,438		6,842		2,474		17,762	-
Field Activities	12,664		2,598		12,363		4,470		32,096	-
FOODS TOTAL	**19,673**	**-**	**4,036**	**-**	**19,205**	**-**	**6,944**	**-**	49,858	-
HUMAN DRUGS										
Center for Drug Evaluation & Research	10,724	8,858	4,883	4,924	22,955	27,095	4,188	3,742	42,750	44,619
Field Activities	1,945	272	886	151	4,163	833	759	115	7,753	1,371
HUMAN DRUGS TOTAL	**12,669**	**9,130**	**5,769**	**5,075**	**27,118**	**27,928**	**4,947**	**3,857**	**50,503**	**45,990**
BIOLOGICS										
Center for Biologics Evaluation & Research	4,069	2,434	6,244	6,907	6,873	5,311	1,587	1,025	18,773	15,677
Field Activities	205	75	314	212	346	163	80	32	945	482
BIOLOGICS TOTAL	**4,274**	**2,509**	**6,558**	**7,119**	**7,219**	**5,474**	**1,667**	**1,057**	**19,718**	**16,159**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	3,487	310	473	20	2,878	811	1,327	128	8,166	1,269
Field Activities	223	10	30	1	184	25	85	4	521	40
ANIMAL DRUGS & FEEDS TOTAL	**3,710**	**320**	**503**	**21**	**3,062**	**836**	**1,412**	**132**	**8,687**	**1,309**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	8,007	782	1,112	82	8,427	1,975	4,697	544	22,243	3,383
Field Activities	839	24	116	3	882	61	492	17	2,329	105
DEVICES TOTAL	**8,846**	**806**	**1,228**	**85**	**9,309**	**2,036**	**5,189**	**561**	**24,572**	**3,488**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**1,207**		**7**		**699**		**765**		**2,678**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**4,953**	**637**	**617**	**84**	**7,500**	**908**	**5,475**	749	**18,545**	**2,378**
TOTAL BA and UF:	**55,332**	**13,402**	**18,718**	**12,384**	**74,112**	**37,183**	**26,399**	**6,355**	**174,561**	**69,324**

** This table does not include the Center for Tobacco data breakdown. The Center for Tobacco charges are reflected within the Center of Tobacco Budget.*

FDA Central Budget*

(Dollars in Thousands)

	FY 2011 Estimates									
	PSC		**Facilities**		**Information Technology**		**Support Services**		**Total**	
	BA	**UF**	**BA**	**UF**	**BA**	**UF**	**BA**	**UF**	**BA**	**UF**
FOODS										
Center for Food Safety & Applied Nutrition	7,009		1,438		6,842		2,474		17,762	-
Field Activities	12,664		2,598		12,363		4,470		32,096	-
FOODS TOTAL	**19,673**	**-**	**4,036**	**-**	**19,205**	**-**	**6,944**	**-**	49,858	-
HUMAN DRUGS										
Center for Drug Evaluation & Research	10,724	8,858	4,883	4,924	22,955	27,095	4,188	3,742	42,750	44,619
Field Activities	1,945	272	886	151	4,163	833	759	115	7,753	1,371
HUMAN DRUGS TOTAL	**12,669**	**9,130**	**5,769**	**5,075**	**27,118**	**27,928**	**4,947**	**3,857**	**50,503**	**45,990**
BIOLOGICS										
Center for Biologics Evaluation & Research	4,069	2,434	6,244	6,907	6,873	5,311	1,587	1,025	18,773	15,677
Field Activities	205	75	314	212	346	163	80	32	945	482
BIOLOGICS TOTAL	**4,274**	**2,509**	**6,558**	**7,119**	**7,219**	**5,474**	**1,667**	**1,057**	**19,718**	**16,159**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	3,487	310	473	20	2,878	811	1,327	128	8,166	1,269
Field Activities	223	10	30	1	184	25	85	4	521	40
ANIMAL DRUGS & FEEDS TOTAL	**3,710**	**320**	**503**	**21**	**3,062**	**836**	**1,412**	**132**	**8,687**	**1,309**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	8,007	782	1,112	82	8,427	1,975	4,697	544	22,243	3,383
Field Activities	839	24	116	3	882	61	492	17	2,329	105
DEVICES TOTAL	**8,846**	**806**	**1,228**	**85**	**9,309**	**2,036**	**5,189**	**561**	**24,572**	**3,488**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**1,207**		**7**		**699**		**765**		**2,678**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**4,953**	**637**	**617**	**84**	**7,500**	**908**	**5,475**	749	**18,545**	**2,378**
TOTAL BA and UF:	**55,332**	**13,402**	**18,718**	**12,384**	**74,112**	**37,183**	**26,399**	**6,355**	**174,561**	**69,324**

** This table does not include the Center for Tobacco data breakdown. The Center for Tobacco charges are reflected within the Center of Tobacco Budget.*

FDA Central Budget

(Dollars in Thousands)

	FY 2012 Estimates									
	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	7,327	1,462	1,503	300	7,153	1,427	2,586	516	18,570	3,704
Field Activities	13,238	45	2,716	9	12,923	44	4,673	16	33,550	115
FOODS TOTAL	**20,566**	**1,507**	**4,219**	**309**	**20,076**	**1,471**	**7,259**	**532**	**52,120**	**3,819**
HUMAN DRUGS										
Center for Drug Evaluation & Research	11,208	10,509	5,104	5,841	23,991	32,150	4,377	4,440	44,680	52,940
Field Activities	2,032	342	925	190	4,349	1,044	793	144	8,100	1,720
HUMAN DRUGS TOTAL	**13,240**	**10,851**	**6,029**	**6,032**	**28,341**	**33,194**	**5,170**	**4,584**	**52,780**	**54,660**
BIOLOGICS										
Center for Biologics Evaluation & Research	4,253	2,790	6,525	8,195	7,183	6,301	1,659	1,216	19,620	18,501
Field Activities	215	90	329	265	362	203	84	39	990	597
BIOLOGICS TOTAL	**4,467**	**2,880**	**6,855**	**8,460**	**7,546**	**6,504**	**1,742**	**1,255**	**20,610**	**19,099**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	3,647	360	494	22	3,010	908	1,388	143	8,540	1,434
Field Activities	231	13	31	1	190	32	88	5	540	50
ANIMAL DRUGS & FEEDS TOTAL	**3,878**	**373**	**526**	**23**	**3,201**	**940**	**1,476**	**148**	**9,080**	**1,484**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	8,370	925	1,162	97	8,808	2,347	4,910	647	23,250	4,015
Field Activities	875	30	121	3	921	76	513	21	2,430	130
DEVICES TOTAL	**9,245**	**955**	**1,283**	**100**	**9,729**	**2,423**	**5,423**	**668**	**25,680**	**4,145**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**1,262**		**7**		**106**		**800**		**2,175**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**5,176**	**756**	**645**	**100**	**7,838**	**1,077**	**5,722**	**888**	**19,380**	**2,821**
TOTAL BA and UF:	**57,834**	**17,321**	**19,564**	**15,024**	**76,835**	**45,608**	**27,592**	**8,075**	**181,825**	**86,028**

** This table does not include the Center for Tobacco data breakdown. The Center for Tobacco charges are reflected within the Center of Tobacco Budget.*

FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services Charges and Assessments
Fiscal Year 2010

ASSESSMENTS:	**$1,448,693**
ALJ examinations OMP is delegating examining authority for all competitive service positions except Administrative Law Judges (ALJ), and is requiring employing agencies to reimburse OPM for the cost of the ALJ program.	$1,440
OPM Job Information Federal Assessment OPM charges fees to Federal Agencies to cover costs associated with maintenance and enhancement to the USAJOBS website, outreach initiatives regarding public service through print ads, and other materials.	$0
Interagency Council Funds Funding to support government wide financial, information technology, procurement, human capital, and other management activities.	$87,351
NIH eRA Grants Management System Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System	$139,863
Presidential Advisory Council on HIV/AIDS Agreement to provide funding to the NIH Office of AIDS research	$0
Capital Security Cost sharing Department of State charge for a "Head Tax" (Capital Security Cost Sharing)	$81,952
Office of Commissioned Corps Force Management SGLI reimbursement	$79,087
Unified Financial Management System Upgrade To support the business need for UFMS to stay current—new version of the Oracle E-Business Suite and Database software.	$1,059,000
FEE FOR SERVICE:	**$32,662,211**
Program Support Center/FOH/OS ($16,747,590): Provides various services to the FDA, including some Information and Systems Management Services. The following is a breakdown of costs.	
Financial Management Services (FMS):	$1,520,415

Strategic Acquisition Service: $77,038

Administrative Operations Service: $13,112,205
Includes costs for security, building operations, shredding, storage, graphics, property disposal, transhare, mail and payroll services.

Federal Occupational Health (FOH): $2,037,932
FDA agency health units and services

Information & System Management Services ($15,914,621):

Freedom of Information (FOIA) $140,570

Unified Financial Management Systems (UFMS) **$**6,437,796
The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.

HCAS O&M $1,982,000
HCAS O&M services provide support for daily operations of the HCAS application.

Telecommunication Services $992,366
Telecommunications team offers expertise on technical design & support for customer systems.

HHS NET $1,072,999

Enterprise Application $5,288,890
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: $27,192,331

Enterprise Information Management **$5,562,652**
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.

Human Resource Center – Rockville **$18,166,211**

International Health Bilateral Agreement **$1,198,192**
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 ($2,265,276):

CFO Audit of Financial Statements $376,325
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

Core Support from National Academy of Science $77,622
Agreement for a group of standing bodies in a number of health areas that can be called upon to provide feedback on various issues or to conduct more deliberative seminars and studies on HHS programs

Regional Health Administrators $388,899
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 $123,032
TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology

Health and Wellness Center $424
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

Department Ethics Program $449,164
The Office of General Counsel provides legal and related support services to the FDA.

IT Access for Disable Persons $27,553
Federal agencies are required to ensure that individuals with disabilities have access to electronic and information technology systems and equipment that are comparable to the access enjoyed by people without disabilities.

Homeland Security Presidential Directive 12 $112,255
Supports the Policy for a Common Identification Standard for Federal Employees and Contractors

Media Monitoring $61,270
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) $5,104
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 2010 Actual, and FY 2011 and 2012 Estimates

Activity	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
ASSESSMENTS	**1,448,693**	**1,815,048**	**1,996,553**
FEE FOR SERVICE	**32,662,211**	**41,401,285**	**45,541,414**
Program Support Center/FOH/OS	*16,747,590*	26,006,117	28,606,729
Information System Management Service	*15,914,621*	*15,395,168*	*16,934,685*
JOINTLY FUNDED PROJECTS	**27,192,331**	**29,034,034**	**31,937,437**
Enterprise Information Management	*5,562,652*	*4,631,581*	*5,094,739*
Human Resources Consolidation Costs	*18,166,211*	*20,767,000*	*22,843,700*
International Health - Bilateral Agreement	*1,198,192*	*1,093,646*	*1,203,011*
Other Jointly Funded Projects	*2,265,276*	*2,541,807*	*2,795,988*
Total	**61,303,235**	**72,250,367**	**79,475,404**

Data from JFA documents for 2010 & 2011

Sources of Funding to FDA by Other Federal Agencies

Federal Agencies	FY 2011 Estimate	FY 2012 Estimate	Reason for Funds
Department of Health and Human Services			
Office of the Director - National Institutes of Health	$50,000	$51,100	Determination of Pesticides in Botanical Dietary Supplement Raw Materials and Finished Products
Office of the Director - National Institutes of Health	$100,000	$102,200	Committee to evaluate the scientific & ethical issues involved in conducting studies of drug safety IOM project
Office of the Director - National Institutes of Health	$83,602	$85,441	Details, cash awards, fare awards, misc.
Office of the Director - National Institutes of Health	$529,224	$540,867	Methylphenidate in Male Rhesus Monkeys
Office of Dietary Supplements - National Institutes of Health	$24,500	$25,039	Pilot training course on Microscopic Examination of Plant Materials
Office of Dietary Supplements - National Institutes of Health	$146,489	$149,712	Assmt of Validities of Analytical Protocols/Prototypes of Dietary Supplements
Clinical Center - NIH	$100,000	$102,200	"Image-Guided Interventional Therapeutics"
Clinical Center - NIH	$10,000	$10,220	Flow Cytometry Facility
Clinical Center - NIH	$10,000	$10,220	Flow Cytometry Facility
National Cancer Institute - NIH	$57,668	$58,937	Medical Fellowship Training
National Cancer Institute - NIH	$213,278	$217,970	Post doc Fellowship Training
National Cancer Institute - NIH	$9,579	$9,790	Core Facility - peptide project
National Cancer Institute - NIH	$40,000	$40,880	Core Facility Biotechnology Services
National Cancer Institute - NIH	$3,773	$3,856	Sequencing for NIH-Medical Oncology Branch
National Cancer Institute - NIH	$1,000	$1,022	Biotechnology Services
National Cancer Institute - NIH	$40,350	$41,238	Roles and Responsibilities -Proteomics Program, CSSI
National Cancer Institute - NIH	$4,000	$4,088	Core Facility - Polypeptides
National Cancer Institute - NIH	$80,000	$81,760	DNA Hypomethylation
National Heart , Lung and Blood Institute - NIH	$57,000	$58,254	Core Facility-Biotechnology Services
National Heart , Lung and Blood Institute - NIH	$155,000	$158,410	HIV Nano Assay Project
National Heart , Lung and Blood Institute - NIH	$105,000	$107,310	HIV Diversity and Blood Safety
National Institute of Arthritis and Musculoskeletal and Skin Diseases	$3,000	$3,066	Core Facility - Protein peptides
National Institute of Child Health and Human Development - NIH	$975	$996	Synthesis of Peptides - Biotechnology Services
National Institute of Child Health and Human Development - NIH	$1,000	$1,022	N-terminal Amino Acid Sequencing of R Nase H1
National Institute of Child Health and Human Development - NIH	$325,000	$332,150	Pediatric Formulations Platform
National Institute of Dental and Craniofacial Research - NIH	$20,828	$21,286	Core Facility-Biotechnology Services
National Institute on Deafness and Other Communication Disorders	$4,954	$5,063	DNA Clone Sequencing Service
National Institute of Diabetes and Digestive and Kidney Disorders - NIH	$91,604	$93,619	Core Facility
National Institue on Drug Abuse	$100,000	$102,200	Drug Discovery
National Institute of Environmental Health Sciences - NIH	$14,679,378	$15,002,324	Chemical Testing-NTP
National Institute of General Medical Sciences	$56,935	$58,188	Pharmacological Research Associate Program (PRAT)
National Institute of Allergy and Infectious Diseases - NIH	$948,167	$969,027	TSE & BSE Infectivity
National Institute of Allergy and Infectious Diseases - NIH	$338,726	$346,178	Warehouse space at Industrial Drive
National Institute of Allergy and Infectious Diseases - NIH	$517,833	$529,225	Biodefense Research Projects
National Institute of Allergy and Infectious Diseases - NIH	$60,000	$61,320	Evaluate the Potential of Enteric Vaccines to Reduce Reactive Arthritis
National Institute of Allergy and Infectious Diseases - NIH	$2,500	$2,555	Core Facility NIAID-FBR Lab Services
National Institute of Allergy and Infectious Diseases - NIH	$250,000	$255,500	Development of anti-Ebola MHC tetramers as a surrogate marker to evaluate a cell-mediated immunity in vaccines
National Institute of Allergy and Infectious Diseases - NIH	$165,000	$168,630	New tools to explore adjuvant Induced Improved Responses & Cross-Clade Protection for Human, Swine and Avian Influenza Pandemic Vaccines
National Institute of Allergy and Infectious Diseases - NIH	$76,000	$77,672	Resistance to infection and intercellular bacteria
National Institute of Allergy and Infectious Diseases - NIH	$70,000	$71,540	Assessing Guinea Pig Model of Shigellosis for Evaluation of Vaccine Safety and Efficacy
National Institute of Allergy and Infectious Diseases - NIH	$165,000	$168,630	Use of bioimaging to follow dissemination of vaccina in mice
National Institute of Allergy and Infectious Diseases - NIH	$100,000	$102,200	Expression Pattern of IFN-a/IFN-n isoforms: potential biomarkers for filovirus vaccine efficancy
National Institute of Allergy and Infectious Diseases - NIH	$95,000	$97,090	Dev. of Murine Model of Community-Acquired Methicillin-Resist Staphylococus Auerus Infection
National Institute of Allergy and Infectious Diseases - NIH	$100,000	$102,200	Calibration of Rabbit and Mouse Spore Inhalation Challenge Models
National Institute of Allergy and Infectious Diseases - NIH	$88,000	$89,936	Final Preclinical Development of Oral Anthrax Vaccine Candidate
National Institute of Allergy and Infectious Diseases - NIH	$114,000	$116,508	For Characteristics of Mechanisms of Action of the Novel Vaccine Adjuvants Mubutide and Unulin

Sources of Funding to FDA by Other Federal Agencies

Federal Agencies	FY 2011 Estimate	FY 2012 Estimate	Reason for Funds
National Institute of Allergy and Infectious Diseases - NIH	$239,500	$244,769	Dev of High Throughput Quantitative PCR Assays to Detect Neutralizing Antibody to Human Respiratory Syncytical Viruses
National Institute of Allergy and Infectious Diseases - NIH	$217,000	$221,774	Assessing the In Vitro & In Vivo Concogenicity & Tumorigenicity of Cellular DNA for Vaccine Safety
National Institute of Allergy and Infectious Diseases - NIH	$85,000	$86,870	Dev and use of assays for characterization & efficacy evaluation of anthrax vaccines
National Institute of Allergy and Infectious Diseases - NIH	$261,000	$266,742	Filovirus Vaccine
Agency For Health Care Research and Quality	$150,000	$153,300	IOM Project
Agency For Health Care Research and Quality	$141,916	$145,038	Detail-GS13 EEO Services
Office of the Secretary	$327,698	$334,907	ERIC Call Center
Office of the Secretary	$6,862	$7,013	Detail
Office of the Assistant Secretary for Preparedness and Response	$25,773	$26,340	BARDA access to CDRH Standards Database
Office of the Assistant Secretary for Preparedness and Response	$174,000	$177,828	Critical Medical Countermeasures-Bioterror agents or influenza disease
Office of the Assistant Secretary for Planning and Evaluation	$125,000	$127,750	FDA Inventory of Clinical Trial Protocols & Clinical Study Data
Office of the National Coodinator for Health	$36,550	$37,354	Contract Specialist- Detail
Office of Consumer Information and Insurance Oversight	$41,867	$42,788	Detail-Grants Mgmt Specialist
Centers for Disease Control	$46,000	$47,012	Prevelance and Molecular Characteristics of Mono B-cell Lymphocytosis among Blood Donors Aged>45 yrs
Centers for Medicare and Medicaid Services	$3,350,000	$3,423,700	Clinical Laboratory Improvement Act (CLIA)
Centers for Medicare and Medicaid Services	$1,650,000	$1,686,300	Health Care Fraud and Abuse Control (HCFAC)- FDA Pharmaceutical Fraud Pilot Program
Healthcare Resources and Services Administration	$85,758	$87,645	Detail
Healthcare Resources and Services Administration	$250,000	$255,500	National Hispanic Prenatal Helpline
Healthcare Resources and Services Administration	$277,693	$283,802	Biosciences Library
DHHS total	**$27,685,980**	**$28,295,072**	
Veterans Administration	**$80,300**	**$82,067**	Provide VA mammography facility inspections pursuant to Public Law 102-539 and Public Law 104-262
Department of Defense			
Defense Medical Standardization Board	$2,500,000	$2,555,000	Evaluation of the shelf-life of drug products
Defense Advance Research Projects Agency	$260,000	$265,720	Appl of Multiplex Allergen extract potency assay DARPA
Defense Advance Research Projects Agency	$428,500	$437,927	Blood Pharming Program
Defense Advance Research Projects Agency	$1,280,000	$1,308,160	Safety & Reliability of Neurological Devices Implanted in the Nervous System
Defense Threat Reduction Agency	$331,000	$338,282	Identificaiton of Molecular Mechanisms of Injury Ellicited by Organophosphates by Whole Genome
Defense Threat Reduction Agency	$100,000	$102,200	Develop enabling vector and antigen expression technologies to allow for the construction of a multivalent vaccine
Naval Research Laboratory	$10,000	$10,220	Subject matter expert support by FDA
DOD total	**$4,909,500**	**$5,017,509**	
Department of Homeland Security			
Department of Homeland Security	$852,000	$870,744	Foodborne Biothreat Agents
Department of Homeland Security	$327,000	$334,194	Assay Evaluation & Development of Novel Botulinum Antigens for use in Biological Toxins Detection Assays
Transportation Security Administration	$515,000	$526,330	Inspections
Federal Emergency Management Agency	$50,000	$51,100	Conference of Radiation Control Program Directors (CRCPD) Cooperative Agreement for Assuring Radiation Protection
DHS total	**$1,744,000**	**$1,782,368**	
Nuclear Regulatory Commission	**$125,000**	**$127,750**	Conference of Radiation Control Program Directors (CRCPD) Cooperative Agreement for Assuring Radiation Protection
National Oceanic and Atmospheric Administration	**$75,000**	**$76,650**	Shellfish Safety Assistance Project
Department of Justice	**$14,306,000**	**$14,620,732**	OCI Asset forfeiture
Department of Agriculture	**$30,000**	**$30,660**	Retail Listeria Monocytogenes Risk Assessment
TOTAL	**$48,955,780**	**$50,032,807**	

FY 2012 Geographic Distribution of Facilities

Building Code	Building Name	FDA Center	City Code	State Code	FDA Region Code	Ownership
12345	12345 Parklawn Drive	OC	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
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-BOS	Resident Post - Boston, MA	ORA	BOSTON	MA	NORTHEAST-NEWYORK	GSA Leased
BS-CAL1	Border Station - Calais, ME	ORA	CALAIS	ME	NORTHEAST-NEWYORK	GSA Owned
BS-COL	Border Station - Columbus, NM	ORA	COLUMBUS	NM	SOUTHWEST-DALLAS	GSA Owned
BS-HIGH	Border Station - Highgate Springs, VT	ORA	HIGHGATE SPRINGS	VT	NORTHEAST-NEWYORK	GSA Owned
BS-HLT	Border Station - Houlton, ME - USPS	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Leased
BS-HLT2	Border Station - Houlton, ME - Truck Facility	ORA	HOULTON	ME	NORTHEAST-NEWYORK	GSA Owned
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
CRAB2	Crabb CVM Building	CVM	ROCKVILLE	MD	HEADQUARTERS	GSA Leased
DDA	Division of Drug Analysis - St Louis	CBER	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
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	District Office and Pacific Regional Lab NW - Seattle	ORA	BOTHELL	WA	PACIFIC-OAKLAND	GSA Owned
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
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	GSA Leased	IL	HEADQUARTERS-FIELD	GSA Leased
MPN1	Metro Park North 1	CVM/CDRH	GSA Leased	MD	HEADQUARTERS	GSA Leased
MPN2	Metro Park North 2	OC/OCI/CDER/CVM	GSA Leased	MD	HEADQUARTERS	GSA Leased
MPN4	Metro Park North 4	CVM/CDER	GSA Leased	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

FY 2012 Geographic Distribution of Facilities

Building Code	Building Name	FDA Center	City Code	State Code	FDA Region Code	Ownership
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-T	Muirkirk - 8501 T Muirkirk Rd	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA Owned
MUIRK-W	Muirkirk - Waste Storage Area	CFSAN/CDER	LAUREL	MD	HEADQUARTERS	GSA 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
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-5A	NCTR - Building 5A-Lab - Animal Rooms	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-5B	NCTR - Building 5B - Labs and Admin	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-5B-HM	NCTR - Haz Mat Portable At 5B	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-5C	NCTR - Building 5C - Admin and Computer Center - Storage	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
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-T-45	NCTR - Building T-45 - Modular Offices - Facility Maint Contractor	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR-T-5	NCTR - Building T-5 - Office Trailer	NCTR	JEFFERSON	AR	HEADQUARTERS-FIELD	FDA Owned
NETS-336	Quonset Hut - Building 336	N/A	DAVISVILLE	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
PKLN	Parklawn Building	OC/ORA/CDER	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

FY 2012 Geographic Distribution of Facilities

Building Code	Building Name	FDA Center	City Code	State Code	FDA Region Code	Ownership
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
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-BCR	Resident Post - Boca Raton, FL	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-CHP2	Border Station - Champlain, NY	ORA	CHAMPLAIN	NY	NORTHEAST-NEWYORK	GSA Owned
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-CLX	Border Station - Calexico, CA - Import Bldg	ORA	CALEXICO	CA	PACIFIC-OAKLAND	GSA Leased
RP-CNP	Resident Post - Los Angeles, CA	ORA	CANOGA PARK	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-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
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-ELP2	Border Station - El Paso, TX	ORA	EL PASO	TX	SOUTHWEST-DALLAS	GSA Owned
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-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-HOU1	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
RP-LAX	Resident Post - LAX - El Segundo	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-MAS	Resident Post - Mandeville, LA - Mandeville Square	ORA	MANDEVILLE	LA	SOUTHEAST-ATLANTA	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

FY 2012 Geographic Distribution of Facilities

Building Code	Building Name	FDA Center	City Code	State Code	FDA Region Code	Ownership
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
WO1	White Oak Building 1	OC	SILVER SPRING	MD	HEADQUARTERS	GSA Owned
WO10	White Oak Building 10	CVM	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
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

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Senate Significant Items
Contained in Senate Report
111 – 221
July 15, 2010

Item 1 – **Antibiotics in Shrimp** – The Committee is concerned about the contamination of farm-raised shrimp imports with banned antibiotics. The Food and Drug Administration currently inspects less than 2 percent of imported shrimp. The Committee strongly encourages FDA to develop, in cooperation with the State testing programs, a program for increasing the inspection of imported shrimp for banned antibiotics. (p.93)

FDA Action

The use of unapproved drugs in farm-raised seafood raises significant public health concerns. FDA is actively working in a variety of ways to assure that farmed raised shrimp and other aqua cultured products are free from unapproved chemotherapeutics residues. FDA has a monitoring program to test for animal drugs in imported as well as in domestic seafood products. This program targets products and sources based on risk and past compliance. Shrimp has been identified as a high priority product in our testing program.

FDA focuses on ensuring the control of food safety hazards associated with unapproved aquaculture drugs in imported seafood through the implementation of the Seafood Hazard Analysis and Critical Control Point (HACCP) program. Under the HACCP system, the importer and the foreign processor share the responsibility for preventative controls and are required to verify that the products they offer for entry are in compliance with the requirements of the US FDA seafood regulation including controls of aquaculture drug hazard.

FDA continues to take regulatory actions against entries where positive samples are found in order to prevent adulterated fishery products from entering domestic commerce.

The FDA district offices work closely with States providing expertise and technical assistance regarding sampling procedure and testing methodology. Analytical methods for a range of unapproved drug residues of concern are available at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/DrugChemicalResiduesMethodology/default.htm.

Item 2 – **Antibiotic Development** – The Committee continues to be concerned about unresolved scientific issues regarding clinical development in the antibacterial drug area, which has been identified as a serious impediment to new antibacterial development. Regulatory uncertainty in the antibiotic drug arena has been a serious impediment to new antibiotic development. In its

report last year, the Committee directed FDA to issue clinical trial guidance for several serious indications. The Committee directs FDA to report by December 3, 2010, on its progress, including the status of FDA's work toward a final guidance for multi-drug and pan-resistant organisms.

The Committee last year also encouraged FDA to identify ways to promote the development and/or appropriate use of priority antibacterial drugs for humans for which current market incentives are inadequate, by working with other governmental entities and interested parties to begin the work. The Committee directs FDA to address these issues in its December 2010 report, as well. (p. 93)

FDA Action
FDA will submit the report as directed by the Committee.

Item 3 – **Antimicrobial Resistance –** Antimicrobial resistance, and the resulting failure of antimicrobial therapies in humans, is a mounting public health concern. To address this problem, the Committee recommends that FDA conduct, and make public, an overall review of the use of antibacterial drugs in food-producing animals and antimicrobial resistance. In addition, the Committee recommends that FDA examine the antibacterial drugs currently approved for use in food-producing animals and identify mechanisms for assuring that such products are aligned with current safety standards. FDA should conduct post market safety reviews to assure that current uses of animal drug products are used in a manner consistent with the standards currently used in premarket safety evaluations. The Committee directs the FDA to report on the progress of this effort within 1 year of the enactment of this act. (p. 94)

FDA Action
As described in the June 2010 draft guidance, FDA has completed a review of the key scientific reports related to the public health concerns associated with the use of antimicrobial drugs in food-producing animals and has outlined several key principles for action to ensure that medically important drugs are used judiciously. These key principles include the recommendation that medically-important antimicrobial drugs be limited to uses in food-producing animals that are considered necessary for assuring animal health, and that this use includes veterinary oversight or consultation.

FDA is reviewing public comments received on the draft guidance and is developing strategies 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. FDA is also exploring what statutory or regulatory changes would facilitate the goal of limiting the use of medically important antimicrobial drugs in food-producing animals to therapeutic use under the supervision of a veterinarian.

FDA is collaborating with other relevant government agencies and is seeking input from its stakeholders to develop a sound strategy for addressing this issue.

FDA intends to publish further details regarding implementation in the near future and will submit a progress report as directed by the Committee.

Item 4 – **Budget Justification** –The Committee directs the agency to submit the fiscal year 2012 budget request in a format that follows the same account structure as the fiscal year 2011 budget request, unless otherwise approved be the Committee. (p. 94)

FDA Action
The FY 2012 Congressional Justification budget submission follows the same account structure as the fiscal year 2011 budget request.

Item 5 – Critical Path and Modernizing Drug Safety – The Committee recommendation includes $22,450,000 for the critical path initiative, including no less than $6,000,000 for critical path partnerships as authorized by section 566 of the Federal Food , Drug and Cosmetic Act (FD&C Act). The Committee expects that this funding will be used to further FDA's work on critical path opportunities and to promote collaborations with other government agencies, academia, patient groups and other interested parties including, but not limited to, the Critical Path Institute, and the National Institute for Pharmaceutical Technology and Education. The Committee is also interested in Critical Path activities that advance safety testing, patient reported outcomes and accelerating therapies for serious diseases. Wherever possible, external awards should be competitive. Worldwide, almost 2 million people die from tuberculosis [TB] and more than 9 million people develop active disease every year. The rise of drug resistant TB can result in a global, untreatable epidemic. The Committee believes that more effective combinations of treatment are needed. Of the $6,000,000 provided for critical path partnerships, not less than $2,000,000 shall be used to support a research partnership to advance the prevention, diagnosis and treatment of TB. The Committee directs FDA to report on critical path spending semi-annually. (p. 94)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 6 – **Demonstration Grants for Improving Pediatric Device Availability –** The Committee recommendation includes $3,000,000 for Demonstration Grants for Improving Pediatric Device Availability, as authorized by the Food and Drug Amendments Act of 2007. (p. 93)

FDA Action

During FY 2011, FDA will support this activity at the funding level recommended by the Committee.

Item 7 – E-Pedigree – The Committee believes that a full electronic track and trace system for prescription drugs is critical to improve the security of the drug supply chain from counterfeit or other substandard products, and to protect consumers. A full electronic track and trace system would include the serialization, authentication, and recording the distribution history (also known as the pedigree) documenting all parties involved in the prior sale, purchase or trade of the prescription drug beginning with the manufacturer. The Committee directs FDA to provide a report to the Committee by March 1, 2011, that describes the status of developing standards for track and trace and authentication; the status of FDA's consideration of technologies for track and trace and authentication; efforts to harmonize, to the extent practical, with international standards and efforts; updates of international efforts for serialization, track and trace, and authentication; and all other activities planned or undertaken with the funding provided in fiscal year 2010 and 2011 for policy development related to the importation of prescription drugs. (p. 95)

FDA Action
FDA will submit the report as directed by the Committee.

Item 8 – **Food Labeling –** The Committee is pleased that FDA recognizes that importance of accurate food labeling in helping consumers follow a healthy diet, and is working to ensure that nutritional claims by food manufacturers are accurate. The Committee recommendation includes an increase of $1,400,000, as requested, for FDA to use data from well-designed studies to support a modernized food label to encourage Americans to eat healthier diets and potentially reduce the prevalence of obesity and its associated health care costs in the United States. In undertaking this effort, the Committee encourages FDA to consider concerns addressed to the Committee regarding
false or misleading structure/function claims, ingredient lists that are difficult to read or may not contain a declaration of the percentage of key ingredients, exaggerated representations regarding whole grain content, and a lack of information regarding caffeine and sugar. (p. 95)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 9 – **Generic Drugs** – The Committee recommendation includes no less than $96,966,000 for the generic drugs program at FDA, of which $55,545,000 is for the Office of Generic Drugs. Total funding for the Office of Generic Drugs is an increase of $4,000,000 above the fiscal year 2010 level, and $2,000,000

above the budget request. The President's budget proposal acknowledges that generic drugs now account for 70 percent of all prescriptions dispensed in the United States, an increase of 20 percent in 4 years. Further, annual generic drug application submissions have nearly tripled since 2001. Although the Committee has provided substantial funding increases for generic drug review, and remains firmly committed to supporting these activities, the demand continues to outpace staffing. The administration's proposals for user fees for generic drug applications have not yet been authorized by the Congress, but could provide a significant increase in funding levels for this important program. The Committee encourages FDA to continue to work with the generic drug industry and the Congress on this issue. (p. 95)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 10 – H1N1 Emergency Use Authorizations – In response to the 2009 H1N1 influenza pandemic, the FDA issued several Emergency Use Authorizations (EUAs). The Committee directs FDA to submit a report to Congress by March 1, 2011, regarding the use of EUA authorities over the past 24 months, the number of EUA declarations issued and whether they remain in effect, and FDA's assessment of whether the EUA authority is sufficient, including an assessment of the strengths and weaknesses of using EUAs. (p. 95)

FDA Action
FDA will submit the report as directed by the Committee.

Item 11 – Mammography –The Committee is aware that the Mammography Quality Standards Act [MQSA] has resulted in improved quality of mammography to make mammograms a more reliable tool to detect breast cancers. Appropriated funds pay for inspections in Government entities and in facilities where at least 50 percent of mammograms performed are funded by the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program, as well as other important activities. The Committee recommends no less than $6,918,000 in appropriated funds, as well as $19,318,000 in user fee collections, for activities related to MQSA. (p. 96)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 12 – **Nanotechnology** – The Committee supports the budget increase of $7,300,000 to expand upon current research in nanotechnology. The Committee is pleased that FDA has established a Nanotechnology Core Facility at the National Center for Toxicological Research, and encourages FDA to design this center 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. 96)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 13 – Orphan Product Development – The Committee is interested in making every tool available to FDA to get new products to those who suffer from rare diseases, and the Committee has been encouraged by the success of the orphan product grant program.

FDA has approved 44 products that received development support from orphan products grants. However, because the cost of clinical trials continues to increase far faster than the rate of inflation, FDA's funds are covering less and less of the true cost of conducting clinical trials. Therefore, the Committee recommendation includes $16,035,000 for orphan product development grants within the budget for the Center for Drug Evaluation and Research. This represents an increase of $2,000,000 above the budget request and is the first substantial increase in funding for these grants since fiscal year 2005. (p. 96)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 14 – **Office of Women's Health** – The Committee believes that it is imperative for FDA to pay sufficient attention to gender-based research, ensuring that products approved by the FDA are safe and effective for women as well as men. The Committee recommendation includes $6,040,000 for the Office of Women's Health. The Committee encourages FDA to ensure that the Office of Women's Health is sufficiently funded to carry out its activities, and to enhance its funding if necessary. (p. 96)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 15 – **Rare Diseases –** The Committee recommendation includes an increase
of $1,000,000 for the office of the Associate Director for Rare Diseases in the Center for Drug Evaluation and Research [CDER]. The Associate Director coordinates the development of policies and procedures for the review and approval of treatments for rare diseases throughout CDER, ensures appropriate training of staff, establishes consistent processes for providing advice to sponsors, and oversees the development of products for rare diseases across multiple scientific disciplines. In conjunction with the Office of Orphan Products Development, the Associate Director supports collaboration among scientists and clinicians throughout FDA, promoting scientific and regulatory innovations to help facilitate timely development and approval of new treatments for patients with rare diseases. The Committee expects the Associate Director to use these funds to hire additional staff with specific expertise in facilitating the development of drugs to treat rare diseases. (p. 96)

FDA Action
Congress has not yet enacted a full year appropriation for FY 2011. Therefore, the funding level for this activity has not yet been finalized.

Item 16 – **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 to more aggressively combat fraud in parts of the seafood industry. (p. 97)

FDA Action
For over 30 years, FDA 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 two years, FDA has delivered 14 joint (FDA & State) Seafood Training courses and is scheduling four more for FY 2011. Along with HACCP food safety principles and label reviews, the joint training sessions include a dedicated section to economic fraud. FDA also works closely with the National Fisheries Institute and NOAAs National Marine Fisheries Service to address economic fraud issues.

Item 17 – **Standards of Identity –** The Committee recognizes that honey is produced in the United States, traded internationally and consumed as both a packaged food an as a food ingredient. However, there have been instances where manufacturers have been marketing products illegally as ‘‘honey’’ or ‘‘pure

honey″ that contain other ingredients. FDA has been in receipt of a citizen petition regarding a proposed standard of identity for honey for a significant and unacceptable length of time, and is directed to respond to this citizen petition within 6 months, and provide monthly status reports to the Committee on this effort until a response has been provided. Further, FDA is directed to work to find ways to protect consumers from misbranded honey and honey-derived products that are currently entering the U.S. market. (p.97)

FDA Action
FDA will submit the reports as directed by the Committee.

Item 18 – Traceability – The Committee directs FDA to initiate one or more traceability projects on food products and/or ingredients known to be linked to foodborne disease outbreaks, or that have significant potential to cause serious adverse health consequences. When designing traceability projects, FDA should consider the challenges identified during previous outbreaks or build on previous efforts to improve product tracing along the supply chain. To prevent duplication of efforts and to more rapidly implement these pilot projects, the Committee encourages FDA to consider pilot projects already under way, either within the United States or the European Union, when implementing this directive. The Committee directs FDA to begin implementation of this project within 1 year, and to report back to the Committee upon the conclusion of the projects. (p.97)

FDA Action
FDA will submit the report as directed by the Committee.

Item 19 – Seafood Safety – The Committee is supportive of the current MOU between NOAA and FDA and encourages both agencies, the Secretary of Commerce, and the Secretary of HHS to continue to work together to strengthen cooperation on seafood safety, seafood labeling, and seafood fraud. The agreements should focus on coordination of testing seafood imports, inspection of imported seafood at both domestic and international facilities, data standardization and collection, joint training and outreach for testing facilities, and information sharing. The Committee encourages an increase in the use of NOAA laboratory testing and the commissioning of NOAA officers by the Secretary of HHS as needed in order to increase capacity for seafood inspection and testing. In addition, the Secretaries are encouraged to share information with the Federal Trade Commission as appropriate on consumer protection issues with respect to fraud in seafood marketing and labeling. (p. 97) (CFSAN)

FDA Action
FDA and NOAA recognize the need and value to work together and strengthen the interagency cooperation in the areas of seafood safety. As a result of this

combined effort and interest, the original 1974 Memorandum of Understanding (MOU) between FDA and NOAA was updated and reissued in 2009. The MOU describes how FDA and NOAA will work toward common goals to promote efficient use of existing resources in both agencies. Other areas specifically addressed in the MOU are formal cross training of the other agency's inspectional staff, shared development of regulations and guidance related to fish or fishery products, and utilizing the inspectional capabilities of the other agency's staff when appropriate and as resources permit.

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Food and Drug Administration
Fact Sheet – Alabama

FDA Presence

- Nine employees in Alabama
- Resident Posts in Birmingham, Mobile, and Montgomery
- Employees report to New Orleans District – in Nashville, TN – which Reports to Southeast Region in Atlanta, Georgia.

Industry Presence in State - 1,846 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

- Three ports of entry – Mobile, Huntsville, Birmingham. Mobile is a large port for exportation of grain products and moderate importation of various 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

- Four FDA employees in Alaska
- Resident Post - Anchorage
- Employees report to Seattle District - Bothell, Washington – which reports to Pacific Region - Oakland, California

Industry Presence in State - 527 FDA-regulated establishments[2]

- Food establishments - includes cosmetics – 78 percent
- Medical device and Radiological establishments – 13 percent
- Human drug establishments – 4 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, making up approximately 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 and 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, California, which 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 in which more than 90 percent of the land is communally owned.

[3] Some firms are in more than one category.

Food and Drug Administration
Fact Sheet – Arizona

FDA Presence

- 34 employees in Arizona
- Resident Posts: Phoenix and Tucson
- Employees report to Los Angeles District, Irvine, California, which reports to Pacific Region, Oakland, California
- Southwest Import District Resident Post - Nogales has 16 employees and San Luis, Arizona has 3 employees who report to the Southwest Import District, Dallas, Texas

Industry Presence in State: 2,535 FDA-regulated establishments

- Food establishments - includes cosmetics – 40 percent
- Medical Device and Radiological establishments – 32 percent
- Human Drug establishments – 15 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 plasmapheresis centers and 4 American Red Cross facilities.
- More than 10 manufacturers of vitamin and mineral Over-the-Counter products.
- The 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 - conduct inspections of mammography facilities.
- Arizona Department of Agriculture - conduct inspections of feed mills for medicated feeds and BSE.

State Partnerships.

- Arizona Department of Agriculture - agree to establish working arrangements concerning their mutual planning and share reports of inspection, investigations, and analytical findings relating to 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 - Arkansas

FDA Presence

- 71 field and 225 research center employees in Arkansas
- Dallas District Resident Post in Little Rock, Arkansas -3 investigators report to Dallas District Office
- Import entries are handled out of the Dallas Southwest Import District Office and through the Dallas District Staff located in Arkansas
- Arkansas Regional Laboratory, Jefferson - 66 employees report to Southwest Region, Dallas, Texas
- Office of Shared Services - 1 employee, HHS - 1 employee National Center for Toxicological Research (NCTR), Jefferson - 225 FTE+ 318 contractors

Industry Presence in State - 1,397 FDA-regulated establishments [4]

- Food establishments - includes cosmetics - 55 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 a 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 - Line entries received for Fiscal Year 2007 was approximately 647. Primary products imported are alcoholic beverages, cosmetics, and animal drugs.

[4] Some firms are in more than one category.

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 and has an agreement with the Jefferson Labs (NCTR) for emergency space and also shares in an informal reciprocal agreement with ARL for the FERN.
- Local Activities, FERN - NCTR, a FDA research center, employs 225 government scientists and 318 contract support personnel who develop, modify or validate FDA regulatory standards. Current work includes: studies applying new technologies, such as genomics, proteomics, and metabolomics, in conjunction with traditional biomarkers to provide data more easily extrapolated 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; and 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 inquires 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 – California

FDA Presence

- 507 FDA employees in California -includes SWID & PRL-SW
- Resident Posts - Fresno, Sacramento, San Jose, and Stockton. South San Francisco Resident Post slated to open in 2011.
- Employees report to San Francisco District, Alameda, which reports to Pacific Region, Oakland
- Resident Posts - San Diego, Santa Barbara, 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 - 20,211 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 - 4 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 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.

Contracts & Partnerships

State Contracts

- California Department of Food & Agriculture (DFA) - 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 Health Services (DHS) - Conduct inspections of food manufacturing facilities, mammography facilities and x-ray testing

State Partnerships

California Department of Food & Agriculture (DFA)

- 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 Health Services (DHS)

- 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.

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.

Food and Drug Administration
Fact Sheet – Colorado

FDA Presence

- 138 FDA employees in Colorado all in the Denver District Office which reports to the Southwest Region, Dallas, Texas

Industry Presence in State - 2,731 FDA-regulated establishments

- Food establishments – includes cosmetics - 43 percent
- Medical device and Radiological establishments - 22 percent
- Human drug establishments – 15 percent
- Animal drug and feed establishments - 16 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 and inspections of mammography facilities
- Colorado Department of Agriculture - Conduct inspections of feed mills for medicated feed and BSE Rule Compliance

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

- 17 FDA employees in Connecticut (15 District, 1 Regional in Hartford, 1 Foreign Cadre in Bridgeport)
- Resident Posts: Hartford - 12 employees, and Bridgeport -3 employees; Report to New England District, Stoneham, Massachusetts, which reports to Northeast Region, Jamaica, New York

Industry Presence in State **- 1,703 FDA-regulated establishments**

- Food establishments - includes cosmetics – 34 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.

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:

- 14 FDA employees in Delaware
- Resident Post: Wilmington
  Reports to: Philadelphia District, Philadelphia, Pennsylvania
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State - 227 FDA-regulated establishments[5]

- Food establishments - includes cosmetics - 38 percent
- Medical device and radiological establishments – 32 percent
- Human drug establishments – 20 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.

State Partnerships

- Delaware Food Safety Council (DFSC), a partnership with the state and local governments, academia, industry, and USDA to address food safety issues.

[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 - 345 FDA-regulated establishments

- Food establishments - includes cosmetics - 56 percent
- Medical device and Radiological establishments - 23 percent
- Human drug establishments - 11 percent
- Biologic establishments - includes blood banks - 8 percent
- Animal drug and feed establishments - 2 percent

Contracts & Partnerships:

State Partnerships

District of Columbia Department of Health, Health Care Regulation and Licensing Administration

- Assist the District of Columbia Department of Health Food Safety Program by providing support to develop and coordinate resources and provide training to augment the Retail Food Safety Program and coordinate other activities, including inspection coverage of food manufacturers and processors, food warehouses, and seafood facilities.

Food and Drug Administration
Fact Sheet - Florida

FDA Presence:

- 173 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
  Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in Florida – 8,398 FDA-regulated establishments

- Food establishments - includes cosmetics – 37 percent
- Medical devices and Radiological establishments – 39 percent
- Human drug establishments – 16 percent
- Animal drug and feed establishments – 4 percent
- Biologics establishments – 4 percent

Industry Highlights:

- 329 high risk food firms of which 297 are high risk seafood firms
- Miami is the largest port in U.S. for importation of fresh seafood
- Miami is fifth largest port in U.S. for importation of FDA regulated commodities
- 363 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 has a cooperative agreement with FDA to conduct BSE surveillance activities.

Partnership

- FDACS, Bureau of Chemical Residue Laboratories shares all volatile pesticide residue results from produce of import and domestic origin with FLA-DO.

Collaborative Activities

- FLA-DO is working in conjunction 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 – 3,100 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, and 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

- Conduct inspections for food sanitation, feed mills, and BSE
  Georgia Department of Natural Resources
- Conduct inspections of mammography facilities

Other Partnerships

- Plan training activities to promote health and scientific education with Morris Brown College
- Conduct educational activities to promote health and dispense information on disease prevention with Spellman College

- Develop models for solving problems 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
  Reports to: San Francisco District, Alameda, California, who
  Reports to: Pacific Region, Oakland, California

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 – 604 FDA-regulated establishments

- Food establishments - includes cosmetics - 57 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 - 3 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 – 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 – 2,180 FDA-regulated establishments

- Food establishments - includes cosmetics - 49 percent
- Animal drug and feed establishments - 29 percent
- Medical device and radiological establishments - 13 percent
- Human drug establishments - 7 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.
- In-vitro diagnostic establishments: Iowa has a heavy concentration of these.
- Bio-research: One of the few bio-equivalency-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

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.

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.

Food and Drug Administration
Fact Sheet - Idaho

FDA Presence:

- Eight FDA employees in Idaho
- Resident Post: Boise, Eastport
  Report to: Seattle District, Bothell, Washington
  Reports to: Pacific Region, Oakland, California

Industry Presence in State - 1,000 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. 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 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

- Local Activities
  Regular interaction with Idaho Tech helps 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 - 5,376 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 soybean and pumpkin producer in the U.S. as well as one of the top two 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, 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

State Partnerships

Illinois Department of Public Health

- Support annual Illinois Food Safety Symposium

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 -2,682 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.

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 – Kansas

FDA Presence:

- 140 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 (4)
- Headquarters Staff: DFO/OITSS Staff: Lenexa (4); & DFI Staff: Lenexa (3), Wichita (1)

Industry Presence in State - 1,911 FDA-regulated establishments

- Food establishments - includes cosmetics - 51 percent
- Animal drug and feed establishments - 23 percent
- Medical device and radiological establishments - 16 percent
- Human drug establishments – 8 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 2004 Legislature passed the Kansas Economic Growth Act, creating the Kansas Bioscience Authority. The Authority will invest an estimated $500 million in the development of the state's bioscience industry.
- 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

- 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 - 1,862 FDA-regulated establishments

- Food establishments - includes cosmetics – 54 percent
- Medical device and Radiological establishments - 21 percent
- Human drug establishments - 12 percent
- Biologic establishments - includes blood banks - 4 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.
- Bi-annual 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 re-assembled x-ray equipment.
- Coordinate testing of new and re-assembled 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:

- 25 FDA employees in Louisiana
- Resident Posts in Louisiana: Baton Rouge, 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 – 2,588 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 – 5 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), and one contract employee (Augusta)
- Resident Post: Augusta (7 employees) and
- Border Stations: Houlton (4 employees) and Calais (5 employees)
  Report to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 1,002 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 also has various ports of entry for imported goods, primarily 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

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.

Food and Drug Administration
Fact Sheet – Maryland

FDA Presence:

- 63 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 - 2,941 FDA-regulated establishments

- Food establishments - includes cosmetics – 49 percent
- Medical device and Radiological establishments - 28 percent
- Human drug establishments – 10 percent
- Biologic establishments - includes blood banks – 5 percent
- Animal drug and feed establishments - 8 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.

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 100 inspections of feed manufacturers, retail operations, haulers and collection of 150 feed samples.

Food and Drug Administration
Fact Sheet – Massachusetts

FDA Presence:

- 185 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 (11 employees)
  Report to: New England District, Stoneham, MA, District employees (97), contractors (2)
  Reports to: Northeast Region, Jamaica, NY
- Regional Food & Drug Director, WEAC (56 employees), State Programs Branch (5), Quality System Manager, and the Regional Emergency Response Coordinator who
  Report to: Northeast Region, Jamaica, NY
- HQ employees: DCIQA (1), DIO (2), DFSR (1), DTS (1), DIT (1)

Industry Presence in State – 4,167 FDA-regulated establishments

- Food establishments - includes cosmetics – 48 percent
- Medical Device and Radiological establishments – 33 percent
- Human drug establishments – 12 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.
- 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.

MA is a recipient of FDA's cooperative agreement intended to develop, implement and exercise an all hazards food and food borne illness Rapid Response Team (RRT). Within the scope of this agreement, the state in conjunction with FDA's New England District Office will host the National Center for Biomedical Research and Training (NCBRT) course: *A Coordinated Response to Food Emergencies: Practice and Execution.* This will be held on January 24-25, 2011.

Food and Drug Administration
Fact Sheet – Michigan

FDA Presence:

- 124 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 - 3,521 FDA-regulated establishments

- Food establishments - includes cosmetics – 44 percent
- Medical Device and Radiological establishments – 29 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

- 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).

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 pesticide residue analysis by FDA.

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 - 5,388 FDA-regulated establishments:

- Food establishments - includes cosmetics - 39 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.

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 corn, sunflowers, soybeans, barley, potatoes, flaxseed, total cheese, American cheese, milk, honey, milk cows, and hogs.
- Minnesota ranks seventh 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:

- Eight 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 – 960 FDA-regulated establishments

- Food establishments - includes cosmetics – 44 percent
- Medical device and Radiological establishments – 25 percent
- Human drug establishments – 13 percent
- Animal drug and feed establishments – 14 percent
- Biologic establishments - includes blood banks – 4 percent

Industry Highlights:

- Two major ports of entry – Gulfport, Pascagoula. Most of the 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.
- Shipbuilding – A sizeable shipbuilding industry is 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 has 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:

- 60 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 – 30)*

Industry Presence in State - 2,763 FDA-regulated establishments

- Food establishments - includes cosmetics – 41 percent
- Medical device and Radiological establishments – 25 percent
- Animal drug and feed establishments - 16 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 the year 2000, the state produced 4.4 million head of cattle and 263 million chickens.

- Bio-technology:

- Missouri ranks 11th among the top 25 biotechnology industry states in U.S.

- Major Veterinary Pharmaceutical Industry.
- The Southwest Import District handles imports for the State of Missouri. The majority of imported products are medical devices and foods.

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.

Local Activities

- Pharmaceutical Technical Exchange Association (PTEA) organized by FDA's Kansas City District to facilitate information exchange among the 200 member firms. PTEA meets semi-annually.

Food and Drug Administration
Fact Sheet – Montana

FDA Presence:

- Seven 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 – 1.218 FDA-regulated establishments

- Food establishments - includes cosmetics – 67 percent
- Medical device and Radiological establishments – 10 percent
- Human drug establishments – 8 percent
- Animal drug and feed establishments – 13 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 the beef industry.
- 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 the State of Montana.

Food and Drug Administration
Fact Sheet – Nebraska

FDA Presence:

- Four FDA employees in Nebraska
- Resident Post: Omaha
- Reports to: Kansas City District, Lenexa, Kansas
- Reports to: Southwest Region, Dallas, Texas

Industry Presence in State - 1,302 FDA-regulated establishments

- Food establishments - includes cosmetics - 43 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 million cattle; 3 million hogs, 15 million chickens/broilers

Imports in Nebraska: The import entries are handled by the Southwest Import District. The primary imported products are fresh fruits/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 one of 8 states awarded funding under a cooperative agreement designed to enhance the state’s 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:
- Three 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 – 823 FDA-regulated establishments
- Medical device and radiological establishments – 44 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.

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.

Food and Drug Administration
Fact Sheet – New Hampshire

FDA Presence:

- Four FDA employees in New Hampshire
- 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 of firms makes up approximately 7% of the New England District Official Establishment Inventory of regulated firms, with an emphasis on foods and medical devices.

State Contracts, Partnerships & Local Activities

None

Food and Drug Administration
Fact Sheet – New Jersey

FDA Presence:

- 102 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 - 5,162 FDA-regulated establishments

- Food establishments - includes cosmetics – 46 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 – 3 percent

Industry Highlights:

- New Jersey is home to some of the largest pharmaceutical Companies in the country. Throughout the 1990's, New Jersey-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.
- New Jersey 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 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 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 of State to conduct food safety inspections.

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:

- There is one FDA employee in New Mexico at this time.
- Albuquerque Resident Post with one employee reports to: Denver District Office in Denver, Colorado
- Denver District Office Reports to Southwest Regional Office in Dallas Texas Santa Teresa Resident Post with one employee and Columbus Resident Post with no 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 – 793 FDA-regulated establishments

- Food establishments - includes cosmetics - 44 percent
- Human drug establishments - 20 percent
- Medical device and Radiological establishments - 20 percent
- Animal drug and feed establishments - 11 percent
- Biologic establishments - includes blood banks - 5 percent

Industry Highlights:

- Cattle and dairy products top the list of major animal products of New Mexico. Cattle, sheep, and other livestock graze most of the arable land of the state throughout the year.
- 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 pinion nuts, pinto beans, and chilies. Third in natural gas production, second in onshore proven gas reserves and first in coal bed methane gas production and reserves. Leader in alternative power sources.
- 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 fiscal year 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:

- 420 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, in addition to an office in Buffalo. We also maintain 2 permanent offices at the Port of Buffalo (Peace Bridge and Lewiston Bridge)
  Report to: New York District, Jamaica (New York) who
  Reports to: Northeast Region, Jamaica (New York)
  Northeast Regional Laboratory, New York who reports to: Northeast Region

Industry Presence in State – 9,921 regulated establishments

- Food establishments - includes cosmetics - 42 percent
- Medical Device and Radiological establishments - 35 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. Approximately 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 entering New York. 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 imports are covered using two shifts from Sunday through Friday. 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 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 the many 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 4,200,440 line entries of FDA-regulated products that were imported through the New York ports of entry for Fiscal Year 2010.

Contracts & Partnerships:

State contracts

New York Department of Agriculture and Markets

- Conducts sanitation, seafood HACCP, juice HACCP, LACF/AF, BSE, medicated feed and tissue 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 channels of communication.
- Provides information on State initiated recalls.
- Collects food samples for pesticide analysis.

Other

- Conduct inspections of mammography facilities by New York City inspectors.
- Enhanced collaborative efforts with Customs and Border Protection resulting in the detection of entries previously circumventing FDA's entry review process.
- NYSDAM and FDA to work together to halt the entry and distribution of adulterated foods of import origin. This collaborative effort will include the sampling of imported foods encountered by NYSDAM in the domestic marketplace for ultimate submission to FDA for analysis. When a violation is confirmed by both Agencies, 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.
- Leveraging with the Canadian Food Inspection Agency and Health Canada to share information, in real time, when high risk violations are encountered in the regulated products crossing the shared border. This

offers enhanced consumer protection to both US and Canadian Consumers.

Food and Drug Administration
Fact Sheet – North Carolina

FDA Presence:

- 17 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 – 2,607 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

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

- Conduct joint statutory inspectional coverage of the medical gas Manufacturing and repacking industries.

Local Activities

North Carolina Food Safety and Security Task Force

Food and Drug Administration
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 - 1,416 FDA-regulated establishments

- Food establishments - includes cosmetics – 53 percent
- Animal drug and feed establishments - 40 percent
- Medical Device and Radiological establishments -4 percent
- Human drug establishments - 2 percent
- Biologic establishments - includes blood banks - 1 percent

Imports:

- There are 22 active ports of entry in the State of North Dakota.
- FDA regulated import entries are predominantly human food whole grain and milled products and non-medicated animal feed.
- North Dakota FDA regulated import entries are predominantly handled out of the 2 ND Northern border ports staffed by FDA in Pembina and Portal.

Industry Highlights:

- Agriculture – Leads the nation in the production of durum wheat, spring wheat, honey, barley, lentils, sunflowers, dry edible beans, dry edible peas, flaxseed, and canola. Other key crops include oats, potatoes, soybeans, and sugar beets.
- Raising of elk, deer and buffalo for meat is a part of the state's agri-industry.
- North Dakota ranks eighth nationally in agricultural exports.

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:

- 178 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 - 4,786 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 world wide 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.

Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Ohio Department of Agriculture (ODA)

- Establish training for state employees in analytical procedures & to conduct 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 assemblies 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:

- Four 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 – 2,022 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:

- Eggs - Oklahoma is a major egg production state.
- Poultry – Oklahoma is home to several Tyson poultry production facilities
- Foods – Oklahoma is 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 is home to major device manufacturers including Smith & Nephew Endoscopy, dental implants and kidney dialysis supplies.
- Dietary Supplements – Oklahoma is home to 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 number of line entries received during fiscal year 08 was 4,831 lines. 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 inquires 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 – 2,956 FDA-regulated establishments

- Food establishments - includes cosmetics – 67 percent
- Medical device and Radiological establishments - 17 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 are valued to exceed $5.25 Billion in commerce.
- Biotechnology, medical device, and medical research activities are growing industries within the State.

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:

- Approximately 113 employees in Pennsylvania
- Residence Posts: Harrisburg, Pittsburgh, Wilkes Barre
  Report to: Philadelphia District, Philadelphia
  Reports to: Central Region, Chicago, Illinois

Industry Presence in State – 4.925 FDA-regulated establishments

- Food Establishments - includes cosmetics – 42 percent
- Medical Device and Radiological establishments - 30 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 to cause food-borne disease from *Salmonella enteriditis.*

Memorandum of Understanding (MOU):

- PA Department of Agriculture, PA Dept. of Health and a number of PA egg producers for egg inspections under the PA Egg Quality Assurance Program.

Food and Drug Administration
Fact Sheet – Puerto Rico

FDA Presence:

- 75 FDA Full Time employees in Puerto Rico
  5 Part-Time Students
  3 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): 5 FT employees- reports to OCI FLA-FO

Industry Presence in State – 1,499 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 (P.R.) is reported to have the 3rd largest bio-manufacturing capacity in the world; 53% of PhRMA affiliates have operations in Puerto Rico.
- PR is both large and specialized based on employment concentration and employment size as a share of U.S. employment in the pharmacy sector (BIO/Batelle).
- In 2001, P.R. ranked 1st in percent share of pharmaceutical global exports and 5th in percent share of pharmaceutical global production. In 2003 P.R. was the world's largest international shipper of pharmaceutical products with a 24.5% share of total shipments. In 2004, Puerto Rico exports in the pharmaceutical industry 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 Puerto Rico.
- Major manufacturers include: Astra Zeneca/IPR, Pfizer, Eli Lilly, Abbott, Wyeth, Bristol Myers Squibb, Merck Sharp & Dhome, Biovail, APP, Amgen, Procter & Gamble, Schering-Plough, J&J Pharmaceutical Partners (Janssen, McNeil, Ortho), Legacy, Roche Pharma, and Warner-Chilcott.
- Some of our major manufacturers have taken a leading role in the development of PAT processes and the development and advanced implementation of anti-counterfeiting technologies such as RFID.
- Major pharmaceutical companies have brought their biotechnology

manufacturing to Puerto Rico or are in the process of doing so:

- Amgen
- Ortho Inc.
- Lilly
- Abbott
- Other companies are moving part of their process development and research to P.R.: Bristol Myers Squibb, Abbott, and Mova Pharmaceuticals. Becton Dickinson is also expanding into this area.
- Our inventory of medical device manufacturers 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 from around the world are also imported for further manufacturing or processing on the Island.
- Puerto Rico has the largest, noncontiguous Foreign Trade Zone (FTZ) system in the United States.
- There is one International Mail Facility located in Carolina, P.R.

<u>International Work</u>

- SJN- District operational staff is fully bilingual. 50% of our chemists and 70% of our 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.

<u>Contracts, MOUs & Partnerships</u>

- <u>P.R. Department of Health- Environmental Health Division:</u>
  - 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.
- <u>P.R. Department of Health- Radiological Health Division:</u>
  - Contract to conduct inspections of mammography facilities.
- <u>P.R. Department of Agriculture:</u>
  - MOU on emergency relocation, complying with COOP requirements.
  - Agrological Lab accepted into FERN.
- <u>P.R. Department of Consumer Affairs</u>

- Pilot to share information on violative dietary supplements and unapproved drugs, particularly in the area of ED and sexual enhancement drugs.

- SJN Public Affairs Partnerships/Consumer Outreach Programs
- Food Defense/ALERT Outreach for Food Retailers and State Inspectors
- Food Safety Education Consortium
- Obesity in Childhood
- Puerto Rico Health Fraud Task Force
- Generic Drugs Campaign
- Women's Health Issues
- Women and Diabetes
- Breast Cancer Awareness

Food and Drug Administration
Fact Sheet – Rhode Island

FDA Presence:

- Six 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 – 635 FDA-regulated establishments

- Food establishments - includes cosmetics – 48 percent
- Medical Device and Radiological establishments – 33 percent
- Human drug establishments – 14 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.

State Contracts and Partnerships

State Contracts

Rhode Island Department of Health

- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections
- Conduct inspections of mammography facilities.
- Participate in FDA's Manufactured Food Regulatory Program Standards

Local Activities

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.

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 – 1,259 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 – 5 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; 75 custom house brokers; major commodities include human foods, house wares, 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 – 1,134 FDA-regulated establishments

- Animal drug and feed establishments - 45 percent
- Food establishments - includes cosmetics - 41 percent
- Medical device and Radiological establishments - 8 percent
- Human Drug establishments - 4 percent
- Biologic establishments - includes blood banks – 2 percent

Imports:

- There is one active port of entry in the State of South Dakota.
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The SD FDA regulated import entries are handled out of the Minneapolis District FDA office.

Industry Highlights:

- Agriculture: Ranks second in the production of alfalfa hay, sunflowers, and flaxseed.
- Other key crops/products include durum wheat, spring wheat, winter wheat, all wheat, corn, all other hay, sorghum, soybeans, oats, proso millet, and honey.
- Cattle and sheep ranching are also a significant parts of the State's economy.

Contracts:

State Contracts

South 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.

South Dakota Department of Environment and Health

- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Tennessee

FDA Presence:

- 63 FDA employees in Tennessee
- Office/Resident Posts: Nashville, Chattanooga, Knoxville and Memphis, who
  Report to: New Orleans District (currently located in Nashville, TN), who
  Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 3,148 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 - 10 percent

Industry Highlights:

- Memphis import operation works around the clock to review entries of regulated products for Fed-Ex, the nation's largest overnight courier service. In FY '08, Memphis reviewed over 248,579 entry lines of FDA-regulated commodities. Import operations covers 20 ports in the four state areas.
- Major medical research centers at universities and hospitals in Memphis and Nashville
- One national biologics testing laboratory and several regional blood banking operations
- Major oral antibiotic manufacturer
- 2 major implantable device manufacturers
- Rapidly expanding freshwater prawn/shrimp industry
- 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 – Tennessee

FDA Presence:

- 64 FDA employees in Tennessee
- Office/Resident Posts: Nashville, Chattanooga, Knoxville and Memphis, who
  Report to: New Orleans District (currently located in Nashville, TN), who
  Reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State – 3,148 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 - 10 percent

Industry Highlights:

- Memphis import operation works around the clock to review entries of regulated products for Fed-Ex, the nation's largest overnight courier service. In FY '08, Memphis reviewed over 248,579 entry lines of FDA-regulated commodities. Import operations covers 20 ports in the four state areas.
- Major medical research centers at universities and hospitals in Memphis and Nashville
- One national biologics testing laboratory and several regional blood banking operations
- Major oral antibiotic manufacturer
- 2 major implantable device manufacturers
- Rapidly expanding freshwater prawn/shrimp industry
- 10 Paddlefish roe (domestic caviar) processors

Contracts & Partnerships:

State contracts

Tennessee Department of Agriculture

- Conduct sanitation inspections of food manufacturers
- Conduct BSE/ feed mill inspections

Special Programs

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:

- 184 FDA employees 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
  Report to: Southwest Import District (SWID) (55 employees in Texas), Dallas
  Report to: Southwest Region, Dallas
- Domestic Resident Posts: Austin, El Paso, Houston, Ft. Worth, San Antonio
  Report to: Dallas District (99), Dallas
  Report to: Southwest Region (25), Dallas
- Office of Regulatory Affairs HQ (1) and Office of Shared Services/Office of Information Management (12)

Industry Presence in State – 9,426 FDA-regulated establishments

- Food establishments - includes cosmetics – 48 percent
- Medical devices and Radiological establishments – 20 percent
- Human drug establishments –12 percent
- Animal drug and feed establishments – 16 percent
- Biologics establishments - includes blood banks – 4 percent

Industry Highlights:

- Seafood – Texas Gulf Coast is the home of numerous seafood firms.
- Imports into Texas – The Southwest Import District (SWID) receives approximately 3,279,038 line entries for fiscal year 08 through Texas ports of entry. 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 & test imported foods, cosmetics, drugs & medical devices and take appropriate action.
- Conduct inspections of medical gas and OTC drug manufacturers and repackers.
- Examine, sample & 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.
- New: 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 inquires and conduct consumer education outreach to diverse constituents, including a large number of Hispanics.

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 - 1,270 FDA-regulated establishments

- Food establishments - includes cosmetics - 38 percent
- Medical device and radiological establishments - 27 percent
- Human drug establishments –19 percent
- Animal drug and feed establishments – 11 percent
- Biologic establishments - includes blood banks - 5 percent

Industry Highlights:

- Agriculture is dependent on irrigation, and more than three-fourths 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 three-fourths 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.
- In eastern Utah petroleum production is a major industry. Near Salt Lake City, petroleum refining is done by a number of oil companies. In central Utah, coal production accounts for much of the mining activity.
- Tourism is a major industry in Southern Utah, with Utah's five national parks (Arches, Bryce Canyon, Canyon lands, Capitol Reef, and Zion) and many other attractions. In Moab, mountain biking is a popular sport. Utah is also noted for its ski resorts, near Salt Lake City, Park City, Ogden, Provo, and Cedar City.
- Imports into Utah - 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 100 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.

Utah Department of Environmental Quality

Conduct inspections of new x-ray assemblies or re-assemblies.

Food and Drug Administration
Fact Sheet – Vermont

FDA Presence:

- Seven 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 – 595 FDA-regulated establishments

- Food establishments - includes cosmetics – 71 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.

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

Food and Drug Administration
Fact Sheet – U.S. Virgin Islands

FDA Presence:

- One FDA employee in U.S. Virgin Islands
- Resident Post: St. Thomas
  Reports to: New England District, Stoneham, Massachusetts, who
  Reports to: Northeast Region, Jamaica, New York

Industry Presence in State – 76 FDA-regulated establishments

- Food establishments - includes cosmetics – 74 percent
- Medical device and radiological establishments – 8 percent
- Human drug establishments – 14 percent
- Biologic establishments - includes blood banks - 3 percent
- Animal drug and feed establishments – 1 percent

Industry Highlights:

- Small businesses employ almost 60 percent of the workforce and account for approximately 40 percent of the gross domestic product
- Two dairy farms.
- Charlotte Amalie is a major port for cruise ship stops.
- There is one International Mail Facility located in St. Thomas.
- Dutch Import laws in effect

Contracts and Partnerships:

State Partnerships

- FDA's San Juan District 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 the use of the experts within the Commonwealth of Puerto Rico to assist USVI in the adoption of new laws and in establishing a milk certification laboratory.
- The Commonwealth has provided training to USVI technologists on milk sampling and analyses, and agreed to analyze USVI's milk samples until USVI's milk certification lab is operational.
- Partnerships 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
- Conference on diabetes and women
- Campaign on generic drugs

Food and Drug Administration
Fact Sheet – Virginia

FDA Presence:

- 34 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 – 3.360 FDA-regulated establishments

- Food establishments - includes cosmetics – 55 percent
- Medical device and Radiological establishments – 25 percent
- Human drug establishments - 8 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 97 inspections of feed manufacturers, retail operations, haulers
- Food/Seafood: Contract includes 485 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:

- 203 FDA employees in Washington
- Resident Posts: Blaine, Seattle, Spokane, 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 – 5,192 FDA-regulated establishments

- Food establishments - includes cosmetics – 67 percent
- Medical device and Radiological establishments – 16 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. One of the largest and most diversified food and agricultural exporters.

Contract**s, 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 attach 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 – 838 FDA-regulated establishments

- Food establishments - includes cosmetics – 55 percent
- Medical device and Radiological establishments - 21 percent
- Animal drug and feed establishments - 12 percent
- Human drug establishments - 9 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 100 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 FDA – Minneapolis District 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 – 4,536 FDA-regulated establishments

- Food establishments - includes cosmetics - 56 percent
- Animal drug and feed establishments – 19 percent
- Medical device and Radiological establishments - 16 percent
- Human drug establishments - 7 percent
- Biologic establishments - includes blood banks - 3 percent

Imports:

- There are 3 ports of entry in the State of Wisconsin.
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The Wisconsin FDA regulated import entries are handled out of the Minneapolis FDA office.

Industry Highlights:

- Milk & Dairy - Leads the nation in total cheese, American cheese, Muenster cheese, dry whey, and milk goat production; second in milk, butter, mozzarella cheese and Italian cheese production.
- 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 – Significant production occurs for: apples, strawberries, oats, and corn for silage, maple syrup, and mint for oil, potatoes, tart cherries, ginseng, milk cows, and honey.
- 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.

Wisconsin Department of Health and Social Services
- Conduct inspections of mammography facilities.

State Cooperative Agreements (Grants)
Wisconsin Department of Agriculture
- BSE cooperative agreement to develop and improve the infrastructure of the state feed safety and BSE prevention programs.

Food and Drug Administration
Fact Sheet – Wyoming

FDA Presence

- Wyoming is covered by the Denver District Office in Denver, 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.
- The 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 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.

GLOSSARY OF ACRONYMS

510(k)	Pre-market notification (Medical devices substantially equivalent to products already on the market)
513(g)	Written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device
AADA	Abbreviated Antibiotic Drug Application
AAFCO	American Association of Feed Control Officials
AAR	After Action Review
ABC	Activity Based Costing
ACE	Angiotensin-converting Enzyme
ADE	Adverse Drug Event
ADAA	Animal Drug Availability Act of 1996
ADR	Adverse Drug Report
ADIMS	Automated Drug Information Management System
ADUFA	Animal Drug User Fee Act
AER	Adverse Event Review
AERS	Adverse Events Reporting System
AFSS	Animal Feed Safety System
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
AMDUCA	Animal Medicinal Drug Use Clarification Act
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
ANPR	Advanced Notice of Proposed Rulemaking
ANSI	American National Standards Institute
APHIS	Animal Plant and Health Inspection Service (USDA)
AR	Anti-microbial Resistance
ARL	Arkansas Regional Laboratory
ASAM	Assistant Secretary for Grants and Acquisitions Management
AVMA	American Veterinary Medical Association
BAMSG	Bacteriology and Mycology Study Group
BCCP	Business Continuity and Contingency Plan
BIMO	Bioresearch Monitoring
BIMS	Biological Investigational New Drug Application Management System
BCCP	Business Continuity and Contingency Plan
BLA	Biologics License Application
BLT	Blood Logging and Tracking System
BPCA	Better Pharmaceuticals for Children Act
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
BSL	Biosafety Level
BT	Bioterrorism
CABS	Conformity Assessment Bodies
CAERS	CFSAN Adverse Event Reporting System
CARS	Compliance Achievement Reporting System
CBER	Center for Biologics Evaluation and Research (FDA)

CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CERTS	Center for Education and Research Therapeutics
CFO	Chief Financial Officer
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CGMPs	Current Good Manufacturing Practices
CHD	Coronary Heart Disease
CIP	Critical Infrastructure Protection
CJD	Creutzfeldt-Jakob disease
CLIA	Clinical Laboratory Improvement Amendments
CMC	Chemistry, Manufacturing, and Controls
CMS	Centers for Medicare and Medicaid
CMV	Cytomegalovirus
COMSTAS	Compliance Status Information System
COBOL	Common Business Oriented Language
COOP	Continuity of Operations
CPI	Consumer Price Index
CPI/U	Consumer Price Index/Urban
CRADA	Cooperative Research and Development Agreement
CRO	Contract Research Organization
CRS	Contamination Response System
CT	Counter Terrorism
CTS	Correspondence Tracking System
CVM	Center for Veterinary Medicine (FDA)
CWD	Chronic Wasting Disease
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOL	Department of Labor
DQRS	Drug Quality Reporting System
DRLS	Drug Registration and Listing System
DSaRM	Drug Safety and Risk Management
DSHEA	Dietary Supplement Health and Education Act
DTPA	Diaminopropanoltetraacetic acid
eCTD	Electronic Common Technical Document
EDR	Electronic Document Room
EDMS	Electronic Data Management System
EIP	Emerging Infection Program
EIR	Establishment Inspection Report
ELA	Establishment License Application
eLEXNET	Electronic Laboratory Exchange Network
EO	Emergency Operations
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
ERS	Economic Research Service
ETS	Environmental Tobacco Smoke
EU	European Union

FAA	Federal Aviation Administration
FACTS	Field Accomplishment and Compliance Tracking System
FAIR Act	Federal Activities Inventory Reform Act
FAO	Food and Agricultural Organization (United Nations)
FBI	Federal Bureau of Investigation
FAS	Foreign Agriculture Service (USDA)
FD	Food Defense
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act of 1997
FD&C Act	Federal Food, Drug and Cosmetic Act
FERN	Food Emergency Response Network
FES	Financial Enterprise Solutions
FHA	Federal Health Architecture
FIS	Field Information System
FLQ	Fluoroquinolone
FMD	Foot and Mouth Disease
FMFIA	Federal Manager's Financial Integrity Act
FORCG	Food Outbreak Response Coordination Group
FPL	Final Printed Label
FPLA	Fair Packaging and Labeling Act
FSI	Food Safety Initiative (National)
FSIS	Food Safety Inspection Service (USDA)
FSSS	Food Safety and Security Staff (CFSAN)
FTC	Federal Trade Commission
FTE	Full-time Equivalent
FURLS	FDA Unified Registration and Listing System
FY	Fiscal Year (October - September)
GAO	General Accounting Office
GAPs	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GeMCRIS	Genetic Modification Clinical Research Information System
GGPs	Good Guidance Practices
GLP	Good Laboratory Practices
GMO	Genetically Modified Organisms
GMPs	Good Manufacturing Practices
GphA	Generic Pharmaceutical Association
GPRA	Government Performance and Results Act of 1993
GRAS	Generally Recognized as Safe Food Ingredients
GSA	General Services Administration
GSFA	General Standards for Food Additives
GTIS	Gene Therapy Information System
HACCP	Hazard Analysis Critical Control Points
HCV	Hepatitis C Virus
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
HR	Human Resources
HSPD	Homeland Security Presidential Directive
HUD	Humanitarian Use Device

IAG	Interagency Agreement
ICAAC	Interscience Conference on Antimicrobial Agents and Chemotherapy
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IDSA	Infectious Disease Society of America
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
ISLI	International Life Sciences Institute
ISO	International Standards Organization
ISRS	Individual Safety Reports
IT	Information Technology
IVD	In Vitro Diagnostic
JECFA	Joint Expert Committee on Food Additives
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JINAD	Generic Investigational New Animal Drug
LACF	Low Acid Canned Foods
LAN	Local Area Network
LBITF	Least Burdensome Industry Task Force
LRN	Laboratory Response Network
MALDI	Matrix Assisted Laser Desorption Ionization
MAB	Metastable Atom Bombardment
MATS	Management Assignment Tracking System
MBM	Meat and Bone Meal
MDAE	Medical Device Adverse Events
MDAER	Medical Device Adverse Event Reports
MDR	Medical Device Reporting System
MDUFMA	Medical Device User Fee and Modernization Act
MedSun	Medical Product Surveillance Network
MEO	Most Efficient Organization
MERS-TM	Medical Event Reporting System for Transfusion Medicine
MFA	Medicated Feed Application
MMBM	Mammalian Meat and Bone Meal
MOU	Memorandum of Understanding
MPRIS	Mammography Program Reporting and Information Systems
MQSA	Mammography Quality Standards Act
MRA	Mutual Recognition Agreement
MUMS	Minor Use/Minor Species
NADA	New Animal Drug Application
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group
NAHMS	National Animal Health Monitoring System
NARMS	National Antimicrobial Resistance Monitoring System

NAS	National Academy of Sciences
NASS	National Agricultural Statistics Survey
NAT	Nucleic Acid Test
NCCLS	National Committee on Clinical Laboratory Standards
NCFST	National Center for Food Safety and Technology (Moffett Center)
NCI	National Cancer Institute
NCIE	Notice of Claimed Investigational Exemptions
NCTR	National Center for Toxicological Research (FDA)
NDA	New Drug Application
NDE/MIS	New Drug Evaluation Management Information System
NIAID	National Institute of Allergy and Infectious Diseases
NIBSC	National Institute for Biological Standards and Control
NIDA	National Institute on Drug Abuse
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act
NME	New Molecular Entity
NOA	Notice of Availability
NOH	Notice of Hearing
NPR	National Partnership for Reinventing Government
NPRM	Notice of Proposed Rulemaking
NRC	National Research Council
NSCLC	Non-Small Cell Lung Cancer
NSE	Not Substantially Equivalent
NTP	National Toxicology Program
nvCJD	new variant Creutzfeldt-Jakob disease
NVPO	National Vaccine Program Office
OAI	Official Action Indicated
OARSA	Office of Applied Research and Safety Assessment (CFSAN)
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review (CBER)
OC	Office of Compliance (CFSAN)
OCD	Obsessive Compulsive Disorder
OCTGT	Office of Cellular, Tissues and Gene Therapies (CBER)
OFAS	Office of Food Additive Safety (CFSAN)
OGD	Office of Generic Drugs (CDER)
OM	Office of Management (FDA)
ONPLDS	Office of Nutritional Products, Labeling, and Dietary Supplements (CFSAN)
OPDFB	Office of Plant and Dairy Foods and Beverages (CFSAN)
OPDiv	Operating Division
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs (FDA)
ORISE	Oak Ridge Institute for Science and Education
OS	Office of Seafood (CFSAN)
OSAS	Office of Scientific Analysis and Support (CFSAN)
OSCI	Office of Science (CFSAN)
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
OTR	Office of Testing and Research (CDER)

OTRR	Office of Therapeutics Research and Review (CBER)
OVRR	Office of Vaccines Research and Review (CBER)
PART	Program Assessment Rating Tool (PART)
PAS	Public Affairs Specialist (FDA)
PAT	Process Analytical Technology
PDPs	Product Development Protocols
PDUFA	Prescription Drug User Fee Act of 1992
PERV	Porcine endogenous retrovirus
PIFSI	Produce and Food Safety Initiative
PISI	Protocol Investigator Site Inspection
PLA	Product License Application
PMA	Premarket Approval (Application to market medical device that requires Premarket approval)
PMN	Premarket Notification
PODS	Project-Oriented Data System
PPP	Pregnancy Prevention Program
PQRI	Product Quality Research Initiative
QSAR	Quantitative Structure Activity Relationship
QSIT	Quality System Inspection Technique
QSR	Quality System Regulation
RA	Rheumatoid Arthritis
RCHSA	Radiation Control for Health and Safety Act
REGO	Reinventing Government Initiative
RIMS	Regulatory Information Management Staff (CBER)
RMS-BLA	Regulatory Management System-Biologics License Application
SAB	Science Advisory Board
SAMHSA	Substance Abuse and Mental Health Services Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SCC	Secretary's Command Center
SE	Salmonella Enteriditis
S.M.A.R.T.	System to Manage Accutane Related Teratogenicity
SN/AEMS	Special Nutritional Adverse Events Monitoring System
SSO	Shared Services Organization
STARS	Submission Tracking and Review System
StmDT104	Salmonella Tphimurium DT 104
TB	Tuberculosis
TOF	Time of flight
TRIMS	Tissue Residue Information System
TSE	Transmissible Spongiform Encephalopathy (includes BSE and CJD)
UFMS	Unified Financial Management System
UK	United Kingdom
UMCP	University of Maryland-College Park
USAMRIID	United States Army Medical Research Institute of Infectious Diseases

USC	United States Code
USDA	United States Department of Agriculture
VAERS	Vaccine Adverse Event Reporting System
VAI	Voluntary Action Indicated
vCJD	variant Creutzfeldt-Jakob disease
VEE	Venezuelean Equine Encephalitis
VFD	Veterinary Feed Directive
VICH	Veterinary International Cooperation on Harmonization
VFD	Veterinary Feed Directive
VICH	Veterinary International Conference on Harmonization
WHO	United Nations World Health Organization
WNV	West Nile Virus
WR	Written Request
WTO	World Trade Organization

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