DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year 2010

Food and Drug Administration

Justification of Estimates for Appropriations Committees

The FY 2010 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 2010 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 2010 Congressional Justifications and accompanying Online Performance Appendices contain the updated FY 2008 Annual Performance Report and FY 2010 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 ACTING FDA COMMISSIONER

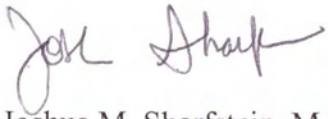
I am pleased to present the FY 2010 Congressional Justification for the Food and Drug Administration (FDA).

The FDA FY 2010 Congressional Justification is a performance budget request that funds important public health priorities for the benefit of the American public. The budget advances the President's agenda and reflects the goals of the Department of Health and Human Services. The budget contains the FY 2010 Annual Performance Plan and the Annual Performance Report, as required by the Government Performance and Results Act.

In FY 2010, FDA requests a funding increase and new user fees to implement Supply Chain Safety and Security. This initiative is designed to assure the safety of foods and medical products and to better protect American patients and consumers. Supply Chain Safety and Security relies on risk-based prevention with verification principles designed to hold all segments of industry accountable for ensuring that their products meet U.S. safety standards. The priorities in this initiative will promote greater safety and security of foreign and domestic sources of ingredients, components, and finished products at all points in the supply chain, including their eventual use by the American public.

The FY 2010 budget advances important Administration proposals to lower the cost of drugs for all Americans. These proposals are designed to protect public health while promoting innovation and providing access to more affordable medicine. The budget also includes a funding increase to help ensure the safe use of medical products after FDA approval. Finally, the budget contains a funding increase for the annual cost of living adjustment for FDA employees and an increase to meet the higher cost of the infrastructure that FDA relies on to achieve its mission.

FDA's FY 2010 budget advances the nation's highest public health priorities. The budget allows FDA to maintain a professional staff that is our most valuable asset. The budget advances the Administration's vision of FDA as a science-based agency that works for the American people and promotes and protects the public health. And, the FDA budget supports the Administration's priorities for economic recovery by allowing the United States to maintain its leadership in food and medical innovation.



Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

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Food and Drug Administration

FY 2010 Congressional Budget Request

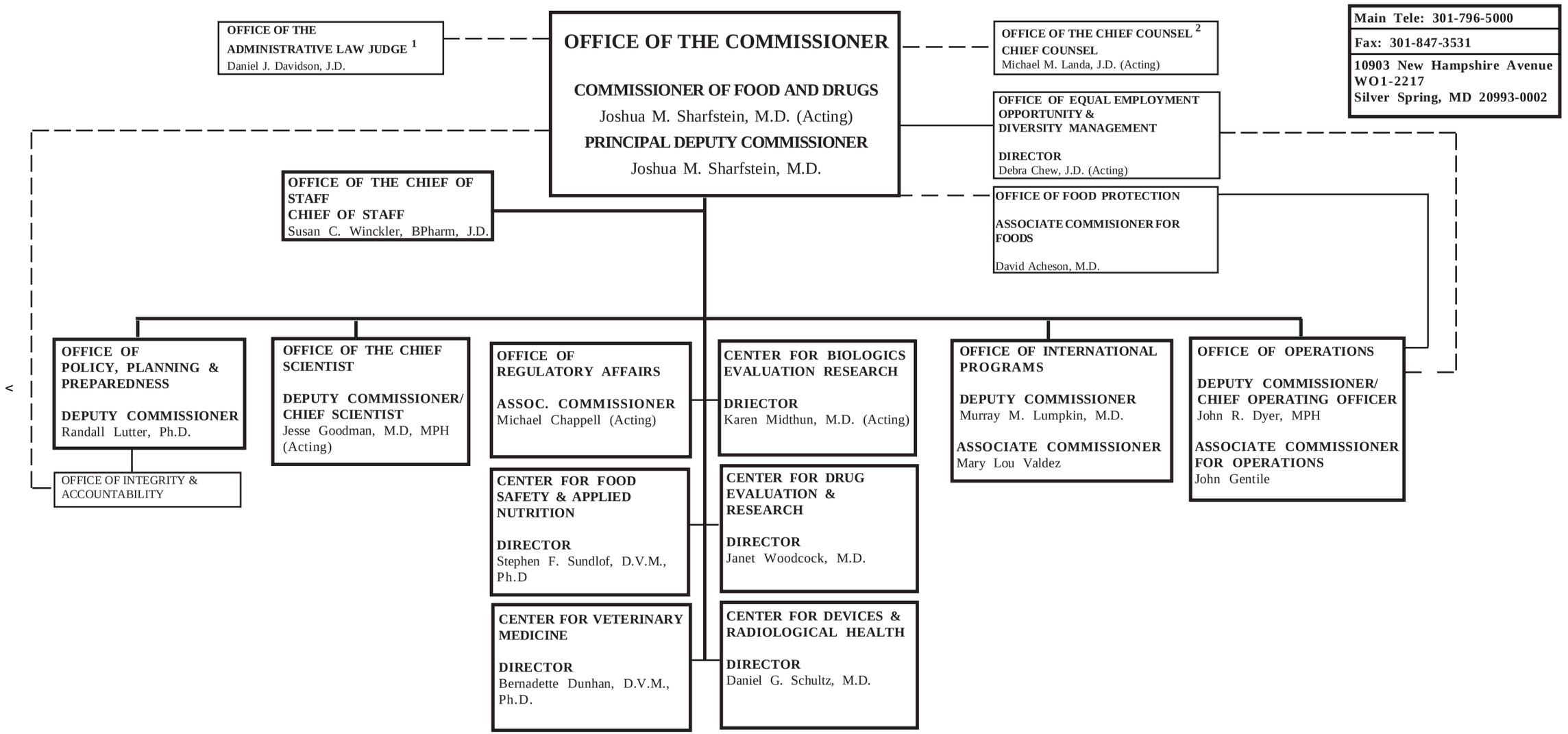
Table of Contents

Food and Drug Administration

FY 2010 Congressional Budget Request

Table of Contents

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



---[1] **Reports Directly to the Secretary, HHS**

---[2] **Reports to the General Counsel of the HHS, and advises the Commissioner of Food and Drugs.**

Approved by the Office of Management Programs 04/22/09

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EXECUTIVE SUMMARY

Introduction and Mission

The Food and Drug Administration (FDA), an agency of the Department of Health and Human Services, is responsible for protecting the public health by assuring the safety of America's foods, the safety, efficacy, and security of human and veterinary drugs, biological products and medical devices, and the safety and security of cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines safer and more effective. FDA also provides the public with accurate, science-based information about medicines and foods to improve their health.

FDA affects the lives of every American every day. Each year, consumers spend nearly $1.5 trillion on FDA-regulated products. This represents 20 percent of all consumer expenditures. FDA is a scientific regulatory agency that employs more than 11,000 scientific, technical, and professional staff to protect and advance public health.

FDA's mission derives from a variety of statutes, beginning with the Pure Food and Drugs Act of 1906, which prohibited interstate commerce in misbranded and adulterated foods, drinks, and drugs. The Food, Drug, and Cosmetics Act (FD&C Act) of 1938 extended FDA responsibility to cosmetics and therapeutic medical devices. Amendments to the FD&C Act also granted FDA important new authorities, including the requirement that manufacturers demonstrate the safety of drugs before they are marketed.

Over the years, Congress further expanded FDA's regulatory responsibilities to cover food additives, medical devices, and blood and vaccine products. FDA's mission also expanded in the area of counterterrorism and homeland security under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Project Bioshield Act of 2004. Most recently, the FDA Amendments Act of 2007 reauthorized user fees for prescription drugs and medical devices and provided new authority to promote development of safe and effective treatments for children, enhance drug safety, and ensure food safety.

Today, FDA carries out its mission through a diverse range of programs related to foods, human drugs, biologics, medical devices and radiological health, animal drugs and feeds, toxicological research that supports FDA's regulatory programs. FDA also operates interdisciplinary programs such as combination products, international programs, and programs that focus on the unique needs of women and pediatric patients.

During 2005, FDA began to develop a new efficiency measure related to human drug safety surveillance. Under the Prescription Drug User Fee Program, FDA conducted studies to evaluate the new human drug review program. FDA expects that these studies will improve the efficiency and effectiveness of new human drug review. The studies will also contribute to FDA achieving long-term outcome goals for new drug approval. FDA also improved processes that will increase the productivity of the generic drugs program. During 2007, FDA reinvigorated its strategic planning process to ensure that annual performance goals align with a coherent framework of strategic and long-term outcome goals.

FY 2010 Budget Overview

The fiscal year (FY) 2010 President's Budget request for FDA is $3,178,369,000. This represents a total program level increase of $510,554,000 above the amount enacted into law for FY 2009. The total program level request includes new budget authority, current law user fees, and new proposed user fees. The FY 2010 increase for user fees is $215,359,000, including $141,000,000 in proposed new user fees. The FY 2010 increase in budget authority is $295,195,000, of which $29,536,000 is for the cost of living pay increase.

FDA's FY 2010 budget supports the priorities articulated in Administration's February 26, 2009 message on the Federal budget. The following information summarizes the FDA budget changes for FY 2010.

The following information summarizes the FDA budget changes for FY 2009.

FDA FY 2010 Priorities

FDA is proposing four initiatives for FY 2010: Protecting America's Food Supply, Safer Medical Products, Current Law User Fees, and Infrastructure to Support Critical Agency Operations. FDA is also proposing user fees to reinspect facilities that fail to meet Good Manufacturing Practices and to pay the cost of export certifications for food and feed. These initiatives lay the foundation for meeting the President's food and medical product priorities. The initiatives permit FDA to achieve its performance commitments, preserve FDA user fee programs, and meet comprehensive FDA public health responsibilities. The following is a synopsis of the four initiatives:

Protecting America's Food Supply + $259,258,000

For FY 2010, FDA is proposing a budget increase of $259,258,000 for protecting America's food supply. The increase for this initiative includes $75,000,000 in new user fees to register food facilities and support food facility inspections. The FY 2010 Protecting America's Food Supply initiative builds on recent investments that Congress made to implement FDA's November 2007 Food Protection Plan and also increases the level of FDA investment in Supply Chain Safety and Security.

The Protecting America's Food Supply initiative provides essential resources to implement the FPP. The initiative also includes $12,872,000 for the cost of living pay increase for the FDA food defense and food safety programs.

Safer Medical Products + $166,433,000

For FY 2010, FDA is proposing a budget increase of $166,433,000 for an initiative to improve the safety of medical products. The funding for this initiative includes $36,000,000 in new user fees for generic drug review.

The FY 2010 Safer Medical Products Initiative contains strategic investments to improve the safety of medical products. The initiative also includes investments that will allow FDA to implement new approaches to effectively regulate the safety and security of the supply chain of medical products that American patients rely on to maintain and improve their health.

The resources in this initiative will allow FDA to measurably improve the safety of medical products: human drugs, vaccines, blood and other biological products, medical devices, animal drugs and medicated feed. The investments in this initiative will increase FDA's capacity to effectively monitor the safety of medical products. Moreover, these investments will provide better information about the safety profile of medical products at earlier stages of development.

The initiative also includes $16,664,000 for the cost of living pay increase for FDA's medical product programs.

Current Law User Fees: + $74,359,000

Four FDA user fees programs facilitate premarket review for human and animal drugs and human devices. Three other user fee programs support the mammography facilities inspection program and provide certification services for color additives and for drug and device products exported from the United States. The budget request includes inflationary increases for FDA user fee programs as well as other increases authorized by law under the prescription drug and medical device user fee programs.

Proposed Reinspection User Fee: + $25,848,000

The proposed reinspection user fee will cover the cost to reinspect FDA-regulated facilities that fail to meet good manufacturing practices or related FDA requirements. FDA currently funds these inspections through discretionary appropriations.

Proposed Food and Animal Feed Export Certification User Fee: + $4,152,000

The proposed user fee for Food and Animal Feed Export Certificates allows FDA to collect user fees for issuing food and animal feed export certificates within 20 days of receiving a request for an export certificate. FDA currently funds these inspections through discretionary appropriations.

Legislative Proposals Associated with the FY 2010 Budget

In addition to the new user fee legislative proposals cites above, President's Budget proposes a new authority for FDA to approve follow-on biologics through a regulatory pathway that protects patient safety and promotes innovation. Safe and effective follow-on biologics are critical to lowering costs for American consumers. Introducing competition within the world of biologics is essential to keeping these drugs affordable.

The FDA Business Case for the FY 2010 Initiatives

The FDA business case papers justifying the funding increases for FY 2010 appear below. The business case papers describe the need for the funding, the specific activities that FDA will fund, the risks of not funding the initiatives, how the initiatives support public health priorities, and the projected annual accomplishments under the initiatives.

FY 2010 Increases

Foods Program: The FY 2010 budget contains a program level increase of $196.9M (+$134.2M in budget authority; +$62.7M in user fees). The increase contains funds to implement the activities and achieve the performance commitments related to the Food Protection Initiative and Supply Chain Safety and Security. This increase also includes the cost of living increase for FDA workforce at the Center for Food Safety and Applied Nutrition (CFSAN) and the workforce that conducts the Field Foods Program in the Office of Regulatory Affairs (ORA). Finally, the increase includes the proposed authorization of new user fees for Food Inspection and Facility Registration and Reinspection User Fees.

Human Drugs Program: The FY 2010 budget contains a program level increase of $130.6M (+$44.3M in budget authority; +$86.2M in user fees). The increase contains funds to implement the Safer Medical Products Initiative and Supply Chain Safety and Security. Specifically, the increase supports the ability of ORA Field components to implement targeted import safety activities. The increase also includes the cost of living increase for FDA workforce at the Center for Drug Evaluation and Research (CDER) and the ORA workforce in the Human Drugs Program. Finally, the increase includes additional user fees to meet performance commitments under the

Prescription Drug User Fee Act and the proposed authorization of new user fees for generic drug review and Reinspection User Fees.

Biologics Program: The FY 2010 budget contains a program level increase of $34.2M (+$23.0M in budget authority; +$11.2M in user fees). The increase contains funds to implement the Medical Products Safety and Development Initiative and Supply Chain Safety and Security. The increase also includes funds for the cost of living increase for FDA workforce at the Center for Biologics Evaluation and Research (CBER) and the ORA workforce in Biologics Program. Finally, the increase includes additional user fees to meet performance commitments based on the Prescription Drug User Fee Act, the Medical Device User Fee and Modernization Act, and the proposed authorization of Reinspection User Fees.

Animal Drugs and Feeds Program: The FY 2010 budget contains a program level increase of $36.7M (+$19.0M in budget authority; +$17.7M in user fees). The increase contains funds to implement the activities and achieve the performance commitments under the Protecting America's Food Supply Initiative, the Safer Medical Products Initiative and Supply Chain Safety and Security. The increase also includes the cost of living increase for FDA workforce at the Center for Veterinary Medicine (CVM) and the ORA workforce in the Animal Drugs and Feeds Program. Finally, the increase also includes funds to meet performance commitments under the Animal Drug User Fee Act, the Animal Generic Drug User Fee Act, and the proposed authorization of new user fees for Food Inspection and Facility Registration and user fees for Export Certification and Reinspections.

Devices and Radiological Health Program: The FY 2010 budget contains a program level increase of $41.8M (+$34.8M in budget authority; +$7.0M in user fees). The increase includes funds for the Safer Medical Products Initiative and Supply Chain Safety and Security. The increase also includes the cost of living increase for FDA workforce at the Center for Devices and Radiological Health (CDRH) and the ORA workforce in the Devices Program. Finally, the increase includes user fees to meet performance commitments based on the Mammography Quality Standards Act, and the Medical Device User Fee and Modernization Act, and the proposed authorization of Reinspection User Fees.

National Center for Toxicological Research (NCTR): The FY 2010 budget contains a program level increase of $6.2M. The increase contains funds for NCTR research activities that support the Protecting America's Food Supply Initiative, the Safer Medical Products Initiative and Supply Chain Safety and Security. The increase also includes cost of living increases for the FDA workforce at NCTR.

Headquarters and Office of the Commissioner: The FY 2010 budget contains a program level increase of $44.8M (+$23.2M in budget authority; +$21.6M in user fees). The increase contains funds to support the Protecting America's Food Supply Initiative, the Safer Medical Products Initiative and Supply Chain Safety and Security. The increase also includes the cost of living increase for FDA workforce in the Office of the Commissioner. Finally, the increase also includes funds to meet performance commitments under the proposed authorization of new user fees for Food Inspection and Facility Registration, and user fees for Export Certification and Reinspection.

Rent Payments and Activities: The FY 2010 budget contains a program level increase of $22.8M (+$14.0M in budget authority; +$8.8M in user fees). The increase will allow FDA to maintain performance and pay higher GSA rent, Other Rent and Rent-Related, and White Oak costs without redirecting resources from core, mission-critical public health activities.

Buildings and Facilities: The FY 2010 budget contains a program level decrease of $3.5M (–$3.5M in budget authority). The reduction in this program area reflects the discontinuation of a program funded in FY 2009. This reduction relates to funding appropriated under Section 725 of Omnibus Appropriation Act, 2009 (PL 111-8). In FY 2010, FDA will use these funds for other FDA priorities.

Protecting America's Food Supply:
Investments for Supply Chain Safety and Security
+$259,258,000/ 678 FTE

1. Why is this initiative necessary?

A. Background

For FY 2010, FDA is proposing a budget increase of $259,258,000 for Protecting America's Food Supply. The budget for this initiative includes $75,000,000 in new user fees to register food facilities and increase food facility inspections and related activities. The FY 2010 Protecting America's Food Supply initiative builds on recent investments by Congress to increase FDA investment in Supply Chain Safety and Security.

The global marketplace poses unprecedented challenges on FDA's ability to protect public health. There are more ready-to-eat foods, and farm-to-table delivery of foods is faster than at any point in history. Moreover, the global nature of the supply chain for foods means that more finished products and ingredients enter the United States from more countries in greater and greater volume.

Since the beginning of the decade, food imports have grown by as much as 15 percent per year. The volume of FDA-regulated foods now exceeds 10 million import entries annually.

FDA employs a scientific risk-based approach to target its resources and to ensure the greatest public health value for the level of food inspection and surveillance that we conduct. Yet, recent food and drug safety incidents demonstrate that, in addition to conducting more frequent and targeted inspections, FDA must expand other activities necessary to secure the supply chain or it will fail to meet its responsibility to protect the American public.

The goal of the FY 2010 investments is to prevent intentional and unintentional food contamination before problems occur and to counter potential food defense and food safety threats before they harm consumers. By focusing greater attention on food production, processing and handling sites throughout the entire supply chain, FDA can better protect the American consumers and the U.S. economy from food safety and food defense threats.

B. Food Registration and Inspection User Fees

FDA's FY 2010 budget includes $75,000,000 for user fees to register food facilities and conduct safety and good manufacturing practices inspections of the facilities that manufacture and process the foods that Americans consume. The new user fees will pay costs associated with activities that are necessary for the safety and security of the supply chain for foods, such as:

- preventive controls to avoid foodborne outbreaks
- an integrated system with states on food inspection and enforcement
- FDA domestic and foreign inspections
- import review and analysis

- surveillance for intentional and unintentional food contamination
- laboratory analysis of food samples
- information technology investments required to support food safety and security.

C. Cost of Living Increase for FDA Food Safety Programs

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 staff required to conduct the operations of FDA food safety programs.

Delivering FDA's food safety mission is a personnel-intensive effort. FDA performs its public health mission through a highly trained professional workforce. Personnel and related costs account for 78 percent of FDA's annual expenditures. To maintain its strong scientific and regulatory capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

This initiative includes funds for the annual cost of living increase for employees who conduct FDA's food defense and food safety programs. If FDA does not receive the resources to pay these costs, FDA cannot fulfill its fundamental mission to the American public. Providing funds to meet the annual pay increase allows FDA to achieve performance commitments for food programs and ensures that FDA can anticipate and respond to public health emergencies.

D. Funding Table

Protecting America's Food Supply

Dollars in millions

Program[1]	FY 2008 Enacted[2]	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
Foods	**$571.902**	**$642.965**	**$777.158**	**+$134.193**
Center[3]	185.720	207.039	232.971	+$25.932
Field Activities[3]	386.182	435.926	544.187	+$108.261
Animal Drugs and Feeds	**79.356**	**89.146**	**104.043**	**+$14.897**
Center	43.382	49.202	56.106	+$6.904
Field Activities	35.974	39.944	47.936	+$7.992
National Center for Toxicological Research	**5.323**	**8.683**	**10.376**	**+$1.693**
Headquarters and OC	**38.226**	**44.239**	**58.296**	**+$14.057**
Total, Budget Authority	**$694.807**	**$785.033**	**$949.872**	**+$164.839**
Proposed Reinspection Fee	**$0.000**	**$0.000**	**$15.267**	**+15.267**
Proposed Export Certification Fee	**$0.000**	**$0.000**	**$4.152**	**+4.152**
Proposed Food Inspection and Facility Registration fee	**$0.000**	**$0.000**	**$75.000**	**+75.000**
Total, Program Level	**$694.807**	**$785.033**	**$1,044.291**	**$259.258**

[1] Includes funds for Dietary Supplements and Nutrition/Food Labeling activities (FY 2008-FY 2010 = $27.220M)

[2] Amounts include June 30, 2008 supplemental appropriation for Dietary Supplements, Nutrition and Food Labeling Activities.

[3] Removes funding for Cosmetic safety activities (FY 2008 = $4.7M, FY 2009-FY2010 = $5.7M)

2. What are the objectives of Supply Chain Safety and Security?

The globalization of the manufacturing and supply of foods that FDA regulates and Americans consume poses unique and demanding challenges for FDA. In the complex and rapidly changing environment driven by globalization, FDA cannot rely on traditional approaches – inspection and sampling at the U.S. border – to protect Americans and ensure the safety of foods. Rapid globalization requires that FDA implement new approaches and conduct new activities to effectively regulate the supply chain. The priorities proposed in this initiative will assure the safety and security of foreign and domestic sources of ingredients, components, and finished products at all points in the supply chain, including their eventual use by American consumers.

Supply Chain Safety and Security relies on risk-based prevention with a verification-focused approach to hold all segments of industry accountable for ensuring that their products meet U.S. safety standards, with FDA verifying compliance with standards. Supply Chain Safety and Security also extends FDA's reach by supporting and leveraging the activities of, and benefiting from information generated by, trusted state, local and foreign regulatory partners.

The following are some of the key principles of FDA Supply Chain Safety and Security that this FY 2010 initiative will support:

Oversight of the Supply Chain – FDA will increase food safety and security by enhancing oversight of entities in the supply chain. FDA will use traditional and innovative mechanisms that include FDA inspections and field exams, integrated federal-state oversight and greater access to inspection data and results acquired from trusted foreign regulatory authorities. These activities will prevent harm by achieving greater compliance with FDA safety standards and detecting and correcting safety risks.

Response – When problems occur, FDA will respond more effectively with rapid and targeted product tracing to more accurately identify firms that are responsible for the problem. FDA will also better identify firms that are not associated with the safety problem. FDA will better coordinate its response with state and local authorities and strengthen its laboratory analysis capability and capacity, including greater electronic connectivity with other federal, state, and local laboratories.

Targeting Areas of Greatest Risk – FDA will allocate resources based on data-driven risk analysis. FDA will achieve this objective by increasing the quality and quantity of relevant data it analyzes on products and manufacturers that are part of the supply chain. FDA's success will increasingly depend on modern information technology systems, better analytic tools, and better recruiting and training of personnel in statistical and decision sciences, informatics, and operations research, as well as the traditional fields of natural sciences and engineering. The result will be a stronger ability to target products or firms that violate FDA safety standards.

Risk Communication – FDA will improve safety through better risk communication. Better risk communication will ensure that consumers understand what to do – and not do – in response to safety problems.

3. What will FDA achieve with this investment?

The budget authority and user fee increases that support Supply Chain Safety and Security of the food supply will produce important health benefits for consumers during FY 2010 and in years to come. These increases will allow FDA to reduce illnesses caused by food contamination.

The foundation of this strategy is a risk-focused science-based approach, applied throughout the supply chain, that builds new and greater food protection capabilities over several years. While there are significant early benefits to this comprehensive approach from existing investments, FDA and its partners will achieve even greater reductions in risk to the food supply as the prevention strategies mature and FDA implements risk-based improvements to field operations.

During FY 2010, FDA will achieve significant results that contribute to food protection:

A. Prevention and Verification

FDA will improve its ability to protect American consumers and strengthen safety and security of the supply chain by working with domestic and foreign industry to develop new control measures for all levels of the food production and processing. FDA will also verify that these control measures are effective when implemented.

FDA will strengthen food safety by improving the science upon which regulatory decisions and enforcement rely. FDA will conduct risk analysis, modeling and evaluation to improve risk-based decision-making that allows FDA to better target our resources to high-risk foods. This work will also include improving FDA's ability to attribute contamination to specific foods and thereby promote faster response and better resource targeting.

FDA will work with food industry, consumer groups, and federal, state, local and foreign partners to identify and generate the additional data to improve our understanding of food vulnerabilities and risks. We will use this information to strengthen food safety and food defense.

FDA will work with other state and federal agencies to collect baseline data to measure the impact of its food safety efforts and measure the reduction of foodborne illnesses in the United States. This will allow FDA to adjust food safety priorities and ensure that food programs achieve the best health results for the American public.

B. Intervention and Detection

FDA's ORA field operations play a central role in oversight of the supply chain. FDA will ensure the adequacy of the prevention strategies that the food industry employs by increasing domestic and foreign risk-based inspections, conducting audits of controls designed to prevent contamination, and performing sampling and surveillance.

Specifically, FDA will conduct the following additional field activities with the FY 2010 increase proposed in this initiative. Because FDA must thoroughly train newly hired

investigators on the technical and subtle aspects of conducting food inspections and surveillance, FDA will achieve the full level of these performance increases during FY 2011 and FY 2012:

- 20,000 additional import food and feed field exams
- 4,000 additional domestic food safety inspections
- 100 additional foreign food and feed inspections

FDA will also expand state capacity to perform risk-based inspections by increasing the number of cooperative agreements and partnerships with states.

FDA will increase the number of chemical labs under the Food Emergency Response Laboratory (FERN) program through cooperative agreements. FDA will also invest in FDA high-volume laboratories for better sample analyses and faster testing.

FDA proposes to establish a new strategic framework for an integrated national food safety system. To achieve this objective, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its federal, state, local, tribal and territorial partners. This will allow FDA to increase information sharing and improve the quantity and quality of food safety data that FDA receives from its food safety partners.

FDA will conduct research in high priority areas such as reducing the risk of *E. coli* in produce. FDA will speed its response to outbreaks by developing and validating technologies to subtype pathogens and developing, evaluating and deploying rapid detection tests to protect consumers.

Working with its federal and state partners, FDA will develop a Pet Event Tracking Network for early reporting of contaminated food or feed. FDA will also conduct research designed to limit the adverse health affects of intentional and unintentional contamination of food.

FDA will upgrade and integrate the information technology systems it uses to screen, sample, detain, and take enforcement actions against imported products. This effort includes developing and validating an accurate database of registered foreign facilities as well as design and use of risk-based software algorithms for import targeting.

C. Response and Recovery

FDA will improve the speed and effectiveness of its response to contamination by strengthening its ability to collect and analyze information necessary to trace products during a food emergency. FDA will also collaborate with state veterinary diagnostic laboratories to ensure more timely and accurate reporting and analysis of feed contamination.

FDA will aggressively strengthen its response to food-related events by instituting a more robust incident command system that fully integrates modern incident command principles into FDA emergency operations. FDA will also improve how it communicates with consumers about food-related emergencies to ensure that communications related to food safety better meet the health and information needs of consumers.

D. Information Technology

Modernizing and enhancing information technology (IT) at FDA will allow FDA to collect, store and analyze large volumes of regulatory, scientific, and risk-based data. Efficiently analyzing this data through IT improvements will help ensure that FDA achieves its mission of protecting the public health by assuring the safety and security of our nation's food supply chain, both imported and domestic.

In the case of food imports, during FY 2010 FDA will upgrade and integrate the IT systems it uses to screen, sample, detain, and take enforcement action against imported food and feed. This will include major upgrades to allow FDA to process the data it receives through automated risk assessment algorithms using a system known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). PREDICT is an automated data mining and pattern discovery system to improve import screening and targeting. Implementing PREDICT will help prevent the entry of adulterated, misbranded, or other foods that violate law or regulations.

FDA will also upgrade and integrate MedWatch Plus and the FDA Adverse Event Reporting System (FAERS) – the IT systems it uses to receive, analyze, and assess product quality and safety reports for foods and feeds. This upgrade and integration will implement the FDAAA-mandated Reportable Food Registry and Early Warning Surveillance and Notification for Pet Foods systems. Taken together, these IT systems will measurably improve FDA's ability to assure the safety and security of imported and domestic food and feed, thus enhancing public health and the safety of American consumers.

E. Cost of Living Pay Increase for FDA Food Protection Programs

Funding the annual cost of living increase allows FDA to sustain ongoing performance in food protection programs. In contrast, failing to fund the cost of living pay increase will cause performance to deteriorate across all FDA food safety programs.

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

A. FDA Supply Chain Safety and Security

Not funding this initiative poses health risks for American consumers and threatens the Federal government's ability to protect food supply. Failing to fund this initiative also diminishes the ability of FDA, States, and local health agencies to prevent or respond to a terrorist attack or a public health emergency related to food. Not providing sufficient resources to sustain the Protecting American's Food Supply strategy will have far-reaching consequences, including:

- Significant outbreaks of foodborne illness will continue in the United States if FDA cannot develop the scientific- and risk-based techniques to identify and eliminate foodborne hazards and prevent contaminated foods from reaching American consumers.

- Imported foods will remain a safety and security threat. Products from countries with high-risk food production, manufacturing, and distribution systems will continue to enter U.S. commerce without appropriate surveillance and intervention.

- FDA and our industry partners will not achieve the ability to rapidly trace the origin of foods implicated in intentional or unintentional adulteration.

- American consumers will continue to suffer significant adverse health consequences, including morbidity and death, because FDA cannot establish a strong, science-based regulatory framework with prevention standards to ensure the safety and defense of food.

- The confidence of Americans in the safety and security of the food supply will remain low. Consumers will avoid certain foods such as fruits and vegetables and will not fully benefit from foods that are essential to a healthy diet. This will increase morbidity and mortality from chronic diseases and result in significant public health impact and costs.

- FDA will have an inadequate ability to collect, store and analyze large volumes of regulatory, scientific, and risk-based information. Without these IT investments, FDA cannot transform a broad array of FDA operations: from bioinformatics, to import surveillance, to scientific computing, to detecting adverse events. Not funding these IT priorities will limit FDA's ability to protect consumers and assure the safety and security of our nation's food supply chain, both imported and domestic.

B. Cost of Living Pay Increase for FDA Food Protection Programs

Failing to fund this initiative will limit FDA's ability to respond to food emergencies. Not funding this initiative also means that FDA must reduce core public health programs, particularly the professional staff that performs our mission.

Failing to fund the cost of living pay increase will result in an FDA-wide loss of 64 FTE. This total includes 43 Field FTEs who conduct inspections and perform other food safety work.

If FDA does not receive these funds, FDA must reduce staff so that FDA can pay mandatory cost of living increases for the remaining staff. The loss of these scientific and technical experts will impair FDA's ability to fulfill its public health responsibilities and limit FDA's ability to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to reduce food defense and food safety threats, effectively regulate the safety and security of the supply chain, and protect the health and security of the American people.

Safer Medical Products:
Investments for Supply Chain Safety and Security
$166,433,000 / 346 FTE

1. Why is this initiative necessary?

A. Background

For FY 2010, FDA is proposing a budget increase of $166,433,000 to improve the safety of medical products. The funding for this initiative includes $36,000,000 in new user fees for generic drug review.

The FY 2010 Safer Medical Products Initiative contains strategic investments to improve the safety of medical products. The initiative also includes investments that will allow FDA to implement new approaches to effectively regulate the safety and security of the supply chain of medical products that American patients rely on to maintain and improve their health.

The resources in this initiative will allow FDA to measurably improve the safety of medical products: human drugs, vaccines, blood and other biological products, medical devices, animal drugs and medicated feed. The investments in this initiative will increase FDA's capacity to effectively monitor the safety of medical products. Moreover, these investments will provide better information about the safety profile of medical products at earlier stages of development.

B. Generic Drug User Fees

Ensuring the safety, quality, and comparability of lower cost generic drugs has never been more important to the American public. Generic drugs account for 70 percent of all prescriptions dispensed in the United States, up from 50 percent just four years ago. The number of generic drug application has nearly tripled since 2001. However, staffing has not kept pace with rising workload during much of this period.

With the globalization of the drug manufacturing, generic drugs or their ingredients are more likely to be produced in countries such as India and China. In India alone, the number of facilities named in generic drug applications grew from eight in 1992 to 963 in 2008. This dramatic growth imposes additional burdens on FDA. It is becoming increasingly difficult to conduct pre-approval inspections of all foreign facilities in a timely way.

In the coming years, patents will expire on more than a dozen blockbuster brand-name drugs that account for tens of billions of dollars in prescription spending annually. Generic competition for these drugs will likely be very strong. Not only will generic drug applications continue to grow, but companies will also be under increasing pressure to cut costs in response to competition. Yet, cost-cutting measures have the potential to comprise drug quality. It is imperative that FDA have the resources to ensure the safety, quality, and comparability of generic drugs and allow Americans to benefit from the savings from lower cost generic drugs.

C. Cost of Living Increase for FDA Medical Product Programs

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 staff required to conduct the operations of FDA medical product programs.

Delivering the FDA mission is a personnel-intensive effort. FDA performs its public health mission through a highly trained professional workforce. Personnel and related costs account for 78 percent of FDA's annual expenditures. To maintain its strong science and regulatory capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

This initiative includes funds for the annual cost of living increase for employees who conduct FDA medical product programs. If FDA does not receive the resources to pay these costs, FDA cannot adequately assure the safety of medical products or fulfill its fundamental responsibilities to the American public. Providing funds to meet the annual pay increase allows FDA to achieve performance commitments for medical product programs and ensures that FDA can anticipate and respond to public health emergencies.

D. Funding Table

Safer Medical Products

Dollars in Millions

Program	FY 2008 Enacted [1]	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
Budget Authority:				
Human Drugs	**$381.288**	**$413.482**	**$457.814**	**+44.332**
Center	$280.282	302.386	329.588	+27.202
Field Activities	$101.006	111.096	128.226	+17.130
Biologics	**$167.965**	**$183.451**	**$206.438**	**+22.987**
Center	$135.457	148.134	166.182	+18.048
Field Activities	$32.508	35.317	40.256	+4.939
Animal Drugs and Feeds	**$23.738**	**$27.325**	**$31.432**	**+4.107**
Center	$20.319	23.833	26.346	+2.513
Field Activities	$3.419	3.492	5.087	+1.595
Devices and Radiological Health	**$258.086**	**$280.587**	**$315.377**	**+34.790**
Center	$192.839	209.061	234.974	+25.913
Field Activities	$65.247	71.526	80.403	+8.877
National Center for Toxicological Research	**$42.079**	**43.828**	**48.369**	**+4.541**
Headquarters and Office of the Commissioner	**$71.576**	**75.722**	**84.816**	**+9.094**
Total, Budget Authority	**$944.732**	**$1,024.395**	**$1,144.247**	**+119.852**
Proposed Generic Drug User Fee:	**$0.000**	**$0.000**	**$36.000**	**+36.000**
Proposed Reinspection Fee	**$0.000**	**$0.000**	**$10.581**	**+10.581**
Total, Program Level	**$944.732**	**$1,024.395**	**$1,190.828**	**$166.433**

[1] *Amounts include June 30,2008 supplemental appropriation.*

2. What are the objectives of Supply Chain Safety and Security?

The globalization of the manufacturing and supply of medical products that FDA regulates and American patients rely on to maintain and improve their health poses unique and demanding challenges for FDA. In the complex and rapidly changing environment driven by globalization, FDA cannot rely on traditional approaches – inspection and sampling at the U.S. border – to protect Americans and ensure the safety of medical products. Rapid globalization requires that

FDA implement new approaches and conduct new activities to effectively regulate the supply chain. The priorities proposed in this initiative will assure the safety and security of foreign and domestic sources of ingredients, components, and finished products at all points in the supply chain, including their eventual use by American consumers.

Supply Chain Safety and Security relies on risk-based prevention with a verification-focused approach to hold all segments of industry accountable for ensuring that their products meet U.S. safety standards, with FDA verifying compliance with standards. Supply Chain Safety and Security also extends FDA's reach by supporting and leveraging the activities of, and benefiting from information generated by, trusted State, local and foreign regulatory partners.

The following are some of the key principles of FDA Supply Chain Safety and Security that this FY 2010 initiative will support:

Oversight of the Supply Chain – FDA will increase medical product safety and security by enhancing oversight of entities in the supply chain. FDA will use traditional and innovative mechanisms that include FDA inspections and field exams, integrated federal-state oversight, and greater access to inspection data and results acquired from trusted foreign regulatory authorities. These activities will prevent harm by achieving greater compliance with FDA safety standards and detecting and correcting safety risks.

Response – When problems occur, FDA will respond more effectively with rapid and targeted product tracing using to more accurately identify firms that are responsible for the problem. FDA will also better identify firms that are not associated with the safety problem. FDA will better coordinate its response with state and local authorities and strengthen its laboratory analysis capability and capacity, including greater electronic connectivity with other federal, state, and local laboratories.

Targeting Areas of Greatest Risk – FDA will allocate resources based on data-driven risk analysis. FDA will achieve this objective by increased the quality and quantity of relevant data it analyzes on products and manufacturers that are part of the supply chain. FDA's success will increasingly depend on modern information technology systems, better analytic tools, and better recruiting and training of personnel in statistical and decision sciences, informatics, and operations research, as well as the traditional fields of natural sciences and engineering. The result will be a stronger ability to target products or firms that violate FDA safety standards.

Risk Communication – FDA will improve safety through better risk communication. Better risk communication will ensure that patients understand what to do – and not do – in response to safety problems.

3. What will FDA achieve with this investment?

A. Specific activities that the funds in this initiative support

The following are examples of investments in FDA's Safer Medical Products Initiative:

Safer Medical Products

Safety of biological products –

FDA will hire experts to bring additional expertise to blood, tissue and vaccine safety teams, which will strengthen the ability of these teams to analyze adverse events. FDA will also modernize blood, tissue, and vaccine standards to enhance product development, safety and quality.

FDA will strengthen the safety of the supply chain for biological products by providing increased support for inspection teams and by working with biological manufacturers to establish quality systems focused on product safety and quality. CBER will also develop new screening tests for emerging blood-borne diseases.

Safety of medical devices –

FDA will strengthen the safety of the supply chain for medical devices by employing a global medical device nomenclature to improve postmarket surveillance and facilitate our ability to share and analyze adverse event reports with other regulators.

FDA will hire and train staff to provide technical assistance to domestic and foreign inspections of medical device manufacturers and to provide support to the device activities of FDA foreign offices.

FDA will strengthen the safety of the supply chain for medical devices by delivering training to field offices on the technical aspects of conducting device inspections. FDA will also conduct audits of inspection reports issues by other countries.

FDA will more rapidly identify product defects in medical devices by developing web-based tools to gather unique device information.

FDA will hire staff to develop new tests and strengthen safety reviews of ophthalmic medical devices.

Safety of human drugs –

FDA will identify internet sites that expose consumers to drug fraud. This effort will improve FDA's ability to conduct enforcement against those who sell and promote fraudulently marketed products.

FDA will perform research to establish generic bioequivalence standards for novel products. FDA will also expand generic drug education that informs patients of the value of generic drugs and strengthens the confidence of health care providers in prescribing and treating patients with generics.

FDA will evaluate how we use of Risk Evaluation and Mitigation Strategies to minimizing drug risks and promoting save drug use.

Safer Medical Products

FDA will develop policies to implement the Administration's policy of allowing Americans to buy safe and effective drugs from other countries. The request includes funds to allow FDA to begin working with stakeholders to develop policy options related to drug importation. In addition, the Administration will work with Congress on legislation to support the infrastructure required to ensure the safety of these medicines.

Safety of veterinary drugs and feeds –

FDA will strengthen the supply chain by improving the sampling of imported animal drugs and feeds for chemical and microbiological contamination and for BSE.

FDA will conduct scientific and risk evaluation of animal biotechnology products. FDA will also review of new animal biotechnology products and coordinate U.S. and foreign regulation on animal health issues within FDA's jurisdiction.

FDA will hire cross-disciplinary staff to provide technical and laboratory support to develop and improve methods to detect pathogens.

FDA will strengthen the supply chain by partnering with states to conduct targeted sample analysis of animal feeds. FDA will also expand laboratory capacity to accommodate increased levels of feed sampling.

Safety of pediatric medical products –

FDA will collect adverse event information related to medical devices from pediatric hospitals and will conduct a pediatric medical trials workshop to address unmet pediatric device needs.

FDA will support additional pediatric medical device research, increase technical assistance for orphan product development, and expand the amount of information that it disseminates related to foreign pediatric clinical trials.

B. Generic Drug User Fees

The FY 2010 budget for Generic Drug User Fees represents the first year of a multi-year program to expand FDA's capacity to ensure the safety, quality, and comparability of lower cost generic drugs. In the short-term, the results of this initiative will include hiring and training of additional staff so that new staff gains the technical expertise that allows FDA to expand its ability to conduct generic drug application reviews.

These funds will support the hiring and training of the expert staff necessary for a modernized and effective generic drug review and oversight program. FDA will also enhance a range of operations related to generic drugs. This effort will include scientific work on generic bioequivalence standards, process improvements to modernize the generic drug review process, a more effective electronic review process, greater capacity to conduct pre-approval inspections,

and more oversight of foreign manufacturing sites. Many of these operations are essential to the safety and security of the supply chain for generic drugs.

Once these building blocks are in place, FDA will be better able to conduct timely, efficient, and effective reviews of a significantly greater number of generic drug applications. FDA will also be able to provide appropriate oversight of manufacturing facilities across the globe to ensure the safety and security of the supply chain of generic drugs. Ultimately, FDA will be able to ensure greater access to generic drugs and maintain confidence that generic drugs that are safe, of high quality, and comparable to their brand competitors. This will ensure the viability of the generic industry and its ability to provide lower cost drugs to the American public.

C. Information Technology

Modernizing and enhancing information technology (IT) at FDA will allow FDA to collect, store and analyze large volumes of regulatory, scientific, and risk-based data. Efficiently analyzing this data through IT improvements will help ensure that FDA achieves its mission of protecting the public health by assuring the safety and security of the drugs, devices, vaccines, and other medical products that patients rely on to protect or improve their health.

Through the FY 2010 IT investments in the Harmonized Inventory Initiative, FDA will develop and validate a database with a complete and reliable inventory of firms, facilities, products, components and ingredients. The database will also identify relationships between firms and points of contact for all FDA regulated products, whether imported or domestic. FDA will also upgrade and integrate the IT systems it uses to receive, analyze, and assess quality and safety reports for medical products. These IT improvements will measurably improve FDA's ability to assure the safety and effectiveness of imported and domestic medical products and thereby protect the safety of American patients.

D. Cost of Living Pay Increase for FDA Medical Product Programs

Funding the annual cost of living increase allows FDA to sustain ongoing performance in the medical product programs that are essential to allowing American patients to enjoy the benefits of safe and effective drugs. In contrast, failing to fund the annual cost of living increase will cause performance to deteriorate across all FDA medical product programs.

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

A. Safer Medical Products

Not funding this initiative will threaten the health of the American Public. FDA will face a significantly diminished capacity to address adverse events, identify and analyze medical product safety signals, and communicate safety information to patients and the medical community. This will lead to preventable injuries and deaths due to adverse events, medical errors, and product defects, with increased health care costs for patients, insurers, and federal and state governments.

Safer Medical Products

B. Generic Drug User Fees

The failure to approve generic drug user fees will result in continued understaffing of generic drug review, gaps in science-based quality standards for generic drugs, and insufficient pre-approval inspections to support the growth in generic applications. This will place serious constraints on FDA's ability to provide proper oversight of the growing number of increasingly complex applications for generic drugs being manufactured in distant foreign facilities with little prior regulatory oversight. This invites a greater opportunity for the public to question the safety, quality and comparability of generic drugs. A loss of confidence in generic drug alternatives will hurt the generic industry and erode the public benefits and health care cost savings provided by lower-cost generic drugs.

C. Information Technology

FDA will have an inadequate ability to collect, store and analyze large volumes of regulatory, scientific, and risk-based information. Without these IT investments, FDA cannot transform a broad array of FDA operations: from bioinformatics, to import surveillance, to scientific computing, to detecting adverse events. Not funding these IT priorities will limit FDA's ability to protect the public health and assure the safety and security of medical products that Americans rely on to protect and improve their health.

D. Cost of Living Pay Increase for FDA Medical Product Programs

Not receiving these funds means that FDA must reduce core public health programs, particularly the professional staff that perform our FDA mission. Failing to fund this initiative will also limit FDA's ability to perform analysis on the safety and effectiveness of medical products that Americans rely on to sustain or improve their health.

Failing to fund the cost of living pay increase will result in an FDA-wide loss of 81 FTEs in medical product program areas. This total includes 24 Field FTEs who conduct inspections and perform other medical product safety work.

If FDA does not receive these funds, FDA must reduce staff so that FDA can pay mandatory cost of living increases for the remaining staff. The loss of these scientific and technical experts will impair FDA's ability to fulfill its public health responsibilities and limit FDA's ability to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to effectively regulate the safety and security of the supply chain of medical products and protect the health and security of the American people.

Infrastructure to Support Critical Agency Operations
GSA Rent + $11,671,000
Other Rent and Rent-Related +$2,329,000

1. Why is this initiative necessary?

The proposed $14,000,000 increase in budget authority will allow FDA to improve performance and provide for rising GSA rent, and Other Rent and Rent-Related costs without redirecting resources from core, mission-critical public health activities.

GSA Rent and Other Rent and Rent-Related Funding History
Budget Authority

Program	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Estimate	+/- FY 2009
GSA Rent Budget Authority	$130,611,000	$134,351,000	$146,022,000	+$11.671,000
Other Rent and Rent-Related Budget Authority	$50,278,000	$50,293,000	$52,622,000	+$2,329,000
Total, Budget Authority [1/]	**$180,889,000**	**$184,644,000**	**$198,644,000**	**+$14,000,000**

1/ User fee funding including increases for these facility related activities are presented in the user fee business case papers.

2. What activities will the funds support?

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 guard services and security systems at these facilities.

The Other Rent and Rent-Related 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-owned, GSA owned or leased and FDA-managed, and FDA-leased properties located nationwide. Costs include commercial rent, utilities, operation and maintenance contracts, janitorial and grounds maintenance contracts, and security and guard services contracts. The account also includes costs for overtime utilities and other above-standard level services provided by GSA in GSA-managed facilities.

FDA currently occupies over 7.2 million square feet of GSA space. Approximately two-thirds of the GSA rent charges for government-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for the Parklawn complex, Module II in Beltsville, CFSAN's College Park complex, and the newly occupied buildings at the White Oak, Maryland campus. In addition, FDA-occupied space comprises approximately 240 leases including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

3. How does this initiative support Executive Branch public health priorities?

The rental properties that provide office and laboratory space for FDA's 11,000 employees are essential facilities that allow FDA to perform its vital public health mission. FDA's consolidation at White Oak provides an environment that encourages efficiency, creativity, and superior performance, while strategically using our human capital.

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

It is important that FDA keep its infrastructure strong and provide a highly functional place to perform our regulatory mission. The increasing mandatory costs associated with GSA rental space and the Other Rent and Rent-Related activity would place enormous pressure on FDA's resources, impairing FDA's ability to accomplish its public health mission.

Current Law User Fees
+$74,359,000

1. Why are these amounts necessary?

FDA user fee programs facilitate enhanced premarket review performance and the timely availability of safe and effective medical devices, human and animal drugs, biological products, and other FDA-regulated products. The budget submission includes increases for existing user fee programs as authorized by statute. The increases expand the available options for treating and curing diseases and other health problems.

The following table identifies the FY 2010 budget submission and funding history for current user fee programs:

Funding History of Current Law User Fees

Description	FY 2008 Actual	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
PDUFA	$450,787,000	$510,665,000	$578,162,000	$67,497,000
MDUFMA	$36,422,000	$52,547,000	$57,014,000	$4,467,000
ADUFA	$13,530,000	$15,260,000	$17,280,000	$2,020,000
AGDUFA	$0	$4,831,000	$5,106,000	$275,000
MQSA	$13,537,000	$19,318,000	$19,318,000	$0
Export Certification	$2,707,000	$2,600,000	$2,700,000	$100,000
Color Certification	$7,379,000	$7,700,000	$7,700,000	$0
Total	**$524,362,000**	**$612,921,000**	**$687,280,000**	**$74,359,000**

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

The currently authorized user fees that FDA collects support two important public health priorities: transforming health care and improving access to FDA-regulated products. The fees allow FDA to improve product review performance, which reduces the time it takes for safe and effective human and animal drugs, medical devices, and other FDA-regulated products to reach the market. User fees supplement appropriated dollars and allow FDA medical product programs to hire additional scientific review staff and review process managers, improve the review process, reduce review time, and provide essential information technology to support product review.

3. What are the risks of not funding this initiative?

Without additional resources, FDA will not be able to perform the following critical work that advances public health:

- Meet the performance commitments for faster medical device review (MDUFMA) and faster human drug (PDUFA) and new and generic animal drug review (ADUFA & 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.

- Sustain patient access to safe and effective new products by providing rapid, transparent, and predictable review of marketing applications.
- Maximize safe and effective use of medical products by communicating benefits and risks more effectively.
- Prevent harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response.
- Increase availability of FDA experts to expand and improve consultation and outreach to industry, thereby reducing medical product development time.

4. What are the increases for each user fee program?

PDUFA: + $67,497,000

In the FDA Amendments Act of 2007 (FDAAA), Congress renewed FDA's authority to the collect Prescription Drug User Fee Act (PDUFA) user fees. Known as PDUFA IV, this authority is effective for five years and 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 ceases to be effective October 1, 2012.

PDUFA IV continues to improve upon previous authorizations. PDUFA IV upgrades and broadens FDA's drug safety program and expands guidance for industry and FDA reviewers. The funds in this initiative allow FDA to invest in information technology that supports human drug review. The funds will also facilitate more efficient development of safe and effective new drugs and support FDA efforts to modernize the drug safety system for the American public.

Based on current information and established PDUFA formulas, the statute authorizes fee increases of $67,497,000 in FY 2010. This increase is based on inflation and workload factors associated with the FDA drug review program.

The following table identifies the FY 2010 increase for PDUFA:

PDUFA Increase for FY 2010

Program	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
CDER	$356,835,000	$406,984,000	$50,149,000
CBER	$73,206,000	$83,747,000	$10,541,000
Field Activities	$10,478,000	$11,795,000	$1,317,000
GSA Rent, Rent Related and White Oak	$37,436,000	$40,366,000	$2,930,000
HQ/OC	$32,710,000	$35,270,000	$2,560,000
Total	**$510,665,000**	**$578,162,000**	**$67,497,000**

The overall success of PDUFA provides FDA with the revenue to hire additional reviewers and support staff and upgrade FDA information technology systems to speed the application review process for new drugs and biological products. FDA accomplishes its PDUFA responsibilities without compromising FDA's high standards for drug approval.

MDUFMA: +$4,467,000

In the 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 the medical device review MDUFMA also provided funds to ensure a sound financial footing for medical device review, enhance the process for premarket review, and modified 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 ceases to be effective October 1, 2012.

The following table identifies the FY 2010 increase for MDUFMA:

MDUFMA Increase for FY 2010

Program	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
CBER	$10,968,000	$11,068,000	$100,000
CDRH	$28,911,000	$32,836,000	$3,925,000
Field Activities	$1,556,000	$1,556,000	$0
GSA Rent and Rent Related	$5,198,000	$5,640,000	$442,000
HQ/OC	$5,914,000	$5,914,000	$0
Total	**$52,547,000**	**$57,014,000**	**$4,467,000**

ADUFA: +$2,020,000

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 animal drug products subject to FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption.

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 ceases to be effective October 1, 2013.

The following table identifies the FY 2010 increase for ADUFA:

ADUFA Increase for FY 2010

Program	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
CVM	$13,362,000	$15,290,000	$1,928,000
Field Activities	$250,000	$250,000	$0
GSA Rent and Rent Related	$992,000	$1,047,000	$55,000
HQ/OC	$656,000	$693,000	$37,000
Total	**$15,260,000**	**$17,280,000**	**$2,020,000**

AGDUFA: +$275,000

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 will enhance the performance of the generic new animal drug review process, enable FDA to better ensure that generic new animal drug products are safe and effective, and give consumers a lower cost alternative to pioneer drugs. Following the ADUFA model, AGDUFA will provide funding for increased review staff, training and development for staff members, and for refining business processes and developing policies targeted at more efficient review. The authority to collect AGDUFA user fees ceases to be effective October 1, 2013.

The following table identifies the FY 2010 increase for AGDUFA:

AGDUFA Increase for FY 2010

Program	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
CVM	$4,118,000	$4,382,000	$264,000
Field Activities	$143,000	$143,000	$0
GSA Rent and Rent Related	$377,000	$377,000	$0
HQ/OC	$193,000	$204,000	$11,000
Total	**$4,831,000**	**$5,106,000**	**$275,000**

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 their lifetime. The Mammography Quality Standards Act (MQSA), which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography.

Congress enacted MQSA to ensure that all women have access to quality mammography for the detection of 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 statute directs the assessment, collection, and use of fees to cover the costs of MQSA inspections, record keeping and development of annual reports. In FY 2010, FDA estimates the same level as the FY 2009.

The following table identifies the FY 2009 and FY 2010 funding for MQSA:

MQSA Funding for FY 2009

Program	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009
CDRH	$6,003,000	$6,003,000	$0
Field Activities	$13,077,000	$13,077,000	$0
HQ/OC	$238,000	$238,000	$0
Total	**$19,318,000**	**$19,318,000**	**$0**

This 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.

Export Certification (Drugs/Biologics/Devices): +$100,000

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device. These 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 these certificates is to promote the export of products made in the U.S. The FY 2010 increase of $100,000 will cover program inflationary costs.

Color Certification: No change

The Federal Food, Drug and Cosmetic Act (FFD&C) requires the certification of color additives. This function, 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. Employee salaries and expenses are funded directly by FDA's Revolving Fund for Certification and Other Services, which is financed entirely by fees paid by commercial organizations. In FY 2010, FDA is estimating the same level as FY 2009.

Reinspection User Fee
+$25,848,000

1. Why is this initiative necessary?

FDA is proposing a new user fee to require establishments that FDA inspects to pay the full costs 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.

The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of reinspection. When FDA identifies violations during an inspection or issues a warning letter following an inspection, FDA conducts follow-up inspections to verify that the corrective action. FDA procedures usually require that FDA conduct a follow-up inspection of the firm within 90 days of issuing a warning letter.

The Budget includes $25,848,000 in Reinspection User Fee revenue. The following table identifies FY 2010 spending for Reinspection User Fees:

Discretionary Budget Authority and Mandatory User Fees – Reinspection User Fees

Description	FY 2010 Reinspection User Fee
Field	$14,446,000
HQ/OC	$8,342,000
GSA Rent and Other Rent-Related Activities	3,060,000
Total	**$25,848,000**

2. What activities will these funds support?

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers to assess their compliance with Good Manufacturing Practice requirements. ORA inspects domestic and foreign facilities. Revenue from the user fee will reimburse ORA and other FDA offices for costs associated with 129 FTE and related expenses required to reinspect firms that fail to comply with FDA regulations designed to protect the public from unsafe products. Fees will also support GSA rent and rent related costs.

3. What will FDA achieve with this investment?

FDA estimates that the user fee revenue will fund approximately 1,250 reinspections in FY 2010.

4. What are the risks of not funding this initiative?

If facilities that fail to comply with FDA regulations do not bear the cost of reinspections, FDA must shift resources from other high-priority program activities to conduct reinspections. Examples of these priority public health activities include efforts to assure drug safety and efforts to protect the nation's food supply from contamination and from potential terrorist acts.

While it is good business practice for firms to ensure the safety of products before they reach consumers, FDA enforcement inspections also help ensure the safety of products before they reach consumers. The Reinspection User Fee provides an additional incentive for facilities to comply with FDA regulations.

Food and Animal Feed Export Certification User Fee
+$4,152,000

1. Why is this initiative necessary?

In FY 2010, FDA estimates that the agency will issue 37,000 food and animal feed export certificates. FDA currently funds this activity through discretionary appropriations.

The Administration is proposing legislation authorizing FDA to collect user fees for issuing food and animal feed export certificates within 20 days of the receipt of a request. The food and animal feed certificate user fee is one of the recommended legislative proposals in FDA's Food Protection Plan.

Under this proposal, these activities will be financed by user fees in FY 2010. The proposed fee would generate an estimated $4,152,000 in revenue, an amount sufficient to cover the cost of issuing certificates. Private sector exporters would reap the benefits of FDA's enhanced ability to facilitate exports of their products , and appropriately bear the cost of the program.

Food and Animal Feed Export Certification User Fee

Description	FY 2010 User Fee
CFSAN	$1,063,000
CVM	$74,000
Field	$3,015,000
Total	**$4,152,000**

2. What activities will these funds support?

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 and feeds. Thus, for FY 2010, the FDA proposes $4,152,000 in user fees to support activities associated with facilitating international trade.

3. What will FDA achieve with this investment?

The user fee proposal will allow FDA to issue an estimated 37,000 food and animal feed export certificates in FY 2010. In its *Affirmative Agenda for International Activities* report, FDA's Center for Food Safety and Applied Nutrition stated its intent to try to find effective and resource-efficient approaches to issuing export certificates for foods.

The purpose of this proposal is to recover FDA's costs to issue food and feed export certificates benefiting U.S. food and feed manufacturers and exporters.

4. What are the risks of not funding this initiative?

FDA must ensure its resources are used for maximum public health impact. Currently, FDA resources to support food export-related activities must be diverted from appropriated funds intended to support FDA's public health activities and programs. FDA is now finding it increasingly difficult to strike an appropriate balance between its paramount mission of protecting the health of American consumers through programs to ensure the safety of domestic and imported products, and its emerging role of facilitating the international trade of U.S.-produced foods and feeds by attesting to the safety of these products exported from the United States.

TITLE VI

RELATED AGENCY 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; **[**$2,622,267,000, of which $7,641,000 shall be for the purposes, and in the amounts, specified in the final paragraph under "Food and Drug Administration, Salaries and Expenses" in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act)**]** *$2,995,218,000*: *Provided*, That of the amount provided under this heading, **[**$510,665,000**]** *$578,162,000* 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 **[**2010**]** *2011* but collected in fiscal year **[**2009**]** *2010*; **[**$52,547,000**]** *$57,014,000* 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; **[**$15,260,000**]** *$17,280,000 s*hall 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; and **[**$4,831,000**]** *$5,106,000* 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: *Provided further,* That fees derived from prescription drug, medical device, animal drug, and animal generic drug assessments for fiscal year **[**2009**]** *2010* received during fiscal year **[**2009**]** *2010,* including any such fees assessed prior to fiscal year **[**2009**]** *2010* but credited for fiscal year **[**2009**]** *2010,* shall be subject to the fiscal year **[**2009**]** *2010* limitations**[**: *Provided further*, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: *Provided further*, That of the total amount appropriated: (1) $845,618,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $908,013,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs, of which no less than $41,358,000 shall be available for the Office of Generic Drugs; (3) $305,731,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $171,022,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $352,334,000shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $58,745,000 shall be for the National Center for Toxicological Research; (7) not to exceed $116,821,000 shall be for Rent and Related activities, of which $41,496,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (8) not to exceed $173,111,000 shall be for payments to the General Services Administration for rent; and (9) $204,823,000 shall be for other

activities, including the Office of the Commissioner; the Office of Scientific and Medical Programs; the Office of Policy, Planning and Preparedness; the Office of International and Special Programs; the Office of Operations; and central services for these offices: *Provided further*, That none of the funds made available under this heading shall be used to transfer funds under section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd): *Provided further*, That funds may be transferred from one specified activity to another with the prior approval of the Committees on Appropriations of both Houses of Congress**]**.

In addition, mammography user fees authorized by 42 U.S.C. 263b, export certification user fees authorized by 21 U.S.C. 381, and priority review user fees authorized by 21 U.S.C. 360n may be credited to this account, to remain available until expended. *(Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2009.)*

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, $12,433,000, 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 $36,000,000, shall be credited as an offsetting collection to this account, to remain available until expended for generic drug review activities. In addition, contingent upon enactment of authorizing legislation, the Secretary shall charge fees for reinspections and export certification: Provided, That such fees, in an amount not to exceed $30,000,000, shall be credited as an

offsetting collection to this account, to remain available until expended for reinspections and issuance of export certifications. In addition, contingent upon enactment of authorizing legislation, the Secretary shall charge fees for food inspections and food facility registrations: Provided, That such fees, in an amount not to exceed $75,000,000, shall be credited as an offsetting collection to this account, and shall remain available until expended.

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 $36,000,000 in 2010, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Reinspection User Fee	The Administration will propose legislation to allow FDA to collect fees to cover the costs of reinspections and associated follow-up work. The additional resources, estimated at $25,878,000 in 2010, will ensure that facilities that fail to comply with health and safety standards bear the cost of reinspection.
Export Certification User Fee	The Administration will propose legislation to allow FDA to collect fees to issue food and animal feed export certificates. The additional resources, estimated at $4,152,000, will enhance FDA's ability to issue export certificates in a timely fashion and facilitate product exportation.
Food Inspection and Facility Registration User Fee	The Administration will propose legislation to allow FDA to collect fees to register food facilities and conduct safety and good manufacturing practices (GMP) inspections of food manufacturing and processing facilities. The additional resources, estimated at $75,000,000, will enable FDA to conduct activities that are necessary for the safety and security of the supply chain for foods.

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Food and Drug Administration
FY 2010 Exhibit for Congressional Appropriations

Dollars in Thousands

FY 2010 Changes	BUDGET AUTHORITY														USER FEES								PROPOSED USER FEES								PROGRAM LEVEL	
	FY 2009 Omnibus		FDA 2010 President's Budget Request										Total Budget Authority Changes		FY 2010 TOTAL (Budget Authority)		PDUFA		MDUFMA		ADUFA		AGDUFA		Generic Drug User Fee		Food and Feed Export Certification User fee		Reinspection User Fee		Food Facility Registration & Inspection User Fee		FY 2010 TOTAL	
			Pay and Rent		Protect America's Food Supply		Safer Medical Products		Drug Importation		Buildings & Facilities																					
	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	**2,774**	**648,722**	**0**	**10,514**	**269**	**123,679**	**0**	**0**	**0**	**0**	**0**	**0**	**269**	**134,193**	**3,288**	**782,915**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**26**	**4,078**	**48**	**6,124**	**154**	**52,500**	**3,516**	**845,617**
CFSAN	*854*	*210,486*	*0*	*2,986*	*67*	*22,946*	*0*	*0*	*0*	*0*	*0*	*0*	*67*	*25,932*	*921*	*236,418*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*7*	*1,063*	*0*	*0*	*19*	*7,500*	*947*	*244,981*
Field Activities	*2,165*	*438,236*	*0*	*7,528*	*202*	*100,733*	*0*	*0*	*0*	*0*	*0*	*0*	*202*	*108,261*	*2,367*	*546,497*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*19*	*3,015*	*48*	*6,124*	*135*	*45,000*	*2,569*	*600,636*
Human Drugs	**1,801**	**413,482**	**0**	**6,697**	**0**	**0**	**81**	**33,635**	**0**	**4,000**	**0**	**0**	**81**	**44,332**	**2,026**	**457,814**	**1,647**	**415,290**	**0**	**0**	**0**	**0**	**0**	**0**	**68**	**32,549**	**0**	**0**	**18**	**2,360**	**0**	**0**	**3,759**	**908,013**
CDER	*1,286*	*302,386*	*0*	*4,435*	*0*	*0*	*56*	*19,767*	*0*	*3,000*	*0*	*0*	*56*	*27,202*	*1,342*	*329,588*	*1,598*	*406,984*	*0*	*0*	*0*	*0*	*0*	*0*	*56*	*26,504*	*0*	*0*	*0*	*0*	*0*	*0*	*2,996*	*763,076*
Field Activities	*659*	*111,096*	*0*	*2,262*	*0*	*0*	*25*	*13,868*	*0*	*1,000*	*0*	*0*	*25*	*17,130*	*684*	*128,226*	*49*	*8,306*	*0*	*0*	*0*	*0*	*0*	*0*	*12*	*6,045*	*0*	*0*	*18*	*2,360*	*0*	*0*	*763*	*144,937*
Biologics	**730**	**183,451**	**0**	**2,803**	**0**	**0**	**26**	**20,184**	**0**	**0**	**0**	**0**	**26**	**22,987**	**836**	**206,438**	**323**	**87,236**	**35**	**11,575**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**482**	**0**	**0**	**1,197**	**305,731**
CBER	*592*	*148,134*	*0*	*2,041*	*0*	*0*	*23*	*16,007*	*0*	*0*	*0*	*0*	*23*	*18,048*	*615*	*166,182*	*313*	*83,747*	*31*	*11,068*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*959*	*260,997*
Field Activities	*218*	*35,317*	*0*	*762*	*0*	*0*	*3*	*4,177*	*0*	*0*	*0*	*0*	*3*	*4,939*	*221*	*40,256*	*10*	*3,489*	*4*	*507*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*3*	*482*	*0*	*0*	*238*	*44,734*
Animal Drugs & Feeds	**573**	**116,471**	**0**	**1,990**	**32**	**13,312**	**15**	**3,702**	**0**	**0**	**0**	**0**	**47**	**19,004**	**620**	**135,475**	**0**	**0**	**0**	**0**	**68**	**15,540**	**21**	**4,525**	**0**	**0**	**0**	**74**	**19**	**2,408**	**39**	**13,000**	**767**	**171,022**
CVM	*338*	*73,035*	*0*	*1,176*	*12*	*6,093*	*11*	*2,148*	*0*	*0*	*0*	*0*	*23*	*9,417*	*361*	*82,452*	*0*	*0*	*0*	*0*	*66*	*15,290*	*20*	*4,382*	*0*	*0*	*0*	*74*	*0*	*0*	*9*	*3,000*	*456*	*105,198*
Field Activities	*235*	*43,436*	*0*	*814*	*20*	*7,219*	*4*	*1,554*	*0*	*0*	*0*	*0*	*24*	*9,587*	*259*	*53,023*	*0*	*0*	*0*	*0*	*2*	*250*	*1*	*143*	*0*	*0*	*0*	*0*	*19*	*2,408*	*30*	*10,000*	*311*	*65,824*
Device & Radiological Products	**1,406**	**280,587**	**0**	**4,859**	**0**	**0**	**69**	**29,931**	**0**	**0**	**0**	**0**	**69**	**34,790**	**1,475**	**315,377**	**0**	**0**	**227**	**33,885**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**24**	**3,072**	**0**	**0**	**1,726**	**352,334**
CDRH	*977*	*209,061*	*0*	*3,369*	*0*	*0*	*52*	*22,544*	*0*	*0*	*0*	*0*	*52*	*25,913*	*1,029*	*234,974*	*0*	*0*	*220*	*32,836*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1,249*	*267,810*
Field Activities	*429*	*71,526*	*0*	*1,490*	*0*	*0*	*17*	*7,387*	*0*	*0*	*0*	*0*	*17*	*8,877*	*446*	*80,403*	*0*	*0*	*7*	*1,049*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*24*	*3,072*	*0*	*0*	*477*	*84,524*
NCTR	**198**	**52,511**	**0**	**690**	**4**	**1,625**	**8**	**3,919**	**0**	**0**	**0**	**0**	**12**	**6,234**	**210**	**58,745**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	***210***	***58,745***
Other Activities	**573**	**120,560**	**0**	**1,983**	**44**	**13,351**	**27**	**6,818**	**0**	**1,000**	**0**	**0**	**71**	**23,152**	**644**	**143,712**	**144**	**35,270**	**22**	**5,914**	**4**	**693**	**1**	**204**	**0**	**1,189**	**0**	**0**	**17**	**8,342**	**33**	**9,500**	***865***	***204,824***
Office of Regulatory Affairs [Non-Add]	***3,706***	***699,611***	***0***	***12,856***	***222***	***107,952***	***49***	***26,986***	***0***	***1,000***	***0***	***0***	***271***	***148,794***	***3,977***	***848,405***	***59***	***11,795***	***11***	***1,556***	***2***	***250***	***1***	***143***	***12***	***6,045***	***19***	***3,015***	***112***	***14,446***	***165***	***55,000***	***4,358***	***940,655***
White Oak Consolidation	**0**	**38,536**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**38,536**	**0**	**2,960**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	***0***	***41,496***
Other Rent & Rent-Related	**0**	**50,293**	**0**	**2,329**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2,329**	**0**	**52,622**	**0**	**20,154**	**0**	**1,376**	**0**	**162**	**0**	**72**	**0**	**0**	**0**	**0**	**0**	**939**	**0**	**0**	***0***	***75,325***
GSA Rent	**0**	**134,351**	**0**	**11,671**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**11,671**	**0**	**146,022**	**0**	**17,252**	**0**	**4,264**	**0**	**885**	**0**	**305**	**0**	**2,262**	**0**	**0**	**0**	**2,121**	**0**	**0**	***0***	***173,111***
Salaries & Expenses Increases	**8,524**	**2,038,964**	**0**	**43,536**	**349**	**151,967**	**226**	**98,189**	**0**	**5,000**	**0**	**0**	**575**	**298,692**	**9,099**	**2,337,656**	**2,114**	**578,162**	**284**	**57,014**	**72**	**17,280**	**22**	**5,106**	**68**	**36,000**	**26**	**4,152**	**129**	**25,848**	**226**	**75,000**	**12,040**	**3,136,218**
Non-Field	*4,818*	*1,116,173*	*0*	*16,680*	*127*	*44,015*	*177*	*71,203*	*0*	*4,000*	*0*	*0*	*304*	*135,898*	*5,122*	*1,252,071*	*2,055*	*526,001*	*273*	*49,818*	*70*	*15,983*	*21*	*4,586*	*56*	*27,693*	*7*	*1,137*	*17*	*8,342*	*61*	*20,000*	*7,682*	*1,905,631*
Field	*3,706*	*699,611*	*0*	*12,856*	*222*	*107,952*	*49*	*26,986*	*0*	*1,000*	*0*	*0*	*271*	*148,794*	*3,977*	*848,405*	*59*	*11,795*	*11*	*1,556*	*2*	*250*	*1*	*143*	*12*	*6,045*	*19*	*3,015*	*112*	*14,446*	*165*	*55,000*	*4,358*	*940,655*
Rents		*223,180*	*0*	*14,000*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*14,000*		*237,180*	*0*	*40,366*	*0*	*5,640*	*0*	*1,047*	*0*	*377*	*0*	*2,262*	*0*	*0*	*0*	*3,060*	*0*	*0*	*0*	*289,932*
Buildings and Facilities	**0**	**12,433**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**12,433**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**12,433**
Sec 725 Construction Grant		**3,497**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-3,497**		**-3,497**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**		
Total	**8,524**	**2,054,894**	**0**	**43,536**	**349**	**151,967**	**226**	**98,189**	**0**	**5,000**	**0**	**0**	**575**	**295,195**	**9,099**	**2,350,089**	**2,114**	**578,162**	**284**	**57,014**	**72**	**17,280**	**22**	**5,106**	**68**	**36,000**	**26**	**4,152**	**129**	**25,848**	**226**	**75,000**	**12,040**	**3,148,651**

NOTE: This table does not include resources for current indefinite user fees for MQSA ($19.318M); Export Certification (FY 2009-$2.6M, FY 2010-$2.7M); Color Certification ($7.7M).

FOOD AND DRUG ADMINISTRATION
Summary of Changes
FY 2010 President's Budget Request

	Budget Authority	User Fees	Program Level	Program Level FTE
FY 2009 President's Budget Request	**$2,054,894,000**	**$612,921,000**	**$2,667,815,000**	**10,953**
FY 2010 Pay and Non-Pay Inflation:				
Pay Increase (non-add)	**$63,104,495**			
Pay Absorption *(non-add)*	*($33,568,495)*			
Subtotal Pay Change *(non-add)* :	***$29,536,000***			
FY 2010 Program Changes:				
Budget Authority				
Ensure a Strong FDA:				
Pay Increase	*$29,536,000*		*$29,536,000*	
Other Rent and Rent-Related Activities	*$2,329,000*		*$2,329,000*	*0*
GSA Rent	*$11,671,000*		*$11,671,000*	*0*
Buildings and Facilities	*($3,497,000)*		*($3,497,000)*	*0*
Subtotal: Ensure a Strong FDA	$40,039,000		$40,039,000	0
Protect America's Food Supply	$151,967,000		$151,967,000	349
Safer Medical Products	$98,189,000		$98,189,000	226
Drug Importation	$5,000,000		$5,000,000	0
Subtotal: Budget Authority Program Changes	**$295,195,000**		**$295,195,000**	
Total Budget Authority Change from FY 2009 Omnibus Budget to FY 2010 Estimate	**$295,195,000**		**$295,195,000**	**575**
FY 2010 User Fee Changes:				
Current User Fees:				
PDUFA		$67,497,000	$67,497,000	131
MDUFMA		$4,467,000	$4,467,000	22
ADUFA		$2,020,000	$2,020,000	0
AGDUFA		$275,000	$275,000	0
MQSA		$0	$0	0
Color Certification		$0	$0	0
Export Certification		$100,000	$100,000	0
Total Current User Fees:		**$74,359,000**	**$74,359,000**	**153**
Proposed User Fee:				
Generic Animal Drugs User Fee		$36,000,000	36,000,000	68
Export Certification Fee		$4,152,000	4,152,000	26
Reinspection Fee		$25,848,000	25,848,000	129
Food Inspection and Facility Registration Fee		$75,000,000	75,000,000	226
Total Proposed User Fees:		**$141,000,000**	**$141,000,000**	**449**
Total User Fee Changes from FY 2009 President's Budget		**$215,359,000**	**$215,359,000**	**602**
Net Program Level Change from FY 2009 Revised President's Budget	**$295,195,000**	**$215,359,000**	**$510,554,000**	**1,177**
TOTAL FDA REQUEST FOR FY 2010	**$2,350,089,000**	**$828,280,000**	**$3,178,369,000**	**12,130**

Food and Drug Administration
FY 2010 Passback Crosswalk - Budget Authority
(Dollars in Thousands)

Program	FY 2009 Omnibus[3]		FY 2010 Increases										FY 2010 President's Budget Request	
			Pay, Rent and Infrastructure		Protect America's Food Supply		Medical Product Initiatives: Safer Medical Products		Medical Product Initiatives: Drug Importation		Sub-Total			
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,019**	**$648,722**	**0**	**$10,514**	**269**	**$123,679**	**0**	**$0**	**0**	**$0**	**269**	**$134,193**	**3,288**	**$782,915**
Center	854	210,486	0	2,986	67	22,946	0	0	0	0	67	25,932	921	236,418
Field Activities	2,165	438,236	0	7,528	202	100,733	0	0	0	0	202	108,261	2,367	546,497
Human Drugs	**1,945**	**$413,482**	**0**	**$6,697**	**0**	**$0**	**81**	**$33,635**	**0**	**$4,000**	**81**	**$44,332**	**2,026**	**$457,814**
Center	1,286	302,386	0	4,435	0	0	56	19,767	0	3,000	56	27,202	1,342	329,588
Field Activities	659	111,096	0	2,262	0	0	25	13,868	0	1,000	25	17,130	684	128,226
Biologics	**810**	**$183,451**	**0**	**$2,803**	**0**	**$0**	**26**	**$20,184**	**0**	**$0**	**26**	**$22,987**	**836**	**$206,438**
Center	592	148,134	0	2,041	0	0	23	16,007	0	0	23	18,048	615	166,182
Field Activities	218	35,317	0	762	0	0	3	4,177	0	0	3	4,939	221	40,256
Animal Drugs and Feeds	**573**	**$116,471**	**0**	**$1,990**	**32**	**$13,312**	**15**	**$3,702**	**0**	**$0**	**47**	**$19,004**	**620**	**$135,475**
Center	338	73,035	0	1,176	12	6,093	11	2,148	0	0	23	9,417	361	82,452
Field Activities	235	43,436	0	814	20	7,219	4	1,554	0	0	24	9,587	259	53,023
Devices and Radiological Health	**1,406**	**$280,587**	**0**	**$4,859**	**0**	**$0**	**69**	**$29,931**	**0**	**$0**	**69**	**$34,790**	**1,475**	**$315,377**
Center	977	209,061	0	3,369	0	0	52	22,544	0	0	52	25,913	1,029	234,974
Field Activities	429	71,526	0	1,490	0	0	17	7,387	0	0	17	8,877	446	80,403
National Center for Toxicological Research	**198**	**$52,511**	**0**	**$690**	**4**	**$1,625**	**8**	**$3,919**	**0**	**$0**	**12**	**6,234**	**210**	**$58,745**
Headquarters and Office of the Commissioner	**573**	**$120,560**	**0**	**1,983**	**44**	**$13,351**	**27**	**$6,818**	**0**	**$1,000**	**71**	**23,152**	**644**	**$143,712**
FDA White Oak Consolidation	**0**	**$38,536**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**0**	**0**	**$38,536**
Other Rent and Rent Related	**0**	**$50,293**	**0**	**$ 2,329**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**2,329**	**0**	**$52,622**
GSA Rental Payments	**0**	**$134,351**	**0**	**$ 11,671**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**11,671**	**0**	**$146,022**
SUBTOTAL, Salaries and Expenses	**8,524**	**$2,038,964**	**0**	**$43,536**	**349**	**$151,967**	**226**	**$98,189**	**0**	**$5,000**	**575**	**$298,692**	**9,099**	**$2,337,656**
Buildings and Facilities	**0**	**$15,930**	**0**	**($3,497)**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**(3,497)**	**0**	**$12,433**
FDA Building and Facilities	*0*	*$12,433*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	**0**	**0**	0	$12,433
Natural Products Center[2]	*0*	*$3,497*	*0*	*-3,497*	*0*	*0*	*0*	*0*	*0*	*0*	**0**	**(3,497)**	0	$0
TOTAL	**8,524**	**$2,054,894**	**0**	**$40,039**	**349**	**$151,967**	**226**	**$98,189**	**0**	**$5,000**	**575**	**$295,195**	**9,099**	**$2,350,089**
Non-Field Activities	4,818	1,116,173	0	16,680	127	44,015	177	71,203	0	4,000	304	135,898	5,122	1,252,071
Field Activities	3,706	699,611	0	12,856	222	107,952	49	26,986	0	1,000	271	148,793	3,977	848,404
Rent Activities, B&F, and White Oak	0	239,110	0	10,503	0	0	0	0	0	0	0	10,503	0	249,613

[1] FY 2008, 2009 and 2010 Estimates do not include an estimated 69 reimbursable, 21 PEPFAR and 5 CRADA FTE.

[2] FY 2009 Omnibus Appropriations Act includes Sec. 725, a general provision appropriating $3.497 million to the National Center for Natural Products Research for construction and renovation.

Food and Drug Administration
FY 2010 Crosswalk - User Fee
(Dollars in Thousands)

			User Fees								Indefininte User Fees						Proposed User Fees								FY 2010 President's Budget Request			
Program	FY 2009 Omnibus		PDUFA		MDUFMA		ADUFA		AGDUFA		MQSA		Color Certification		Export Cert		Generic Drug User Fee		Export Certification User Fee		Reinspection User Fee		Food Inspection and Facility Registration User Fee		User Fee Change		User Fee 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	FTE	$000	FTE	$000
Foods	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**26**	**$4,078**	**48**	**$6,124**	**154**	**$52,500**	**228**	**$62,702**	**228**	**$62,702**
Center	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	1,063	0	0	19	7,500	26	8,563	26	8,563
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	3,015	48	6,124	135	45,000	202	54,139	202	54,139
Human Drugs	**1,545**	**$363,955**	**102**	**$51,335**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**68**	**$32,549**	**0**	**$0**	**18**	**$2,360**	**0**	**$0**	**188**	**$86,244**	**1,733**	**$450,199**
Center	1,505	356,835	93	50,149	0	0	0	0	0	0	0	0	0	0	0	0	56	26,504	0	0	0	0	0	0	149	76,653	1,654	433,488
Field Activities	40	7,120	9	1,186	0	0	0	0	0	0	0	0	0	0	0	0	12	6,045	0	0	18	2,360	0	0	39	9,591	79	16,711
Biologics	**336**	**$88,039**	**20**	**$10,672**	**2**	**$100**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**3**	**$482**	**0**	**$0**	**25**	**$11,254**	**361**	**$99,293**
Center	324	84,174	20	10,541	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	10,641	344	94,815
Field Activities	12	3,865	0	131	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	482	0	0	5	613	17	4,478
Animal Drugs and Feeds	**89**	**$17,873**	**0**	**$0**	**0**	**$0**	**0**	**$1,928**	**0**	**$264**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$74**	**19**	**$2,408**	**39**	**$13,000**	**58**	**$17,674**	**147**	**$35,547**
Center	86	17,480	0	0	0	0	0	1,928	0	264	0	0	0	0	0	0	0	0	0	74	0	0	9	3,000	9	5,266	95	22,746
Field Activities	3	393	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	2,408	30	10,000	49	12,408	52	12,801
Devices and Radiological Health	**187**	**$49,040**	**0**	**$0**	**20**	**$3,925**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**24**	**$3,072**	**0**	**$0**	**44**	**$6,997**	**231**	**$56,037**
Center	172	34,914	0	0	19	3,925	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	3,925	191	38,839
Field Activities	15	14,126	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	24	3,072	0	0	25	3,072	40	17,198
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**
Headquarters and Office of the Commissioner	**164**	**39,711**	**9**	**$2,560**	**0**	**0**	**0**	**37**	**0**	**11**	**0**	**0**	**0**	**$0**	**0**	**$0**	**0**	**$1,189**	0	0	**17**	**8,342**	**33**	**9,500**	**59**	**$21,639**	**223**	**61,350**
FDA White Oak Consolidation	**0**	**2,745**	**0**	**$215**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	0	0	**0**	**$0**	**0**	**$0**	**0**	**$215**	**0**	**$2,960**
Other Rent and Rent Related Activities	**0**	**20,184**	**0**	**$1,463**	**0**	**$108**	**0**	**$9**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	0	0	**0**	**$939**	**0**	**$0**	**0**	**$2,519**	**0**	**$22,703**
GSA Rental Payments	**0**	**21,074**	**0**	**$1,252**	**0**	**$334**	**0**	**$46**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$2,262**	0	0	**0**	**$2,121**	**0**	**$0**	**0**	**$6,015**	**0**	**$27,089**
Export Certification	**18**	**2,600**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**100**	**0**	**$0**	0	0	**0**	**$0**	**0**	**$0**	**0**	**$100**	**18**	**$2,700**
Color Certification	**36**	**7,700**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**0**	**0**	**$0**	**0**	**$0**	0	0	**0**	**$0**	**0**	**$0**	**0**	**$0**	**36**	**$7,700**
Buildings & Facilities	**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**
Total	**2,375**	**$612,921**	**131**	**$67,497**	**22**	**$4,467**	**0**	**$2,020**	**0**	**$275**	**0**	**$0**	**0**	**$0**	**0**	**$100**	**68**	**$36,000**	**26**	**$4,152**	**129**	**$25,848**	**226**	**$75,000**	**602**	**$215,359**	**2,977**	**$828,280**
Non-Field	2,305	$543,414	122	$63,250	19	$4,025	0	$1,965	0	$275	0	$0	0	$0	0	$0	56	$27,693	7	$1,137	17	$8,342	61	$20,000	282	$126,787	2,587	$670,201
Field	70	$25,504	9	$1,317	3	$0	0	$0	0	$0	0	$0	0	$0	0	$0	12	$6,045	19	$3,015	112	$14,446	165	$55,000	320	$79,823	390	$105,327
Rent Activities, B&F, and White Oak	0	$44,003	0	$2,930	0	$442	0	$55	0	$0	0	$0	0	$0	0	$0	0	$2,262	0	$0	0	$3,060	0	$0	0	$8,749	0	$52,752

Food and Drug Administration
FY 2010 Crosswalk - Program Level
(Dollars in Thousands)

Program	FY 2009 Omnibus		FY 2010 Increases								Total Budget Authority Change	
			Pay, Rent and Infrastructure		Protect America's Food Supply		Medical Product Initiatives: Safer Medical Products		Medical Product Initiatives: Drug Importation			
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,019**	**$648,722**	**0**	**$10,514**	**269**	**$123,679**	**0**	**$0**	**0**	**$0**	**269**	**$134,193**
Center	854	210,486	0	2,986	67	22,946	0	0	0	0	67	25,932
Field Activities	2,165	438,236	0	7,528	202	100,733	0	0	0	0	202	108,261
Human Drugs	**1,945**	**$413,482**	**0**	**$6,697**	**0**	**$0**	**81**	**$33,635**	**0**	**$4,000**	**81**	**$44,332**
Center	1,286	302,386	0	4,435	0	0	56	19,767	0	3,000	56	27,202
Field Activities	659	111,096	0	2,262	0	0	25	13,868	0	1,000	25	17,130
Biologics	810	**$183,451**	**0**	**$2,804**	**0**	**$0**	**26**	**$20,184**	**0**	**$0**	**26**	**$22,987**
Center	592	148,134	0	2,041	0	0	23	16,007	0	0	23	18,048
Field Activities	218	35,317	0	762	0	0	3	4,177	0	0	3	4,939
Animal Drugs and Feeds	573	**$116,471**	**0**	**$1,990**	**32**	**$13,312**	**15**	**$3,702**	**0**	**$0**	**47**	**$19,004**
Center	338	73,035	0	1,176	12	6,093	11	2,148	0	0	23	9,417
Field Activities	235	43,436	0	814	20	7,219	4	1,554	0	0	24	9,587
Devices and Radiological Health	**1,406**	**$280,587**	**0**	**$4,859**	**0**	**$0**	**69**	**$29,931**	**0**	**$0**	**69**	**$34,790**
Center	977	209,061	0	3,369	0	0	52	22,544	0	0	52	25,913
Field Activities	429	71,526	0	1,490	0	0	17	7,387	0	0	17	8,877
National Center for Toxicological Research	**198**	**$52,511**	**0**	**$690**	**4**	**$1,625**	**8**	**$3,919**	**0**	**$0**	**12**	**$6,234**
Headquarters and Office of the Commissioner	**573**	**$120,560**	**0**	**$1,983**	**44**	**$13,351**	**27**	**$6,818**	**0**	**$1,000**	**71**	**$23,152**
FDA White Oak Consolidation	**0**	**$38,536**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
Other Rent and Rent Related Activities	**0**	**$50,293**	**0**	**$2,329**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$2,329**
GSA Rental Payments	**0**	**$134,351**	**0**	**$11,671**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$11,671**
Buildings and Facilities	**0**	**$15,930**	**0**	**($3,497)**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**($3,497)**
FDA Building and Facilities	**0**	**$12,433**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
Natural Products Center [2]	**0**	**$3,497**	**0**	**($3,497)**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**($3,497)**
Total	**8,524**	**$2,054,894**	**0**	**$40,039**	**349**	**$151,967**	**226**	**$98,189**	**0**	**$5,000**	**575**	**$295,195**
Non-Field	4,818	1,116,173	0	16,680	127	44,015	177	71,203	0	4,000	304	135,898
Field	3,706	699,611	0	12,856	222	107,952	49	26,986	0	1,000	271	148,793
Rent Activities, B&F, and White Oak	0	239,110	0	10,503	0	0	0	0	0	0	0	10,503

Food and Drug Administration
FY 2010 Crosswalk - Program Level
(Dollars in Thousands)

	User Fees																									
	PDUFA		MDUFMA		ADUFA		AGDUFA		MQSA		Color Certification		Export Certification		Generic Drug User Fee		Export Certification User Fee		Reinspection User Fee		Food Inspection and Facility Registration User Fee:		Total User Fee Change		FY 2010 TOTAL PROGRAM LEVEL CHANGE	
	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**	**$26**	**$4,078**	**48**	**$6,124**	**154**	**$52,500**	**228**	**$62,702**	**497**	**$196,896**
Center	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	1,063	0	0	19	7,500	26	8,563	93	$34,496
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	3,015	48	6,124	135	45,000	202	54,139	404	$162,400
Human Drugs	**102**	**$51,335**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**68**	**$32,549**	**$0**	**$0**	**18**	**$2,360**	**0**	**$0**	**188**	**$86,244**	**268**	**$130,576**
Center	93	50,149	0	0	0	0	0	0	0	0	0	0	0	0	56	26,504	0	0	0	0	0	0	149	76,653	205	$103,855
Field Activities	9	1,186	0	0	0	0	0	0	0	0	0	0	0	0	12	6,045	0	0	18	2,360	0	0	39	9,591	64	$26,721
Biologics	**20**	**$10,672**	**2**	**$100**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**3**	**$482**	**0**	**$0**	**25**	**$11,254**	**51**	**$34,241**
Center	20	10,541	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20	10,641	43	$28,689
Field Activities	0	131	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	482	0	0	5	613	8	$5,552
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**0**	**$1,928**	**0**	**$264**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$74**	**19**	**$2,408**	**39**	**$13,000**	**58**	**$17,674**	**105**	**$36,678**
Center	0	0	0	0	0	1,928	0	264	0	0	0	0	0	0	0	0	0	74	0	0	9	3,000	9	5,266	32	$14,683
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	2,408	30	10,000	49	12,408	73	$21,995
Devices and Radiological Health	**0**	**$0**	**20**	**$3,925**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**24**	**$3,072**	**0**	**$0**	**44**	**$6,997**	**114**	**$41,787**
Center	0	0	19	3,925	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	3,925	71	$29,838
Field Activities	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	24	3,072	0	0	25	3,072	42	$11,949
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**	**12**	**$6,234**
Headquarters and Office of the Commissioner	**9**	**$2,560**	**0**	**$0**	**0**	**$37**	**0**	**$11**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$1,189**	**$0**	**$0**	**17**	**$8,342**	**33**	**$9,500**	**59**	**$21,639**	**130**	**$44,790**
FDA White Oak Consolidation	**0**	**$215**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$215**	**0**	**$215**
Other Rent and Rent Related Activities (OR&R)	**0**	**$1,463**	**0**	**$108**	**0**	**$9**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**0**	**$939**	**0**	**$0**	**0**	**$2,519**	**0**	**$4,848**
GSA Rental Payments	**0**	**$1,252**	**0**	**$334**	**0**	**$46**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$2,262**	**$0**	**$0**	**0**	**$2,121**	**0**	**$0**	**0**	**$6,015**	**0**	**$17,686**
Export Certification	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$100**	**0**	**$0**	**$0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$100**	**0**	**$100**
Color Certification	**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**
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**	**$0**	**0**	**($3,497)**
FDA Building 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**	**$0**	**0**	**$0**
Natural Products Center [2]	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**($3,497)**
Total	**131**	**$67,497**	**22**	**$4,467**	**0**	**$2,020**	**0**	**$275**	**0**	**$0**	**0**	**$0**	**0**	**$100**	**68**	**$36,000**	**26**	**$4,152**	**129**	**$25,848**	**226**	**$75,000**	**602**	**215,359**	**1,177**	**510,554**
Non-Field	122	63,250	19	4,025	0	1,965	0	275	0	0	0	0	0	100	56	27,693	7	1,137	17	8,342	61	20,000	282	126,787	585	262,685
Field	9	1,317	3	0	0	0	0	0	0	0	0	0	0	0	12	6,045	19	3,015	112	14,446	165	55,000	320	79,823	591	228,616
Rent Activities, B&F, and White Oak	0	2,930	0	442	0	55	0	0	0	0	0	0	0	0	0	2,262	0	0	0	3,060	0	0	0	8,749	0	19,252

Food and Drug Administration
FY 2010 All Purpose Table - Budget Authority
(Dollars in Thousands)

Program	FY 2008							
	Enacted [1]		Actual		FY 2009 Omnibus[3]		FY 2010 President's Budget Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**2,792**	**$576,659**	**2,614**	**$507,797**	**3,019**	**$648,722**	**3,288**	**$782,915**
Center	812	188,167	753	167,189	854	210,486	921	236,418
Field Activities	1,980	388,492	1,861	340,608	2,165	438,236	2,367	546,497
Human Drugs	**1,880**	**$381,288**	**1,712**	**$353,909**	**1,945**	**$413,482**	**2,026**	**$457,814**
Center	1,243	280,282	1,144	266,269	1,286	302,386	1,342	329,588
Field Activities	637	101,006	568	87,640	659	111,096	684	128,226
Biologics	**795**	**$167,965**	**725**	**$154,831**	**810**	**$183,451**	**836**	**$206,438**
Center	579	135,457	526	125,383	592	148,134	615	166,182
Field Activities	216	32,508	199	29,448	218	35,317	221	40,256
Animal Drugs and Feeds	**551**	**$103,094**	**530**	**$97,365**	**573**	**$116,471**	**620**	**$135,475**
Center	325	63,701	319	59,890	338	73,035	361	82,452
Field Activities	226	39,393	211	37,475	235	43,436	259	53,023
Devices and Radiological Health	**1,395**	**$258,086**	**1,365**	**$237,734**	**1,406**	**$280,587**	**1,475**	**$315,377**
Center	969	192,839	945	177,455	977	209,061	1,029	234,974
Field Activities	426	65,247	420	60,279	429	71,526	446	80,403
National Center for Toxicological Research	**196**	**$47,402**	**192**	**$44,443**	**198**	**$52,511**	**210**	**$58,745**
Headquarters and Office of the Commissioner	**559**	**$110,402**	**541**	**$97,606**	**573**	**$120,560**	**644**	**$143,712**
FDA White Oak Consolidation	**0**	**$38,536**	**0**	**$38,536**	**0**	**$38,536**	**0**	**$38,536**
Other Rent and Rent Related	**0**	**$50,293**	**0**	**$50,278**	**0**	**$50,293**	**0**	**$52,622**
GSA Rental Payments	**0**	**$130,612**	**0**	**$130,611**	**0**	**$134,351**	**0**	**$146,022**
SUBTOTAL, Salaries and Expenses	**8,168**	**$1,864,337**	**7,678**	**$1,713,110**	**8,524**	**$2,038,964**	**9,099**	**$2,337,656**
Buildings and Facilities	**0**	**$6,157**	**0**	**$7,534**	**0**	**$15,930**	**0**	**$12,433**
FDA Building and Facilities	0	2,433		3,810	0	12,433	0	12,433
Natural Products Center[2]	0	3,724		3,724	0	3,497	0	0
TOTAL	**8,168**	**$1,870,494**	**7,678**	**$1,720,644**	**8,524**	**$2,054,894**	**9,099**	**$2,350,089**
Non-Field Activities	4,683	1,018,250	4,420	938,235	4,818	1,116,173	5,122	1,252,071
Field Activities	3,485	626,646	3,258	555,450	3,706	699,611	3,977	848,404
Rent Activities, B&F, and White Oak	0	$225,598	0	$226,959	0	$239,110	0	$249,613

[1] FY 2008, 2009 and 2010 Estimates do not include an estimated 69 reimbursable, 21 PEPFAR and 5 CRADA FTE.

[2] FY 2009 Omnibus Appropriations Act includes Sec. 725, a general provision appropriating $3.497 million to the National Center for Natural Products Research for construction and renovation.

[3] The FY 2009 FTE level in these Congressional Justifications reflects a correction of -36 FTE's made after the MAX budget database closed for production of the President's Budget for FY 2010.

Food and Drug Administration
FY 2010 ALL PURPOSE TABLE - User Fees
(Dollars in Thousands)

PROGRAM	FY 2008 Enacted FTE	FY 2008 Enacted $000	FY 2008 Actual FTE	FY 2008 Actual $000	FY 2009 Omnibus FTE	FY 2009 Omnibus $000	FY 2010 President's Budget Request FTE	FY 2010 President's Budget Request $000
Salaries and Expenses, Definite Appropriations:								
Prescription Drug User Fee Act (PDUFA):								
Human Drugs (PDUFA)	**1,348**	**$327,000**	**1,284**	**$327,017**	**1,545**	**$363,955**	**1,647**	**$415,290**
Center	1,308	320,084	1,252	321,282	1,505	356,835	1,598	406,984
Field	40	6,916	32	5,735	40	7,120	49	8,306
Biologics (PDUFA)	**288**	**$70,086**	**312**	**$72,414**	**303**	**$76,564**	**323**	**$87,236**
Center	278	66,824	304	70,890	293	73,206	313	83,747
Field	10	3,262	8	1,524	10	3,358	10	3,489
Headquarters and Office of the Commissioner (PDUFA)	**135**	**$29,531**	**166**	**$ 21,936**	**135**	**$32,710**	**144**	**$35,270**
Direct to Consumer (DTC)	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
Human Drugs (DTC)								
Center	0	$0	0	$0	0	$0	0	$0
Biologics (DTC)								
Center	0	$0	0	$0	0	$0	0	$0
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
FDA Consolidation at White Oak	**0**	**$0**	**0**	**$ 4,190**	**0**	**$2,745**	**0**	**$2,960**
Other Rent and Rent Related (PDUFA)	**0**	**$9,297**	**0**	**$ 13,409**	**0**	**$18,691**	**0**	**$20,154**
GSA Rental Payments (PDUFA)	**0**	**$23,498**	**0**	**$ 11,821**	**0**	**$16,000**	**0**	**$17,252**
Subtotal PDUFA	**1,771**	**$459,412**	**1,762**	**$450,787**	**1,983**	**$510,665**	**2,114**	**$578,162**
Medical Device User Fee Act (MDUFMA):								
Biologics (MDUFMA)	**33**	**$10,576**	**30**	**$6,263**	**33**	**$11,475**	**35**	**$11,575**
Center	31	10,109	28	6,005	31	10,968	31	11,068
Field	2	467	2	258	2	507	4	507
Devices and Radiological Health (MDUFMA)	**153**	**$27,614**	**170**	**$24,261**	**207**	**$29,960**	**227**	**$33,885**
Center	146	26,647	164	23,289	201	28,911	220	32,836
Field	7	967	6	972	6	1,049	7	1,049
Headquarters and Office of the Commissioner (MDUFMA)	**22**	**$5,450**	**21**	**$ 2,967**	**22**	**$5,914**	**22**	**$5,914**
Other Rent and Rent Related Activities (MDUFMA)	**0**	**$1,169**	**0**	**$ 850**	**0**	**$1,268**	**0**	**$1,376**
GSA Rental Payments (MDUFMA)	**0**	**$3,622**	**0**	**$ 2,081**	**0**	**$3,930**	**0**	**$4,264**
Subtotal (MDUFMA)	**208**	**$48,431**	**221**	**$36,422**	**262**	**$52,547**	**284**	**$57,014**
Animal Drug User Fee Act (ADUFA):								
Animal Drugs and Feeds	**58**	**$11,523**	**59**	**$12,260**	**68**	**$13,612**	**68**	**$15,540**
Center	58	$11,523	59	$12,260	66	$13,362	66	$15,290
Field	0	$0	0	$0	2	$250	2	$250
Headquarters and Office of the Commissioner (ADUFA)	**4**	**$732**	**4**	**$563**	**4**	**$656**	**4**	**$693**
Other Rent and Rent Related Activities (ADUFA)	**0**	**$0**	**0**	**$109**	**0**	**$153**	**0**	**$162**
GSA Rental Payments (ADUFA)	**0**	**$1,441**	**0**	**$598**	**0**	**$839**	**0**	**$885**
Subtotal (ADUFA)	**62**	**13,696**	**63**	**13,530**	**72**	**15,260**	**72**	**17,280**
Animal Generic Drug User Fee Act (AGDUFA):								
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**21**	**$4,261**	**21**	**$4,525**
Center	0	0	0	0	20	4,118	20	4,382
Field	0	0	0	0	1	143	1	143
Headquarters and Office of the Commissioner (AGDUFA)	**0**	**$0**	**0**	**$0**	**1**	**$193**	**1**	**$204**
Other Rent and Rent Related Activities (AGDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$72**	**0**	**$72**
GSA Rental Payments (AGDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$305**	**0**	**$305**
Subtotal (AGDUFA)	**0**	**$0**	**0**	**$0**	**22**	**$4,831**	**22**	**$5,106**
Total Definite Appropriations	**2,041**	**$521,539**	**2,046**	**$500,739**	**2,339**	**$583,303**	**2,492**	**$657,562**
Indefinite Appropriations:								
Mammography Quality and Standards Act (MQSA):								
Devices and Radiological Health	**34**	**$18,171**	**29**	**$13,289**	**34**	**$19,080**	**34**	**$19,080**
Center	26	5,717	21	4,047	26	6,003	26	6,003
Field Activities	8	12,454	8	9,242	8	13,077	8	13,077
Headquarters and Office of the Commissioner (MQSA)	**2**	**$227**	**2**	**$ 248**	**2**	**$238**	**2**	**$238**
Subtotal (MQSA)	**36**	**$18,398**	**31**	**$13,537**	**36**	**$19,318**	**36**	**$19,318**
Export Certification	**18**	**$2,500**	**17**	**$ 2,707**	**18**	**$2,600**	**18**	**$2,700**
Color Certification Fund	**36**	**$7,000**	**39**	**$ 7,379**	**36**	**$7,700**	**36**	**$7,700**
Total Indefinite Appropriations	**90**	**$27,898**	**87**	**$23,623**	**90**	**$29,618**	**90**	**$29,718**
Proposed New User Fees:								
Generic Drug User Fee (GDUFA):								
Human Drugs	**0**	**$0**	**0**	**$0**	**0**	**$0**	**68**	**$32,549**
Center	0	0	0	0	0	0	56	26,504
Field	0	0	0	0	0	0	12	6,045
Headquarters and Office of the Commissioner (GDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$1,189**
Other Rent and Rent Related (Generic Drug)	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
GSA Rental Payments (GDUFA)	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$2,262**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**68**	**$36,000**
Food Export Certification User Fee:								
Foods	**0**	**$0**	**0**	**0**	**0**	**$0**	**26**	**4,078**
Center	0	0	**0**	0	0	0	7	1,063
Field	0	0	**0**	0	0	0	19	3,015
Animal Drugs and Feeds								
Center	0	0	**0**	0			0	$74
Subtotal	**0**	**0**	**0**	**0**	**0**	**0**	**26**	**4,152**
Reinspection User Fee:								
Office of Regulatory Affairs	**0**	**$0**	**0**	**$0**	**0**	**$0**	**112**	**$14,446**
Foods Program Estimate	0	0	0	0	0	0	48	6,124
Human Drugs Program Estimate	0	0	0	0	0	0	18	2,360
Biologics Program Estimate	0	0	0	0	0	0	3	482
Animal Drugs and Feeds Program Estimate	0	0	0	0	0	0	19	2,408
Devices and Radiological Health Program Estimate	0	0	0	0	0	0	24	3,072
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**17**	**$8,342**
FDA White Oak Consolidation	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**
Other Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**939**
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**2,121**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**129**	**$25,848**
Food and Reinspction User fees Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**155**	**30,000**
Food Inspection and Facility Registration User Fee:								
Foods	**0**	**$0**	**0**	**$0**	**0**	**$0**	**154**	**$52,500**
Center	0	0	0	0	0	0	19	7,500
Field Activities	0	0	0	0	0	0	135	45,000
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**0**	**$0**	**39**	**$13,000**
Center	0	0	0	0	0	0	9	3,000
Field Activities	0	0	0	0	0	0	30	10,000
Headquarters and Office of the Commissioner	**0**	**$0**	**0**	**$0**	**0**	**$0**	**33**	**$9,500**
Subtotal	**0**	**$0**	**0**	**$0**	**0**	**$0**	**226**	**$75,000**
Total Proposed New User Fees	**0**	**0**	**0**	**0**	**0**	**0**	**449**	**141,000**
Total User Fees	**2,131**	**549,437**	**2,133**	**524,362**	**2,429**	**612,921**	**3,031**	**828,280**

Food and Drug Administration
FY 2010 ALL PURPOSE TABLE - Total Program Level
(Dollars in Thousands)

PROGRAM	FY 2008 Enacted [1]		FY 2008 Actual		FY 2009 Omnibus [3]		FY 2010 President's Budget Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**2,792**	**$576,659**	**2,614**	**$507,797**	**3,019**	**$648,722**	**3,516**	**$845,617**
Center	812	188,167	753	167,189	854	210,486	947	244,981
Field	1,980	388,492	1,861	340,608	2,165	438,236	2,569	600,636
Human Drug	**3,228**	**$708,288**	**2,996**	**$680,926**	**3,490**	**$777,437**	**3,759**	**$908,013**
Center	2,551	600,366	2,396	587,551	2,791	659,221	2,996	763,076
Field	677	107,922	600	93,375	699	118,216	763	144,937
Biologics	**1,116**	**$248,627**	**1,066**	**$233,508**	**1,146**	**$271,490**	**1,197**	**$305,731**
Center	888	212,390	858	202,278	916	232,308	959	260,997
Field	228	36,237	209	31,230	230	39,182	238	44,734
Animal Drugs and Feeds	**609**	**$114,617**	**589**	**$109,625**	**662**	**$134,344**	**767**	**$171,022**
Center	383	75,224	378	72,150	424	90,515	456	105,198
Field	226	39,393	211	37,475	238	43,829	311	65,824
Devices and Radiological Health	**1,582**	**$303,871**	**1,564**	**$275,284**	**1,647**	**$329,627**	**1,760**	**$371,414**
Center	1,141	225,203	1,130	204,791	1,204	243,975	1,275	273,813
Field	441	78,668	434	70,493	443	85,652	485	97,601
National Center for Toxicological Research	**196**	**$47,402**	**192**	**$44,443**	**198**	**$52,511**	**210**	**$58,745**
Headquarters and Office of the Commissioner	**722**	**146,342**	**733**	**123,320**	**737**	**160,271**	**867**	**205,061**
FDA White Oak Consolidation	**0**	**38,536**	**0**	**42,726**	**0**	**41,281**	**0**	**41,496**
Other Rent and Rent Related Activities	**0**	**60,759**	**0**	**64,646**	**0**	**70,477**	**0**	**75,325**
GSA Rent	**0**	**159,173**	**0**	**145,111**	**0**	**155,425**	**0**	**173,111**
TOTAL, Salaries & Expenses	**10,245**	**$2,404,274**	**9,754**	**$2,227,386**	**10,899**	**$2,641,585**	**12,076**	**$3,155,536**
Export Certification	**18**	**2,500**	**17**	**2,707**	**18**	**2,600**	**18**	**2,700**
Color Certification Fund	**36**	**7,000**	**39**	**7,379**	**36**	**7,700**	**36**	**7,700**
Buildings and Facilities	**0**	**$6,157**	**0**	**$7,534**	**0**	**$15,930**	**0**	**$12,433**
FDA Building and Facilities	0	2,433	0	3,810	0	12,433	0	12,433
Natural Products Center[2]	0	3,724	0	3,724	0	3,497	0	0
TOTAL PROGRAM LEVEL	**10,299**	**$2,419,931**	**9,811**	**$2,245,006**	**10,953**	**$2,667,815**	**12,130**	**$3,178,369**
Non-Field Activities	6,747	1,504,594	6,497	1,411,808	7,178	1,659,587	7,764	1,922,272
Field Activities	3,552	650,712	3,314	573,181	3,775	725,115	4,366	953,731
Rent Activities, B&F, and White Oak	0	264,625	0	260,017	0	283,113	0	302,365
Less User Fees:								
Current Law:								
Prescription Drugs (PDUFA)	1,771	459,412	1,762	450,787	1,983	510,665	2,114	578,162
Medical Devices (MDUFMA)	208	48,431	221	36,422	262	52,547	284	57,014
Animal Drugs (ADUFA)	62	13,696	63	13,530	72	15,260	72	17,280
Animal Generic Drug (AGDUFA)	0	0	0	0	22	4,831	22	5,106
Mammography Quality (MQSA)	36	18,398	31	13,537	36	19,318	36	19,318
Export Certification	18	2,500	17	2,707	18	2,600	18	2,700
Color Certification Fund	36	7,000	39	7,379	36	7,700	36	7,700
Proposed User Fees:								
Generic Drug (GDUFA)	0	0	0	0	0	0	68	36,000
Export Certification User Fee	0	0	0	0	0	0	26	4,153
Reinspection User Fee	0	0			0	0	129	25,847
Food Inspection and Food Facility Registration User Fee	0	0	0	0	0	0	226	75,000
SUBTOTAL User Fees	**2,131**	**549,437**	**2,133**	**524,362**	**2,429**	**612,921**	**3,031**	**828,280**
TOTAL USER FEES	**2,131**	**$549,437**	**2,133**	**$524,362**	**2,429**	**$612,921**	**3,031**	**$828,280**
TOTAL BUDGET AUTHORITY	**8,168**	**$1,870,494**	**7,678**	**$1,720,644**	**8,524**	**$2,054,894**	**9,099**	**$2,350,089**

[1] FY 2008 Enacted and FY 2009 Estimates do not include an estimated 69 reimbursable, 21 PEPFAR and 5 CRADA FTE.
[2] FY 2009 Omnibus Appropriations Act includes Sec. 725, a general provision appropriating $3.497 million to the National Center for Natural Products Research for construction and renovation.
[3] The FY 2009 FTE level in these Congressional Justifications reflects a correction of -36 FTE's made after the MAX budget database closed for production of the President's Budget for FY 2010.

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FOODS

The FY 2010 program level budget request for the FDA Foods Program including user fees is $845,617,000. The following table shows a three-year funding history for the Foods Program.

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	**$576,659,000**	**$507,797,000**	**$648,722,000**	**$845,617,000**	**$196,895,000**
Center	$188,167,000	$167,189,000	$210,486,000	$244,981,000	$34,495,000
FTE	812	753	854	947	93
Field	$388,492,000	$340,608,000	$438,236,000	$600,636,000	$162,400,000
FTE	1,980	1,861	2,165	2,569	404
Program Level FTE	**2,792**	**2,614**	**3,019**	**3,516**	**497**
Budget Authority	**$576,659,000**	**$507,797,000**	**$648,722,000**	**$782,915,000**	**$134,193,000**
Center	$188,167,000	$167,189,000	$210,486,000	$236,418,000	$25,932,000
Field	$388,492,000	$340,608,000	$438,236,000	$546,497,000	$108,261,000
Pay Increase (non add)				*$10,514,000*	*$10,514,000*
Protect America's Food Supply (non-add)				*$123,679,000*	*$123,679,000*
Budget Authority FTE	**2,792**	**2,614**	**3,019**	**3,288**	**269**
Center	812	753	854	921	67
Field	1,980	1,861	2,165	2,367	202
Proposed User Fees	**$0**	**$0**	**$0**	**$62,702,000**	**$62,702,000**
Reinspection				**$6,124,000**	**$6,124,000**
Field				$6,124,000	$6,124,000
FTE				48	48
Export Certification				**$4,078,000**	**$4,078,000**
Center				$1,063,000	$1,063,000
FTE				7	7
Field				$3,015,000	$3,015,000
FTE				19	19
Inspection and Facility Registration				**$52,500,000**	**$52,500,000**
Center				$7,500,000	$7,500,000
FTE				19	19
Field				$45,000,000	$45,000,000
FTE				135	135
User Fee FTE	**0**	**0**	**0**	**228**	**228**

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*

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The Center for Food Safety and Applied Nutrition (CFSAN) administers the FDA Foods Program with the assistance of the Office of Regulatory Affairs (ORA) field offices nationwide. CFSAN, in conjunction with the FDA field force, is responsible for protecting and promoting the public health by ensuring that the food supply of the nation is safe, sanitary, wholesome, and properly labeled and that cosmetic products are safe and properly labeled. The FDA Foods Program is responsible for all domestic and imported food, with the exception of meat; poultry; and frozen, dried and liquid eggs.

The FDA Foods Program regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $62 billion worth of cosmetics. This regulation takes place from either the products' point of U.S. entry or processing to their point of sale, with approximately 136,000 registered domestic food establishments, and approximately 189,000 registered foreign facilities, and more than 3,500 cosmetic firms.

The Office of Regulatory Affairs (ORA) provides FDA leadership on enforcement, import, inspection, and regulatory laboratory policies. Through ORA field offices nationwide, ORA supports the Foods Program by conducting risk-based domestic and foreign inspections of food establishments to assess industry compliance with current Good Manufacturing Practices (cGMP) and Hazard Analysis and Critical Control Point (HACCP) requirements for FDA-regulated foods. In addition to overseeing the regulated products on a surveillance or “for cause” basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods. In instances of criminal activity, the ORA Office of Criminal Investigations (OCI) complements the regular field force. The ORA Field Foods Program is funded by appropriated dollars that allow ORA to perform inspections and fund inspections through State contracts.

The Office of Information Management (OIM) provides FDA’s leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the

platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Food Safety and Nutrition Program by maintaining its legacy systems and databases used for managing and tracking its programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Food Safety and Nutrition Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The FDA Foods Program executes its regulatory responsibilities in four areas: Ensuring Food Protection, Improving Nutrition, Improving Dietary Supplement Safety and Improving Cosmetic Safety.

Ensuring Food Protection – CFSAN Activities

The FDA Food Protection Program, encompassing both food safety and food defense, is a comprehensive and integrated strategic approach that involves multiple parts of the FDA. The overarching program goal is to keep the food supply of the nation safe from both unintentional and deliberate contamination. The program builds in safety measures focusing FDA efforts on preventing problems first, using risk-based interventions to ensure preventive approaches are effective, and instituting a rapid response as soon as contaminated food, feed, or harm is detected. Driven by science and modern information technology, the FDA Food Protection Program aims to identify potential hazards and counter those before they can do harm.

In FY 2009 CFSAN scientists have optically mapped chromosomes of *Salmonella* strains from 2008 outbreaks of *S*. Saintpaul (linked to peppers) and Typhimurium (linked to peanut butter paste). Visualization of the genomes showed that foodborne and clinical isolates from each outbreak were identical, verifying Pulse-field Gel Electrophoresis (PulseNet) analysis that established the source strain for each outbreak. During the course of the year CFSAN scientists have used a high-density DNA microarray containing whole genomes of 38 common outbreak strains of *Salmonella* to analyze foodborne and clinical isolates from 2008 outbreaks. The array enabled quick identification of unique gene and plasmid content in the strains and sites containing single nucleotide polymorphisms (SNPs). CFSAN scientists also have developed a method for the isolation of *Yersinia pestis* using a novel enrichment broth and the Pathatrix immunomagnetic capture system which was successfully evaluated by 19 Food Emergency Response Network (FERN) laboratories. This Pathatrix method is faster and more accurate than existing methods. Before the method is moved out of the research environment where it was developed, CFSAN must make sure different laboratories will get the same results no matter where they are located or what microbiologist is using the method. Since 19 different laboratories were able to use the method successfully, it means that the method works (validated) and is ready for use by the FERN laboratories. This is a proactive effort to making sure CFSAN is ready with a good detection method should an emergency such as an outbreak or a bioterrorism event occur involving this bacterial pathogen, *Yersinia pestis* (the organism that causes plague or black death). The validation process is an important process in methods development and implementation.

Additionally, CFSAN published a final rule that allows the use of irradiation to make fresh iceberg lettuce and fresh spinach safer and last longer without spoiling. Irradiating fresh iceberg lettuce and spinach will help protect consumers from disease-causing bacteria such as *Salmonella* and *Escherichia coli* O157:H7, which continue to be public health problems in the United States. CFSAN issued a final rule to require the declaration of the color additives cochineal extract and carmine on all food and cosmetic products. FDA took this action to protect the small number of consumers who are allergic to these color additives.

CFSAN completed the Tomato Safety Initiative assessment activities covering the Eastern Shore of Virginia and 3 regions of Florida (field related). In addition, FDA published the Employee Health & Personal Hygiene Handbook, referencing the FDA Food Code, designed to prevent food workers from transmitting pathogens including viruses to food.

CFSAN FDA also published a white paper on allergen cleaning validation (J. Food Prot (2008) 71: 445 - 458) The objectives of this review were (i) to study the incidence and cause of allergen cross-contact, (ii) to assess the science upon which the cleaning of food contact surfaces is based, and (iii) to identify best practices for cleaning allergenic foods from food contact surfaces.

Food Protection Program – ORA Activities

In support of the FDA Food Protection Program, ORA focused on implementing a risk-based surveillance and inspection strategy. Through risk-based domestic and foreign inspections of food establishments, ORA assesses industry compliance with GMP and HACCP requirements. In addition, ORA responds to public health emergencies and investigates incidences of intentional and naturally occurring product contamination.

Field personnel also play a lead role in response to foodborne illness outbreaks by conducting tracebacks of implicated foods. Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks. During April through July 2008, more than 1,300 people fell ill from what was first believed to be a multi-State *Salmonella St. Paul* tainted raw tomatoes outbreak. The outbreak continued after FDA issued the tomato alert in May and tested large numbers of tomato samples. Thereafter, CDC conducted a second case study and determined the need to expand the alert to other types of produce, including serrano and jalapeno peppers. FDA and FERN labs were utilized to test these additional foods and found contaminated jalapeno peppers originating from Mexico that matched the outbreak strain of Salmonella.

To complement the analytical work of FDA labs, 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. During the *Salmonella St. Paul* outbreak, FERN labs provided increased laboratory capacity and capability to allow FDA to create an additional assignment for the outbreak response that targeted retailers and distributors of the products in question. During the course of the approximately four week assignment, over 140 samples were tested by FERN labs of which 11 samples were found positive for Salmonella. While none of the contaminated samples matched the outbreak strain, States did take actions on the results, including recalls of the product.

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. With FY 2008 Food Protection increases, FERN added three additional chemical labs in FY 2008 which will increase the surge capacity in FY09 to 1,650 chemical samples per week. ORA will continue to maintain the FERN lab networks in FY 2010.

In addition to domestic food work, ORA conducted 100,718 import food field exams in FY 2008 to monitor the safety of imported products being offered for entry in the United States. The number of import food field exams conducted exceeded FDA's goal by 18 percent. For example, in August 2008, two individuals and two corporations pled guilty in New York to charges of trafficking in counterfeit Colgate toothpaste. These defendants imported over 518,000 tubes of counterfeit Colgate toothpaste from China that failed to contain fluoride and, in some cases, contained microorganisms, such as bacillus spores, and diethylene glycol (DEG), used as a coolant for hydraulics and brake fluids.

However, ORA cannot rely solely on physical examinations of imports to reduce the potential risk. To complement the import inspection program, ORA has made substantial progress in the development of PREDICT, a new electronic system for better risk-based screening of imports. PREDICT uses automated data mining, pattern analysis, exogenous information, expert rules, and detection of data anomalies in determining which shipments need human review. In January 2008, ORA completed evaluation of a three-month pilot test of the prototype system and determined it successful based on several criteria: user acceptance, violation rates; and integration of systems. Further development continues to incorporate additional criteria and to expand the system to encompass all FDA-regulated products. Better electronic, risk-based screening is essential to FDA's efforts to focus inspectional resources on high-priority shipments.

Improving Nutrition – CFSAN Activities

The principal mission of the FDA Nutrition Program is to promote healthful dietary practices by ensuring that packaged and other foods are truthfully and properly labeled. This allows consumers to use this information to make informed choices to improve their health and help them reduce the risk of chronic disease. FDA conducts research, issues guidance and rules, and develops education and outreach programs on improving the accuracy, truthfulness, and usefulness of the food label and nutrition information. CFSAN launched a major consumer research initiative several years ago in response to the Office of Management and Budget Program Assessment Rating Tool (PART) evaluation of the mission of the FDA. FDA agreed to create a long-term outcome goal (PART goal) to increase the consumer understanding of diet-disease relationships, especially between dietary fats and coronary heart disease. The PART goal proposed baseline performance indicators of consumer understanding of three dietary fats (*trans*, saturated, and omega-3 fats). CFSAN developed the baseline indicators in 2005 from a nationally representative telephone survey. The protocol for implementing the survey is under review.

FDA recently initiated two education and outreach efforts. First, with the Cartoon Network, FDA released a public service campaign for tweens to "Spot the Block" that is aimed at building

awareness of the nutrition label and label reading skills. Second, FDA released a web-based program to inform consumers about using the nutrition labels for "Healthy Weight Management." In addition, CFSAN expanded an existing project with the National Science Teachers Association (NSTA) to include nutrition education for middle and high school teachers to help teach students to make healthful food choices using the Nutrition Facts Panel.

In early 2008, FDA prepared a report on folic acid fortification in response to a Congressional Committee report that suggested that the FDA should increase current levels of folic acid fortification in enriched cereal-grain products. In the report, FDA scientists reviewed the current literature and the present fortification standards, and identified a number of issues that FDA would need to consider in revising the current standards.

FDA held a public hearing to address the use of "may contain" labeling for allergens in food products. In 2009, FDA published guidance on the evidence-based system used to evaluate research studies in support of health claims, including qualified health claims. It represents the agency's current thinking on 1) the process for evaluating the scientific evidence for a health claim, 2) the meaning of significant scientific agreement (SSA) and 3) credible scientific evidence to support a qualified health claim. In addition, the FDA published a Federal Register Notice in December 2007 regarding the re-evaluation of scientific evidence for two authorized health claims and two qualified health claims using the evidence-based system. Since then, FDA re-evaluated and amended the regulation authorizing a health claim on the relationship between calcium and a reduced risk of osteoporosis to include vitamin D so that in addition to a claim for calcium and osteoporosis an additional claim may be made for vitamin D and osteoporosis. The amended regulation also eliminated the requirement that the claim list sex, age, and race as specific risk factors for the development of osteoporosis as well as other requirements referring to mechanisms of the reduction and amounts of calcium. FDA also revaluated and adopted as a final rule without change two other health claims, soluble fiber from certain foods and the risk of coronary heart disease; and dietary noncariogenic carbohydrate sweeteners and dental caries.

Improving Nutrition - ORA Activities

ORA determines the compliance of domestic and imported foods with labeling regulations promulgated under the Federal Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act, and the Fair Packaging and Labeling Act. In addition to ensuring that required information is displayed on product labels, ORA verifies the accuracy of health claims made on labels through product sampling and analysis.

An important component of ORA's Food Labeling Program is the regulation of domestic and imported food related products. In February 2008, FDA permanently enjoined two firms that were manufacturing and distributing foods as drugs. A manufacturer and a distributor of various juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules, and two of their top executives, signed a consent decree permanently enjoining the firms from manufacturing and distributing any products with drug claims in labeling and from distributing foods with unauthorized health claims. The companies had a history of promoting unapproved claims on their product labels, brochures, and web sites, stating that the products cure, treat, mitigate, or prevent various diseases.

Improving Dietary Supplement Safety – CFSAN Activities

The mission of the FDA Dietary Supplement Program is to ensure that these products are safe and properly labeled and that any disease or health-related claims are scientifically supported. FDA regulation of dietary supplements falls under the authority of the Federal Food, Drug, and Cosmetic Act in general and the Dietary Supplement Health and Education Act of 1994 (DSHEA) in particular.

Recent surveys indicate that 60-70 percent of the U.S. population use dietary supplements. Many supplements are imported and potentially manufactured without using current good manufacturing practice (cGMP) requirements. In FY 2007, FDA published a final rule establishing cGMP requirements for dietary supplements. The regulation requires that proper controls be in place so dietary supplements are processed in a consistent manner and meet quality standards, including standards for identity, purity, strength, and composition. Beginning in June 2008, FDA began to conduct cGMP inspections, based on the final rule, of both domestic and foreign dietary supplement manufacturing facilities that have more than 500 employees. Dietary supplement cGMP inspections will begin for medium size companies (20-500 employees) in June 2009 and for small companies (fewer than 20 employees) in June 2010.

FDA scientists recently completed a survey to determine the extent of lead (Pb) contamination in vitamins labeled for use by women and children. The results showed that estimates of Pb exposure were below the provisional total tolerable intake levels for young children, older children, pregnant and lactating women, and adult women. In addition, multi-residue methods have been developed for determining 150 pesticides in dietary supplements such as ginseng.

FDA also continues the operation and further development of its voluntary adverse events reporting database called CAERS (CFSAN Adverse Events Reporting System). CAERS collects adverse event reports and complaints from consumers, manufacturers, and healthcare providers, enabling staff to conduct reviews of reports for potential safety issues. Since becoming operational in June 2003, CAERS has received an average of 4,769 reports of adverse events and/or consumer complaints a year. In 2008, a breakdown of adverse event and/or product complaint reports shows as examples: 190 cosmetic, 201 seafood, 1,190 dietary supplement, 111 infant formula or baby food, and 312 bakery product reports

In FY 2008, CAERS began to receive mandatory adverse event reports from dietary supplement manufacturers based on the newly mandated reporting requirements of the Dietary Supplement and Nonprescription Drug and Consumer Protection Act of 2006. FDA published guidance on reporting serious adverse events associated with dietary supplements and instructions on how to fill out a MedWatch Form 3500A. The FDA Post-market Safety Review Program is monitoring this data for signals of potential adverse reactions to dietary supplements and ingredients.

Improving Dietary Supplements – ORA Activities

ORA plays a vital role in ensuring the safety of dietary supplements by collecting and analyzing products to check label accuracy in order to ensure the safety of supplements before they enter

into the U.S. market. ORA also oversees all recalls of contaminated or fraudulent products to remove potentially dangerous products from the U.S. marketplace.
In February 2008, following an OCI investigation, five business owners and their companies were indicted in the Western District of Missouri on charges related to the fraudulent marketing of dietary supplements. The defendants conspired to promote multiple dietary supplements through internet web sites and made illegal drug claims their products could treat, cure, mitigate and prevent disease. These companies continued to illegally market their products despite FDA warning letters and an FDA inspection.

Improving Cosmetics Safety – CFSAN Activities

The mission of the FDA Cosmetics Program is to protect the public health by ensuring the safety of cosmetics. Cosmetics marketed in the United States, whether manufactured here or imported, must comply with the FD&C Act, the Fair Packaging and Labeling (FP&L) Act, and regulations promulgated by FDA under these laws.

The domestic cosmetic industry has annual U.S. sales in the tens of billions, with thousands of facilities in the U.S. alone. Cosmetic products and ingredients also enter the U.S. from a broad range of countries, most of which have different regulatory systems and standards. From 2000-2007, the number of entries of imported cosmetics products almost tripled. In 2008, cosmetics accounted for a little over 9 percent of all imports under FDA jurisdiction, third-highest among FDA-regulated product areas. The past 5-10 years also have seen an explosion in the numbers and types of cosmetic products sold annually. These changes in the industry present both scientific and regulatory challenges that have been increasingly difficult for FDA to meet with existing resources.

As an example, cosmetics represent one of the fastest growing areas for application of nanotechnology. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties, which may pose different safety issues. As part of FDA efforts to develop guidance for industry on this issue and to protect public health, in FY 2008 FDA held a public meeting to discuss the scientific and regulatory issues concerning the use of nanoscale materials in regulated products, including cosmetics. FDA is also conducting collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and their potential health hazards when used in cosmetics. FDA is currently drafting guidance for industry and other stakeholders on the use of nanoscale materials in cosmetics.

FDA implemented a Voluntary Cosmetic Registration Program (VCRP) as a means of maintaining information about cosmetic products currently in the marketplace. FDA uses information from the VCRP, along with other data, to develop guidance and regulations for industry and to identify additional science needed to assess the safety of cosmetic ingredients. In FY 2007, FDA made significant enhancements to its current web-based system; and the number of cosmetic products accepted for filing in the system increased almost 30 percent over FY 2006 level. In FY 2009, FDA eliminated the backlog of old paper-based registrations and completed a purge of old and obsolete paper-based registrations. The current annual level of product

registration is now more than 15 times higher than with the prior paper-based system. FDA continues to provide industry training on the VCRP.

In 2007, the FDA Cosmetics Program re-established an international effort to cooperate on cosmetics regulation, referred to as ICCR. This effort includes regulatory authorities from FDA, Health Canada, the European Commission, and the Ministry of Health, Education, Labor and Welfare of Japan, as well as a joint regulator-industry caucus on one day of the meeting. The first meeting of the group was held on September 25-28, 2007, in Brussels and the second meeting on July 30-August 4, 2008 in Rockville, MD. Issues addressed were: alternatives to animal testing, cosmetic good manufacturing practices (GMPs), nanotechnology, nomenclature, and sharing of information among the regulators. One of the outcomes has been a consensus decision to make use of International Standards Organization (ISO) standards for GMPs. Discussion on alternatives to animal testing will be prominent in 2009, as the first phase of the European Union ban on animal testing of cosmetic ingredients has already taken effect as of March 2009, with additional actions scheduled in 2010 and 2011. New discussions on International Nomenclature of Cosmetic Ingredients (INCI) nomenclature have also been initiated.

The safety of cosmetics is a public health priority and FDA must therefore have the resources to maintain the capacity to issue necessary regulations and guidance. FDA also must maintain robust systems for collecting adverse event reports and voluntary cosmetic product registrations and the resources for product surveys and laboratory investigations. Information from these sources is essential for the FDA risk-based approach to post-market monitoring, inspection, and other enforcement activities. The net result will be improved public health protection through increased availability of safe cosmetic products and removal of unsafe cosmetic products from the marketplace.

Improving Cosmetics Safety – ORA Activities

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 the marketplace.

On November 16, 2007, FDA seized approximately $2 million of Age Intervention Eyelash, a "cosmetic" product sold and distributed by Jan Marini Skin Research, Inc., of San Jose, California. FDA considered Age Intervention Eyelash, promoting increased eyelash growth, a dangerous cosmetic that included a drug ingredient, bimatoprost (which treats elevated eye pressure) that the company made unapproved drug claims and that the use of the product was potentially harmful. On June 19, 2008, a motion for default judgment was granted, directing the U.S. Marshal’s Service to destroy the goods.

Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Food Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$438,721,000	$438,721,000	$0	2,774
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 Omnibus	$648,722,000	$648,722,000	$0	3,019
FY 2010 Estimate	$845,617,000	$782,915,000	$62,702,000	3,516

Budget Request

The FY 2010 President's Budget requests $845,617,000 in program level funding for the Foods Program, including user fees, in the support of 3,516 FTEs. The CFSAN portion of the request is $244,981,000 and 947 FTEs, an increase above the FY 2009 Omnibus of $34,495,000 and an increase of 93 FTEs to maintain current service levels. The Field portion of the request is $600,636,000 supporting 2,569 FTEs, an increase above the FY 2009 Omnibus of $162,400,000 and 404 FTEs.

In FY 2010, CFSAN will continue to take the lead in maintaining and improving an already sound food safety protection capability by accomplishing the goals and objectives established in the FDA Food Protection Plan and the Import Safety Action Plan as well as continuing cooperation and information sharing between the U.S. and China.

FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners. FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Field Feeds Programs in the following four areas:

- Develop a National Workplan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples;
- Ensure that programmatic objectives and implementation are coordinated;
- Continue to develop uniform, national standards for such subjects as manufacturing, inspections, and enforcement;
- Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners;

- Increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for Federal, State, local, tribal and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

Furthermore, ORA is requesting funding in FY 2010 to continue building its workforce for more field food and feed work and support for the field food and feed work. In order to do so, ORA is requesting funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work such as:

- Increase of 20,000 food and feed import exams by the end of 2011
- Increase of 2,000 domestic food and feed inspections by the end of 2012
- Increase of 50 foreign food and feed inspections by the end of 2012.

Cost of Living Pay Increase

The CFSAN portion of FDA's requested pay increase is $2,986,000 . Without these funds CFSAN would need to reduce FTE in order to adequately cover payroll, which will lead to a decrease in FDA's ability to protect the public health.

Information Technology

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Food Safety and Nutrition Program by maintaining its legacy systems and databases used for managing and tracking its programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Food Safety and Nutrition Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

User Fees Authority and Increases

Reinspection and Food Export Certification User Fee

This proposal for $25,848,000 and 129 FTEs in Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. ORA's Food request is for $6,124,000 and 48 FTE . This new user fee will amend the Food, Drug, and

Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

The FY 2010 budget also proposes a new user fee to support export certification activities. FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collection user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. The total proposed collections for the FDA in FY 2010 are $4,152,000 with $1,063,000 of the collections being allocated to CFSAN.

Food Inspection and Facility Registration User Fee

The FY 2010 budget proposes a User Fee for Food Inspection and Facility Registration for $75,000,000. This proposal allocates $7,500,000 to CFSAN, and $45,000,000 to the Field Foods Program. Food facilities would be charged user fees for inspections and registration of their establishments. These user fees would fund FDA inspections at the facilities.

Foods Performance Measures Table

Long Term Objective: Increase access to safe and nutritious new food products.

Measure	FY	Target	Result
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. *(Output)*	*2010*	70%	Oct 31, 2011
	2009	60%	Oct 31, 2010
	2008	60%	Oct 31, 2009
	2007	50%	100% (Target Exceeded)
	2006	70%	87% (Target Exceeded)
	2005	75%	100% (Target Exceeded)

Long Term Objective: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

Measure	FY	Target	Result
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)*	*2010*	347 enrolled	Dec 31, 2010
	2009	332 enrolled	Dec 31, 2009
	2008	317 enrolled	320 enrolled (Target Not Met)
	2007	240 enrolled	302 enrolled (Target Not Met)
	2006	N/A	259 enrolled (Target Not In Place)
	2005	N/A	185 enrolled (Target Not In Place)
214102: Percentage of the enrolled jurisdictions which meet 2 or more of the Standards *(Outcome)*	*2010*	32%	Dec 31, 2010
	2009	32%	Dec 31, 2009
	2008	32%	32% (Target Met)
	2007	26%	32% (Target Exceeded)
	2006	N/A	24% (Target Not In Place)

Long Term Objective: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.

Measure	FY	Target	Result
212401: Increase by 40 percent the	*2007*	45%	May 31, 2009

Measure	FY	Target	Result
percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. *(Outcome)*	*2005*	N/A	32% (Target Not In Place)
212402: Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. *(Outcome)*	*2007*	81%	May 31, 2009
	2005	N/A	74% (Target Not In Place)
212403: Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease. *(Outcome)*	*2007*	34%	May 31, 2009
	2005	N/A	31% (Target Not In Place)

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure	FY	Target	Result
214201: Number of prior notice import security reviews. *(Output)*	*2010*	80,000	December, 2010
	2009	80,000	December, 2009
	2008	80,000	80,543 (Target Exceeded)
	2007	60,000	84,088 (Target Exceeded)
	2006	N/A	89,034 (Historical Actual)
	2005	N/A	86,187 (Historical Actual)
214202: Number of import food field exams. *(Output)*	*2010*	140,000	December, 2010
	2009	120,000	December, 2009
	2008	85,000	100,718 (Target Exceeded)
	2007	71,000	94,743 (Target Exceeded)
	2006	N/A	94,545 (Historical Actual)
	2005	N/A	84,997 (Historical Actual)
214203: Number of Filer Evaluations. *(Output)*	*2010*	1,000	December, 2010
	2009	1,000	December, 2009
	2008	1,000	1,356 (Target Exceeded)
	2007	1,000	1,355 (Target Exceeded)
	2006	N/A	1,441 (Historical Actual)

Measure	FY	Target	Result
	2005	N/A	1,407 (Historical Actual)

	FY	Target	Result
214204: Number of examinations of FDA refused entries. *(Output)*	*2010*	5,000	December, 2010
	2009	5,000	December, 2009
	2008	4,000	5,926 (Target Exceeded)
	2007	3,000	5,510 (Target Exceeded)
	2006	N/A	5,846 (Historical Actual)
	2005	N/A	5,655 (Historical Actual)
214205: Number of high risk food inspections. *(Output)*	*2010*	6,750	December, 2010
	2009	6,100	December, 2009
	2008	5,700	6,230 (Target Exceeded)
	2007	5,625	6,421 (Target Exceeded)
	2006	N/A	6,795 (Historical Actual)
	2005	N/A	7,568 (Historical Actual)
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	*2010*	5 data exchange additions/conversions	December, 2010
	2009	5 data exchange additions/conversions	December, 2009
	2008	5 data entry labs	11 labs (Target Exceeded)
214206: Maintain accreditation for ORA labs. *(Outcome)*	*2010*	13 labs	December, 2010
	2009	13 labs	December, 2009
	2008	13 labs	13 labs (Target Met)
	2007	13 labs	13 labs (Target Met)
	2006	N/A	13 labs (Historical Actual)
	2005	N/A	6 labs (Historical Actual)
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	*2010*	2,500 rad & 2,100 chem	December, 2010
	2009	2,500 rad & 1,650 chem	December, 2009
	2008	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem (Target Met)

Measure	FY	Target	Result
	2007	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem (Target Met)
	2006	N/A	1,200 chem (Target Met)
	2005	N/A	0

Other Outcome Indicators Measured in the HHS Strategic Plan

Measure	FY	Target	Result
Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species.	*2010*	12.3 cases/100,000	December, 2011
	2009	TBD	December, 2010
	2008	TBD*	December, 2009
	2007	N/A	12.8 cases/100,000 (Target Exceeded)
	2006	N/A	12.7 cases/100,000 (Historical Actual)
	2005	N/A	12.7 cases/100,000 (Historical Actual)
Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7.	*2010*	1.0 cases/100,000	December, 2011
	2009	TBD	December, 2010
	2008	TBD*	December, 2009
	2007	N/A	1.2 cases/100,000 (Target Exceeded)
	2006	N/A	1.3 cases/100,000 (Historical Actual)
	2005	N/A	1.1 cases/100,000 (Historical Actual)
Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*.	*2010*	.24 cases/100,000	December, 2011
	2009	TBD	December, 2010
	2008	TBD*	December, 2009
	2007	N/A	.27 cases/100,000 (Target Exceeded)
	2006	N/A	.31 cases/100,000 (Historical Actual)
	2005	N/A	.30 cases/100,000 (Historical Actual)
Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species.	*2010*	6.8 cases/100,000	December, 2011
	2009	TBD	December, 2010
	2008	TBD*	December, 2009

Measure	FY	Target	Result
	2007	N/A	14.9 cases/100,000 (Target Exceeded)
	2006	N/A	14.7 cases/100,000 (Historical Actual)
	2005	N/A	14.5 cases/100,000 (Historical Actual)

* CDC has not published the final FY 2007 FoodNet data, although it was expected to be published this fall.

1. Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. (213301)

Context: The likely number of submissions to the food and color additives premarket review program was uncertain for FY 2007 and FY 2008 because of statutory triggers in section 409(h) of the FD&C Act that might have dramatically increased the number of submissions to this program. The factors impacting the uncertainty in submission numbers have lessened and performance has stabilized despite reduced program resources.

Performance: Because of the 360 day review time associated with this goal, the FY 2008 actual data would not normally be available until October 2009; however, all petitions filed in FY 2008 have been completed as of the end of March 2009. Although this program has reached or exceeded its performance goal each of the last four years, program resources have been reduced. One reason goals have continued to be met is that the actual number of submissions has fallen off over that time period. An increase in the number or complexity of incoming submissions could reduce performance.

2. 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* and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214101 and 214102)

Context: Strong and effective regulatory programs at the state, local and tribal level are needed to prevent foodborne illness and reduce the occurrence of foodborne illness risk factors in retail and foodservice operations. The voluntary use of the Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing foodborne illness. The success that FDA's National Retail Food Team has had in increasing enrollment and use of the Standards reflects continued recognition that the Standards help programs improve food safety in foodservice and retail food establishments. Effective use of the Standards is assured by having enrolled complete program self-assessments to identify program strengths and areas for improvement.

Performance: FDA exceeded its FY 2008 target by enrolling 18 additional states, local and tribal retail food inspection programs enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards. This raised the total number of enrolled jurisdictions to 320. 102 of these 320, or 32%, of the enrolled jurisdictions reported meeting at least 2 of the 9 Program Standards, based on their own self assessments. The FY 2009 targets in the Outputs Table are

based on an expectation of enrolling fifteen additional enrolled jurisdictions. These targeted increases are more modest than previous year's enrollments in recognition that, in addition to enrolling new jurisdictions, ORA personnel must devote time and resources to assisting the growing number of enrollees with Program Standards implementation. In fact, the target for FY 2009 is to maintain the current percentage of those enrolled jurisdictions that meet 2 or more of the Standards at 32%. Based on enrollment activity in the first quarter of FY 2009 we are on target for meeting the existing FY 2009 Targets. The FY 2010 Targets shown in the table above are based on an expectation that additional local jurisdictions will enroll in FY 2010 and make progress toward meeting the Standards as the result, in part, of FY 2009 efforts by FDA to make funds available to jurisdictions who agree to provide FDA with written reports on their progress.

3. Increase consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease (CHD). (212401, 212402, 212403)

Context: Coronary Heart Disease (CHD) is the leading cause of death among Americans, accounting for more than 1 in 5 deaths annually. CHD is also the leading cause of premature, permanent disability in the labor force. Dietary factors, especially consumption of some fats, play a significant role in CHD risk. One modifiable factor that is important for reducing mortality and morbidity associated with heart disease is consumer understanding of the consequences of dietary choices with respect to CHD. Increased understanding will strengthen motivation to adopt and maintain recommended healthy dietary behavior and to make informed dietary choices. The target is directly in line with several of the Department's priorities and strategic goals. First, improving the American diet through informed choice about fats that increase or reduce the risk of heart disease is one of several important steps toward reducing the enormous morbidity and mortality burden of CHD. This burden is borne disproportionately by minority populations, including African-Americans, Hispanics, and Native Americans. As the leading cause of death and a significant cause of illness and disability, CHD also imposes substantial costs on the U.S. health care system.

Performance: The baseline data for FY 2005 has been developed. Although the target year for accomplishment was FY 2007, the Health and Diet Survey is currently in the field and data is expected to be available for analysis by the end of May, 2009.

4. Number of prior notice import security reviews. (214201)

Context: FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

Performance: During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

5. Number of import food field exams on products with suspect histories. (214202)

Context: The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than 18.7 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA used Food Protection Resources to increase the number of import food field exams by 20,000 exams which brings the FY 2009 Target to 120,000 exams over the FY 2008 accomplishments. In FY 2010, FDA will use the FY 2009 resources to increase the number of import food field exams by 20,000 exams which brings the FY 2010 Target to 140,000 exams.

Performance: In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

6. Number of Filer Evaluations of import filers. (214203)

Context: The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated

import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices. The FY 2010 target is being maintained.

Performance: In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

7. Number of examinations of FDA refused entries. (214204)

Context: FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. For FY 2010, the target will be maintained.

Performance: In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

8. Number of high risk food inspections. (214205)

Context: High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on

a firm's compliance history. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target has been increased to 6,750 to reflect the FY 2009 Appropriations.

Performance: In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 inspections of high-risk domestic food establishments.

9. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. (214303)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2008, 151 laboratories representing multiple government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

Performance: In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. Explanation of why this goal was significantly exceeded: This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

10. Establish and maintain accreditation for ORA labs. (214206)

Context: FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena.

Performance: In FY 2008, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan

District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

11. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305)

Context: A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which will increase the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA will add three additional FERN chemical labs in FY 2009 which will increase the surge capacity in FY 2010 to 2,100 chemical samples per week.

Performance: In FY 2008, FDA met this performance goal surge capacity target of 2,500 rad samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 rad samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

Foods Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS		FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FOOD & COLOR ADDITIVE PETITIONS					
Petitions Filed		7	8	10[1]	10[1]
Petitions Reviewed [1]		7	7	9[1]	9[1]
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES					
Notifications Received		105	85[3]	100[4]	100[4]
Notifications Reviewed[2]		115	81[3]	100[4]	100[4]
INFANT FORMULA NOTIFICATIONS					
Notifications Received[5]		35	29	35	35
Notifications Reviewed [6]		33	27	32	35
FDA Review Time		90 Days	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [7]					
Submissions Received [8]		91	94	64	64
Submissions Reviewed [9]		86	62	64	64
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] Our current estimates assume continued funding of the FCN program in FY 2009 and FY 2010.
[4] Number of submissions received in current FY includes some received late in the FY.
[5] Number of submissions reviewed includes some submissions that were received in the previous FY.
[6] A single notification may address one or more new dietary ingredients. For example, FDA as received at least 15 notifications that pertain to 2 up to 16 new dietary ingredients in a single notification
[7] 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.
[8] 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.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***6,562***	***7,263***	***7,467***
Domestic Food Safety Program Inspections	3,611	3,850	4,100
Imported and Domestic Cheese Program Inspections	391	400	400
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	438	450	450
Domestic Fish & Fishery Products (HACCP) Inspections	1,827	1,850	1,850
Import (Seafood Program Including HACCP) Inspections	359	500	500
Juice HACCP Inspection Program (HACCP)	377	300	300
Interstate Travel Sanitation (ITS) Inspections	1,042	1,555	1,555
Domestic Field Exams/Tests	2,638	2,425	2,425
Domestic Laboratory Samples Analyzed	12,043	14,500	14,500
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT	***152***	***200***	***600***
All Foreign Inspections	152	200	600
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT	***6,714***	***7,463***	***8,067***
IMPORTS			
Import Field Exams/Tests	100,718	120,000	140,000
Import Laboratory Samples Analyzed	23,052	26,200	26,200
Import Physical Exam Subtotal	**123,770**	**146,200**	**166,200**
Import Line Decisions	9,441,024	9,526,745	9,613,245
Percent of Import Lines Physically Examined	1.31%	1.53%	1.73%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	80,543	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,777***	***11,076***	***11,575***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***786***	***500***	***500***
State Contract Food Safety (Non HACCP) Inspections	7,791	9,797	10,297
State Contract Domestic Seafood HACCP Inspections	914	1,148	1,148
State Contract Juice HACCP	50	75	75
State Contract LACF	37	75	75
State Partnership Inspections	786	500	500
State Contract and Grant Foods Funding	$9,100,000	$9,775,000	$10,400,000
Number of FERN State Laboratories	16	19	19
Annual FERN State Cooperative Agreements/Operations Funding	$11,535,000	$13,450,000	$10,988,000
Total State & Annual FERN Funding	**$20,635,000**	**$23,225,000**	**$21,388,000**
TOTAL FOOD INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***16,277***	***19,040***	***20,143***

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***92***	***100***	***100***
All Inspections (Domestic and Foreign)	92	100	100
IMPORTS			
Import Field Exams/Tests	1,892	2,000	2,000
Import Laboratory Samples Analyzed	301	230	230
Import Physical Exam Subtotal	**2,193**	**2,230**	**2,230**
Import Line Decisions	1,588,082	1,721,372	1,865,849
Percent of Import Lines Physically Examined	0.14%	0.13%	0.12%
TOTAL COSMETICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL COSMETICS ESTABLISHMENT	***92***	***100***	***100***

HUMAN DRUGS

The FY 2010 program level budget request for the FDA Human Drugs Program is $908,013,000.

The following table shows a three-year funding history for the Human Drugs Program.

FDA Program Resources Table

	FY 2008		FY 2009	FY 2010 President's	FY 2010 +/- FY
	Enacted	Actuals	Omnibus	Budget Request	2009 Omnibus
Program Level	**$708,288,000**	**$680,926,000**	**$777,437,000**	**$908,013,000**	**$130,576,000**
Center	$600,366,000	$587,551,000	$659,221,000	$763,076,000	$103,855,000
FTE	2,551	2,396	2,791	2,996	205
Field	$107,922,000	$93,375,000	$118,216,000	$144,937,000	$26,721,000
FTE	677	600	699	763	64
Program Level FTE	**3,228**	**2,996**	**3,490**	**3,759**	**269**
Budget Authority	**$381,288,000**	**$353,909,000**	**$413,482,000**	**$457,814,000**	**$44,332,000**
Center	$280,282,000	$266,269,000	$302,386,000	$329,588,000	$27,202,000
Field	$101,006,000	$87,640,000	$111,096,000	$128,226,000	$17,130,000
Pay Increase (non add)				*$6,697,000*	*$6,697,000*
Safer Medical Products (non-add)				*$33,635,000*	*$33,635,000*
Drug Importation (non-add)				*$4,000,000*	*$4,000,000*
Budget Authority FTE	**1,880**	**1,712**	**1,945**	**2,026**	**81**
Center	1,243	1,144	1,286	1,342	56
Field	637	568	659	684	25
User Fees	**$327,000,000**	**$327,017,000**	**$363,955,000**	**$450,199,000**	**$86,244,000**
Center PDUFA	$320,084,000	$321,282,000	$356,835,000	$406,984,000	$50,149,000
FTE	1,308	1,252	1,505	1,598	93
Field PDUFA	$6,916,000	$5,735,000	$7,120,000	$8,306,000	$1,186,000
FTE	40	32	40	49	9
Proposed User Fees	**$0**	**$0**	**$0**	**$34,909,000**	**$34,909,000**
Center Generic Drugs				$26,504,000	$26,504,000
FTE				56	56
Field Generic Drugs				$6,045,000	$6,045,000
FTE				12	12
Field Reinspection				$2,360,000	$2,360,000
FTE				18	18
User Fees FTE	**1,348**	**1,284**	**1,545**	**1,733**	**188**

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*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA Human Drugs Program is responsible for ensuring that prescription, generic, and over-the-counter (OTC) drug products are adequately available to the public and are safe and effective. The program is also responsible for monitoring marketed drug products for unexpected health risks, and for monitoring and enforcing the quality of marketed drug products.

Responsibilities and functions carried out by the Center for Drug Evaluation and Research (CDER) can be traced back to the earliest days of the Food and Drug Administration (FDA) and the 1906 Pure Food and Drugs Act. Largely in response to the deaths of 107 people who took the Elixir Sulfanilamide which contained diethylene glycol, Congress enacted the Food and Drug Cosmetic Act in 1938, legislation that required that new drugs be shown to be safe before marketing. That legislation and the Drug Amendments Act of 1962 (the "Kefauver-Harris Act"), which stipulated that a drug be "effective for its intended use," form the cornerstones of the CDER mission: to assure that safe and effective drugs are available to the American people.

In the 1990s, Congress focused on ensuring the timeliness of drug product application reviews and drug approvals for marketing. In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA) which essentially doubled FDA's resources to review applications. Most recently, the provisions of the Food and Drug Amendments Act (FDAAA) of 2007 increases the Center's authorities for ensuring a more robust program for monitoring drug products after they have been approved for marketing.

The Human Drugs Program operates with funding from both appropriations and user fees. The PDUFA legislation of 1992 first authorized FDA to collect user fees from the pharmaceutical industry, and that authority was reauthorized by the Food and Drug Modernization Act (FDAMA) of 1997, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and most recently, by FDAAA.

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

The Human Drugs Program conducts its activities with assistance from the Office of Regulatory Affairs (ORA). ORA provides FDA leadership on enforcement, import, inspection, and laboratory policies. Through its field offices nationwide, ORA supports the Drugs Program by conducting risk based domestic and foreign premarket and postmarket inspections of drug manufacturers to assess their compliance with Good Manufacturing Practices (GMP). In addition to overseeing the regulated products on a surveillance or "for cause" basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. ORA's Field Drugs program is funded by appropriated and user fee dollars.

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Drug Program by maintaining its legacy systems and databases used for managing and tracking its drug review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also works with the Drugs Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The Human Drugs Program executes its regulatory responsibilities in three areas: new drug safety and effectiveness, generic drug review, and post-market safety and surveillance.

New Drug Safety and Effectiveness—Center Activities

The process for approving drug products by reviewing the product's safety and effectiveness begins with the companies who must first conduct clinical research to test their products. CDER staff monitors their research to ensure the safety of people who volunteer for studies and to maintain the quality and integrity of scientific data. 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 effective and if its health benefits outweigh its risks, FDA approves the drug for sale. CDER does not actually test the drug when reviewing the data. By setting clear standards for the evidence required to approve a drug, FDA helps bring new drugs to American consumers more rapidly. This area encompasses the activities CDER is responsible for prior to a drug being approved for marketing – otherwise known as "pre-market" activities.

CDER's new drug review process encompasses all activities associated with reviewing investigational new drugs (INDs), new drug applications (NDAs), biologics license applications (BLAs), supplements to new applications, and any amendments filed to application submissions. CDER evaluates NDAs while giving products for diseases such as cancer and Acquired Immune Deficiency Syndrome (AIDS) priority status, assessing them by an accelerated evaluation process that makes promising products for serious or life-threatening diseases available earlier in

the development process. CDER has consistently met its performance target of reviewing and acting upon 90 percent of “priority” NDAs/BLAs within six months.

In FY2008, CDER approved a total of 79 new products, including 75 NDAs and 4 BLAs, 21 of which were new molecular entities (NMEs), unique new compounds that previously have not been approved by FDA. Significant approvals in 2008 included Raltegravir®, the first agent of the pharmacological class known as HIV integrase strand transfer inhibitor, an important new product for many HIV-infected patients whose infections are not being controlled by currently available medications; Xenazine®, the first product for treatment approved for any symptom of Huntington’s disease.

CDER reviews and evaluates over-the-counter (OTC) drugs to ensure that they are safe, effective, and high quality while also assisting consumers on how to best use OTC products by providing clear, easy-to-read drug information. These drugs play an increasingly vital role in America’s healthcare system. The trend to self-medicate has increased greatly in recent years as healthcare costs have risen and consumers want to be empowered to treat minor ailments with OTC drug products.

OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients and the dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet the same, uniform criteria. CDER has maintained high performance by routinely exceeding its targets for completing review and action on 100 percent of applications to switch a prescription drug to OTC status and for making significant progress on developing new OTC monographs.

CDER protects children who need prescription or OTC drug products by working with manufacturers to encourage studies in children so that age-appropriate labeling and dosing is available for products. CDER has consistently exceeded its performance targets for increasing the number of drugs that are adequately labeled for children and ensure the surveillance of adverse events in the pediatric population. One way CDER measures that performance is by tracking the number of written requests, or formal requests to drug sponsors, to conduct pediatric studies for a drug product. In 2008, CDER issued 5 Written Requests to sponsors for on-patent drugs and 19 drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity represents early indications of the impact of a shift in Center policy.

CDER provides medical and scientific expertise and information to federal and state agencies, healthcare providers, and consumers regarding the safety, efficacy, and availability of drug products in case of natural disaster, terrorist event, or other emergency. The Center also works to ensure that terrorists do not use regulated drug and therapeutic biological products as vehicles of terrorism against Americans. CDER has consistently exceeded its performance target of increasing the number of medical countermeasures available. For example, in 2008, CDER approved Levaquin (levofloxacin) tablets, injection, and oral solution for inhalational anthrax (post-exposure) to reduce the incidence or progression in pediatric patients; the drug previously was approved to treat adults after exposure to inhaled anthrax. In addition, FDA awarded a

contract to study the optimal dosing regimen to be used to protect pregnant women and children after they have been exposed to anthrax.

A large part of CDER's public health missions involves ensuring that companies market only the highest quality products. CDER ensures drug product quality by facilitating effective and efficient scientific assessment of relevant pharmaceutical and biotechnology information in regulatory applications submitted to FDA. CDER facilitates scientific and technological innovations that improve understanding of product performance, quality, and efficiency of development, manufacturing, and quality assurance processes. CDER uses a risk-based compliance inspection model for prioritizing inspections according to the risk to product quality. CDER evaluates its inspection findings for trends in deficiencies, focusing on product quality standards and manufacturers' compliance with GMP regulations. In FY 2008, CDER met its goal of inspecting 500 foreign and domestic establishments identified as high-risk human drug manufacturers by inspecting 534 high-risk firms.

New Drug Safety and Effectiveness—Field Activities

The Food, Drug, and Cosmetic Act states that FDA may approve an NDA or an ANDA only if the methods and facilities used for the manufacture, processing, and testing of the drug are found adequate to ensure its strength, quality, and purity.

After CDER scientists review NDA and ANDA applications, ORA examines the adequacy of the firm's facilities 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 other information which may impact on the firm's ability to manufacture the product in compliance with GMP. Inspectional coverage is necessary to assure that new drug applications are not approved if the applicant has not demonstrated an ability to operate with integrity and in compliance with all applicable requirements.

In support of the President's Emergency Plan for AIDS Relief (PEPFAR), ORA and CDER conducted 45 foreign inspections associated with AIDS product approval applications in FY 2008. These inspections supported an expedited review process to help ensure that those being served by the President's Plan would receive safe, effective, and quality manufactured antiretroviral drugs.

ORA also performs bioresearch monitoring inspections to verify that studies submitted in support of the safety and effectiveness of products being reviewed are properly conducted so that FDA can be assured that study results are scientifically valid. Inspections also help ensure that the rights and welfare of people participating in studies are protected.

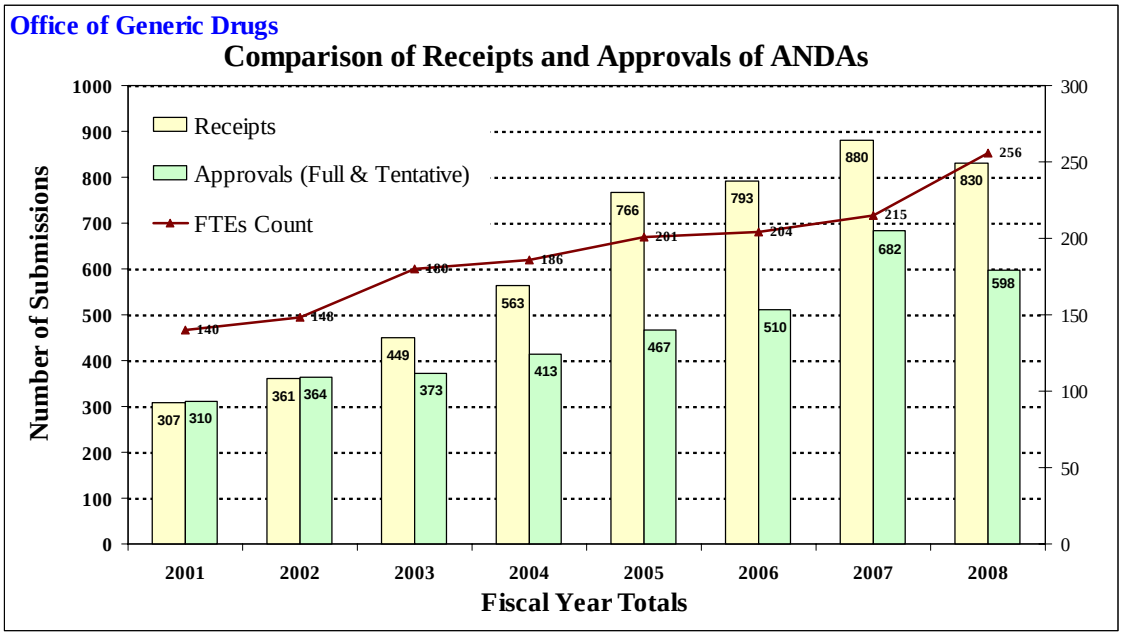
Generic Drug Review—Center Activities

Generic drugs are widely known to be a cost-effective treatment alternative, costing consumers 20-70 percent less than brand-name drugs. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 billion to $10 billion a year compared to the price of trade-name products. The basic requirements for approval of generic and trade-name drugs are the same as 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 to the innovator drug product by showing that the active ingredient in their product is absorbed at a rate and extent similar to the innovator counterpart.

Every year, FDA expands the availability of high-quality generic drug products and provides consumers and healthcare providers with information on their safety and effectiveness. With each new generic version of a brand-name drug the FDA approves, consumers have an additional option to save money on their prescription drug needs.

CDER has experienced a dramatic increase in workload with the number of generic drug applications or ANDAs almost doubling over the past 5 years at a time when staffing levels increased at a much lower rate. The following graph illustrates the increased workload demand and shows that in FY 2008, CDER approved or tentatively approved 598 applications, the equivalent of more than 2 approvals/tentative approvals made each business day of the year.



To measure its performance, CDER tracks the number of total actions taken on ANDAs. The total number of actions includes approvals, tentative approvals, not approvable, and approvable actions on applications. CDER took 1934 actions in FY 2008 compared to 1779 in FY 2007.

Among the approvals in FY 2008 were a number of first-generics providing lower-cost alternatives to brand products including: Alendronate Tablets (generic competitor to Fosamax ®) for treatment of osteoporosis; Risperidone Tablets (generic competitor to Risperdal ®)) for treatment of depression; Divalproex Sodium Delayed Release Tablets (generic competitor to Depakote ®)) for seizure disorders; Ropinirole Tablets (generic competitor to Requip ®) – for treatment of restless leg syndrome; Galantamine Tablets (generic competitor to Razadyne ®) – for treatment of dementia associated with Alzheimer's disease; Dorzolamide and Timolol Maleate Ophthalmic Solution (generic competitor to CoSopt ®) – for treatment of ocular hypertension.

Generic Drug Review —Field Activities

ORA supports the generic drug program through pre-approval inspections to verify application data and assess the firm's ability to manufacture products in accordance with GMP. In FY 2008, ORA conducted 132 domestic and 92 foreign site pre-approval inspections intended to ensure that FDA-regulated generic drugs meet requirements outlined in the Federal Food, Drug, and Cosmetic Act as to the safety, quality, and purity of the product. This supports the availability of high-quality generic drug products and provides consumers an additional option to save money on their prescription drug needs.

Post-market safety and surveillance—Center Activities

FDA must be vigilant to protect Americans from injuries and deaths caused by unsafe, illegal, fraudulent, substandard, or improperly used products. The relatively small size required to make pre-marketing clinical trials practical means that CDER cannot learn everything about the safety of a drug before its approval. As a result, a degree of uncertainty always exists about the risks of drugs. If FDA detects any new and unexpected health risks, CDER takes steps to inform the public and change how a drug is used. When necessary, FDA will remove a drug from the market. In addition, FDA monitors the promotion of drug and biologic products to assure the American public that information provided presents a fair balance of risks and benefits and is not false or misleading.

A primary function of post-market drug surveillance involves a team of epidemiologists and safety evaluators who collect and analyze data regarding drug usage and side effects. CDER collects and stores this data in its Adverse Event Reporting System (AERS). AERS houses millions of adverse event reports. The number of adverse events submitted to CDER annually reached over 522,871 in FY 2008 and is projected to be over 600,000 by FY 2010. 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, remove a drug from the market.

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, healthcare professionals, and consumers. Throughout this process, FDA works closely with manufacturers to see where streamlining can improve efficiency without compromising drug quality. CDER monitors potentially fraudulent internet sites to identify targets for investigation and sampling of products. CDER consults with industry and coordinates FDA program activities to alleviate drug shortages in the U.S. market. CDER assists industry in voluntary product recalls and assists in the investigation, evaluation, and correction of the conditions and practices that led to the recalls.

The FDAAA recognized FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. In FY 2008 CDER enhanced its capacity to oversee post-market drug safety

through increased staffing and the implementation of new post-market safety authorities under FDAAA. CDER's hiring efforts in this area are not complete but to date, there has been a 27 percent staffing increase in the Office of Surveillance and Epidemiology.

CDER has also utilized new drug safety authorities under FDAAA. FDAAA provides FDA new authority to require drug sponsors to submit a Risk Evaluation and Mitigation Strategy (REMS) when a drug first comes on the market, or later if FDA becomes aware of new safety data about the drug. REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product and requires the sponsor to submit post-marketing studies, or clinical trials to address safety issues. In March 2008, CDER identified 25 drugs whose sponsors were required to submit safety plans by September 21, 2008. In addition, CDER have approved 13 REMS for new drugs.

In 2008 CDER took significant safety actions to manage a very diverse set of safety concerns and risks in products used to treat a wide range of diseases. For example, FDA issued a Public Health Advisory recommending that over-the-counter cough and cold products should not be used to treat infants and children less than 2 years of age because of serious and potentially life-threatening side effects.

Over the past few years, FDA has been leading an aggressive effort to improve the management of important drug safety issues. These activities, combined with additional resources provided both in appropriations and user fees, provide a foundation for CDER placing the necessary focus on post marketing drug surveillance. The 1992 PDUFA legislation began a period of unprecedented accountability for the new drug review program by calling for institutionalizing regulatory project management and prioritizing and tracking pre-market review activities. Drawing from lessons learned from prior regulatory modernization initiatives such as PDUFA, CDER is now able to turn its attention to transform the post-market drug safety program.

Post-market safety and surveillance - Field Activities

ORA's role to reduce injuries and deaths associated with marketed products has several components. The first component involves the review of adverse event and complaint files at manufacturers 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 component 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 particular, the Office of Criminal Investigations (OCI) is expanding its efforts to develop cases that address the marketing of counterfeit products. The increasing globalization of crime has created new challenges to law enforcement. In February 2007, FDA issued a press release warning consumers that a number of Americans who placed orders for specific drug products over the internet instead received haloperidol, a powerful anti-psychotic drug. Some consumers became ill and had to seek medical attention. In March - April 2008, a Greek and an Egyptian

national was arrested by OCI for illegally importing and distributing counterfeit, misbranded and unapproved medications into the United States. OCI determined that the Greek national was responsible for shipping the haloperidol tablets to United States consumers; and these two individuals supplied and distributed counterfeit, misbranded, and unapproved drugs for an international illegal pharmaceutical distribution ring.

In support of CDER's monitoring of the safety of drugs once they are on the market, ORA performed 534 domestic and foreign high-risk drug inspections in FY 2008.

Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Human Drugs Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$508,905,000	$297,715,000	$211,190,000	2,947
FY 2007 Actual	$543,565,000	$315,138,000	$228,427,000	2,915
FY 2008 Actual	$680,926,000	$353,909,000	$327,017,000	2,996
FY 2009 Omnibus	$777,437,000	$413,482,000	$363,955,000	3,490
FY 2010 Estimate	$908,013,000	$457,814,000	$450,199,000	3,759

Budget Request

The FY 2010 budget request for the Human Drugs Program is $908,013,000. It is an increase of $130,576,000 above the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009.

Human Drugs Increase

Base funding for human drug review and safety encompasses all of the Human Drug program for ensuring the safety and effectiveness of America's drug supply. Critical activities are focused in three areas: new drug safety and effectiveness, generic drug review, and postmarket safety and effectiveness activities.

With the payroll funding increase, the Human Drugs program will sustain its performance for FY 2010. For 2009, CDER will continue to review and act upon standard and priority applications within the PDUFA-required timelines. CDER expects to continue that performance in FY 2010. In FY 2009 and FY 2010, CDER expects to sustain its generic drug approval performance from FY 2008. In FY 2009 and FY 2010, CDER will balance its focus on drug safety before and after drugs are approved for marketing.

Cost of Living Pay Increase

The Human Drug Program's portion of FDA's requested pay increase is $6,697,000. Of this amount, CDER's portion of this increase is $4,435,000 and the Field portion of this increase is $2,262,000.

Prescription Drug User Fees

With the enactment of the FDAAA in September 2007, the collection of user fees for the regulatory review of prescription drug products was authorized for the fourth time. PDUFA IV enhances premarket review and gives FDA more resources to create a modern post-market drug safety system that follows products across their full life cycle. Changes in PDUFA IV include a change in the workload adjuster to better reflect the IND workload, an adjustment for rent activities, and the addition of fees for direct to consumer advertising. In addition PDUFA IV

changed the CPI fiscal year to the Federal fiscal year to correspond to FDA's budget process, and modified the inflation factor calculation to reflect a five-year average of FDA's salary and benefit costs.

PDUFA IV user fees help the Human Drugs Program speed review of applications for new drug products, speed the development of products by publishing industry guidance to improve the quality of applications and improve procedures and standards so that reviews are more rigorous, consistent, and predictable, make innovative, new medical treatments available to patients faster with greater assurance of safety, effectiveness, and quality, and conduct premarket inspections, including bioresearch monitoring inspections.

Generic Drugs Proposed User Fees +$32,549,000 and 68 FTEs

The proposed Generic Drugs User Fee program will modify the Food, Drug, and Cosmetic Act to permit the establishment of user fees for applications to market generic drugs (ANDAs), and to establish annual fees for approved generic products. The proposal will provide an initial investment in the generic drug review program by building an expanded capacity to protect the public health, promote public confidence in generic drugs thus sustaining the viability of the generic industry. The additional fees will enhance FDA's ability to conduct timely and complete reviews of generic drug applications with quality standards equivalent to the brand industry, and support the development of regulatory scientific standards for equivalence thus encouraging the further expansion of new generic drug alternatives in more complex dosage forms resulting in the lowering public and private spending on pharmaceuticals

Human Drugs Performance Measures Table

Long Term Objective: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

Measure	FY	Target	Result
223201: Percentage of Standard NDAs/BLAs within 10 months. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	88% (Target Not Met)
	2006	90%	95% (Target Exceeded)
	2005	90%	99% (Target Exceeded)
223202: Percentage of Priority NDAs/BLAs within 6 months. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	90% (Target Met)
	2006	90%	97% (Target Exceeded)
	2005	90%	88% (Target Not Met)
223101: Number of Written Requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. *(Output)*	*2010*	7/7	Nov 30, 2010
	2009	5/7	Nov 30, 2009
	2008	8/8	5/19 (Target Not Met)
	2007	7/7	30/13 (Target Met)
	2006	N/A	18/12 (Historical Actual)
	2005	N/A	12/14 (Historical Actual)
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year. *(Output)*	*2010*	1900	Nov 30, 2010
	2009	1900	Nov 30, 2009
	2008	1780	1934 (Target Exceeded)
	2007	N/A	1779 (Historical Actual)
	2006	N/A	1456 (Historical Actual)
	2005	N/A	1496 (Historical Actual)

Measure	FY	Target	Result
223206: Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. *(Output)*	*2010*	100%/5	Nov 30, 2010
	2009	100%/5	Nov 30, 2009
	2008	100%/5	100%/9 (Target Met)
	2007	100%/5	100%/9 (Target Met)
	2006	NA	100%/8 (Historical Actual)
	2005	NA	100%/17 (Historical Actual)
223207: Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007. *(Outcome)*	*2007*	514 Days	May 31, 2011
	2006	N/A	May 31, 2010
	2005	N/A	May 31, 2009
223208: Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007. *(Outcome)*	*2007*	16.4 months	May 31, 2010
	2006	N/A	May 31, 2009
	2005	N/A	17.8 months (Historical Actual)
223102: Number of medical countermeasures in which there has been coordination and facilitation in development. *(Output)*	*2010*	4	Nov 30, 2010
	2009	4	Nov 30, 2009
	2008	5	6 (Target Exceeded)
	2007	4	4 (Target Met)
	2006	N/A	6 (Historical Actual)
	2005	N/A	11 (Historical Actual)

Long Term Objective: Improve information systems for problem detection and public communication about product safety.

Measure	FY	Target	Result
222301: Improve the Safe Use of Drugs in Patients and Consumers. *(Output)*	*2010*	Act upon 55% of issues within timelines	Nov 30, 2010
	2009	Act upon 50% of issues within timelines	Nov 30, 2009

Measure	FY	Target	Result
	2008	Conduct pilot and act upon 50% of issues within timelines	Conducted pilot and acted upon 50% of issues within timelines (Target Met)
	2007	Implement safety issue tracking system	Implemented (Target Met)
	2006	N/A	Standardized communication processes (Target Met)
	2005	N/A	Reviewed and provided comments on 100% of RiskMAPs for NMEs or products FDA or sponsor initiated discussions (Target Met)
222201: Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. *(Efficiency)*	*2010*	$12 per report	Nov 30, 2010
	2009	$12 per report	Nov 30, 2009
	2008	$13 per report	$10.59 per report (Target Exceeded)
	2007	$15 per report	$13.64 per report (Target Exceeded)
	2006	N/A	$16.47 per report (Historical Actual)
	2005	N/A	$17.35 per report (Historical Actual)
222202: Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. *(Outcome)*	*2007*	12.5%	19.6% (Target Exceeded)
	2006	N/A	13.2% (Historical Actual)
	2005	N/A	9.4% (Historical Actual)

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers

Measure	FY	Target	Result
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	*2010*	700	December 31, 2010
	2009	600	December 31, 2009
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)
	2006	N/A	510 (Historical Actual)
	2005	N/A	600 (Historical Actual)

1. Percentage of Standard NDAs/BLAs and Priority NDAs/BLAs within 10 months. (223201 and 223202)

Context: This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes new drug and biologics licensing applications. Central to that focus is FDA's commitment to meeting PDUFA goals and requirements. The Food and Drug Administration Amendments Act of 2007 reauthorized collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. A key determinant in knowing if CDER is effective and efficient is to measure the time to "first action." The first action is the first regulatory action CDER takes (complete response, approvable, not approvable, or approval letter) at the end of the review of the original NDA/BLA submission (the first review cycle). The "first action time" refers to the time it takes to review and take an action on the original submission. This statistic is different from "total approval time" which is the time it takes from the original receipt of the application until it is approved, which may take more than one review cycle. "Total approval time" includes time spent reviewing an application in each of the review cycles plus the time taken by the sponsor to respond to the issues raised in the complete response or approvable/not approvable letter(s) and to re-submit the application for review. CDER's featured targets under this performance goal are to measure time to first action for "priority" submissions and "standard" submissions. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. In FY 2009, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: CDER will not have the final performance numbers for the FY 2008 submission cohort until November 2009. The latest information on CDER's performance toward the targets for this performance goal is from FY 2007. In FY 2007, CDER met the PDUFA review performance goals for reviewing priority NDAs and BLAs, including meeting the goal for reviewing priority NMEs and new BLAs, but did not meet the PDUFA review performance goals for reviewing standard NDAs and BLAs, including not meeting the goal for reviewing standard NMEs and new BLAs. CDER met its FY 2007 performance target for priority reviews. However, CDER narrowly missed its target of 90% review of standard applications. CDER's 88% performance on standard applications represents early indications of the impact of a shift in Center policy to put equal emphasis on post-market safety review decisions as on pre-market review decisions.

2. Number of Written Requests (WRs) issued for drugs that need to be studied in the pediatric population and number of drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity. (223101)

Context: The context of the Pediatric Program's performance goal in CDER covers the activities and requirements of the various laws passed to ensure safe and effective drug products are available for children, including the Best Pharmaceuticals for Children Act (BPCA), which provides incentives to manufacturers who conduct studies in children including a 6-month extension of marketing exclusivity for conducting pediatric studies requested by FDA, and the Pediatric Research Equity Act (PREA) which provides FDA the authority to require pediatrics

studies for certain new and already marketed drug and biological products. In FY 2009, the targets are five written requests and seven drugs reported to the pediatric advisory committee.

Performance: The target for FY 2008 performance was to issue at least 8 written requests to drug sponsors for drugs that need to be studied in the pediatric population and report to the pediatric advisory committee on adverse events for 8 drugs that receive pediatric exclusivity. CDER issued 5 Written Requests to sponsors for on-patent drugs, as required by the Best Pharmaceuticals for Children Act. CDER reported to 2 Pediatric Advisory Committee meetings on adverse events for 19 drugs that received pediatric exclusivity. CDER's 5 Written Requests (WRs) issued for drugs and 19 drugs reported to the pediatric advisory committee on adverse events for drugs that receive pediatric exclusivity represents early indications of the impact of a shift in Center policy.

3. The total number of actions taken on abbreviated new drug applications in a fiscal year. (223205)

Context: The Office of Generic Drugs (OGD) has experienced a dramatic increase in workload, with the number of generic drug applications almost doubling over the past 4 years at a time when staffing levels have increased less than 20%. Consequently, the previous measure (the percentage of new applications for which first action is taken within 180 days) no longer reflects FDA's current program management challenge to increase throughput and productivity to address the higher workload while maintaining standards of quality and safety. Therefore, FDA has determined that a more meaningful performance goal for the generic drug program is the number of total actions taken on abbreviated new drug applications. The total number of actions includes approvals, tentative approvals, not approvable, and approvable actions on applications.

Performance: In FY 2008, the Office of Generic Drugs exceeded its goal by more than 150 actions, while also exceeding the number of actions in FY 2007. In FY 2009, the target is 1900 actions, an increase of almost 7% over the FY 2008 target. This reflects the estimated increase in performance as new staff, hired in FY 2008, are trained and achieve full performance levels.

4. Percentage of Rx-to-OTC Switch applications within 10 months of receipt in which there was a complete review action and the number of OTC Drug Monographs on which there was significant progress. (223206)

Context: OTC drug products can be legally marketed in the United States under an approved new drug application (NDA) or pursuant to an OTC drug monograph. OTC drugs can be approved under an NDA through an Rx-to-OTC switch or by direct to OTC. OTC drug monographs are "recipes" for marketing OTC drug products without the need for FDA pre-clearance. The monographs list the allowed active ingredients, dosage or concentration, the required labeling, and packaging and testing requirements if applicable. The monographs save manufacturers costs and reduce barriers to competition, as they allow both large and small companies to enter the market place with OTC drug products that have to meet the same, uniform criteria. Final monographs (agency final rules) need to be completed for a number of large product categories (e.g., external analgesics, internal analgesics, antimicrobials, oral health care products, laxatives). FDA is working to review OTC monographs for 29 categories of drug

products to eliminate unsafe and ineffective products from the OTC market. The ability to reach these goals is contingent upon the addition of experienced staff in all facets of rulemaking development as well as improvement in the efficiency of the FDA document clearance process.

Performance: FDA exceeded its FY 2008 target by completing review and action on 100% of Rx-to-OTC switch and direct to OTC applications within 10 months of receipt. All Rx-to-OTC switch applications received in FY 2008 with action goal dates in FY 2008 were acted on within 10 months of receipt. There were 4 approval actions encompassing a total 7 switch products.

FDA made significant progress on the following 9 monographs: (1) Internal Analgesic, Antipyretic, and Antirheumatic Drug Products - Organ Specific Warnings, Final Rule (proposed rule published 12/06); (2) Pediatric Dosing for OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products - Amendment of the Final Rule (Advisory Committee meeting held 10/18/07 ; Part 15 Hearing held 10/2/08) ; (3) UVA Testing and Labeling for OTC Sunscreen Drug Products, Final Rule (proposed rule published 8/07); (4) OTC Topical Acne Drug Products Containing Benzoyl Peroxide, Final Rule; (5) Vaginal Contraceptive Drug Products – Proposed Amendment to the Proposed Rule ; (6) Laxative Professional Labeling, Proposed Rule; (7) Topical Antimicrobial Drug Products - Consumer Antiseptics; (8) Labeling for OTC Drug Product - Convenience Size Labeling Rule (proposed rule published 12/06); and (9) Cold Cough Allergy, Bronchodilator and Antiasthmatic Drug Products – Labeling for Bronchodilators to Treat Asthma (Ephedrine Single Ingredient) Final Rule.

5. Reduction in FDA approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications approved for CDER and CBER, using the 3-year submission cohort for FY 2005-2007. (223207)

Context: Reducing unnecessary delays in the approval time for safe and effective drugs that truly represent new therapies [i.e., new molecular entities (NMEs) and biologics] means earlier patient access for these medicines. Reducing unnecessary delays in drug approval also helps to both control the cost of new drug development, cited as a factor affecting the cost to consumers, and supports market competition among innovators. This is both good for the drug industry and good for consumers. New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition both from new drugs with therapeutic value – but not blockbuster potential, and new innovators that don't have access to the capital available to more established pharmaceutical companies. Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated, helping speed patient access to new drugs, and reducing the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty. The targeted reductions in this FDA outcome goal represent approximately 10.5 percent reductions in total FDA review times for priority and standard NMEs and BLAs. Using Tufts estimates of potential cost reductions by phase of drug development, a 10 percent reduction in regulatory review time yields a 1.6 percent reduction in total capital costs, now estimated at $802 million, translating to a savings of $12.8 million per NME approved.

Performance: The FDA approval time for the fastest 50 percent of standard NME and biologics licensing applications (BLAs) approved in CDER and CBER for the FY 2001-2003 cohort is 523

days as compared to 575 days for the baseline FY 1999-2001 submission cohort. This is a reduction of 52 days versus the FY 2005-2007 target of a reduction of 61 days. Performance for the FY 2004 submission cohort was 547 days.

6. Reduction in FDA time to approval or tentative approval for the fastest 70 percent of original generic drug applications approved or tentatively approved of those submitted using the 3-year submission cohort for FY 2005-2007. (223208)

Context: FDA achievement of this goal will create earlier access to lower cost drug alternatives for patients. The high cost of drugs limits patient access to treatment. The lower income and uninsured populations are particularly affected. Research has shown that 42 percent of the uninsured do not fill prescriptions because of financial reasons. The Center for Medicaid and Medicare Services has stated that the new Medicaid prescription drug coverage has come in under budget and points to the availability of more generic products as a factor in this outcome. Increasing the availability of generic drugs will make many important treatments more affordable to the poor and the elderly and significantly improve access to treatment. Optimal access and use of generic drugs will enable policy decision makers to contain costs in both the Medicare and Medicaid programs. This will only become more important as more of the top selling brand name drugs go off patent over the next few years.

Performance: The FDA approval time for the fastest 70 percent of original generic drug applications approved for the FY 2003-2005 cohort is 17.8 months as compared to 17.9 months for the baseline FY 1998-2000 submission cohort. This is an increase from the FY 2002-2004 cohort of 16.0 months. In the last several years, submissions of abbreviated new drug applications have increased exponentially.

7. Number of medical countermeasures in which there has been coordination and facilitation in development. (223102)

Context: In the Federal Government's response to a biological, chemical, or radiological/nuclear attack or to a natural disaster, drugs will be mobilized from the CDC's Strategic National Stockpile (SNS). However, not all drugs in the SNS are FDA-approved as countermeasures against threat agents or emerging infections. FDA has been taking an aggressive and proactive approach to identify and facilitate development of new therapeutic options as well as to obtain information on existing approved drugs that may be used for an unapproved indication. Identification of gaps in the therapeutic armamentarium and development of a plan to address these gaps will move the FDA closer to a goal of labeling medical countermeasures that reside in the SNS. For example, although ciprofloxacin and doxycycline are FDA approved for post-exposure prophylaxis of anthrax, these drugs are not recommended for use in children and pregnant women unless no other drug is available. Amoxicillin may be recommended as an alternative for these special populations, but it is not FDA approved and the optimal dose and dosing frequency are unknown. Hollow fiber studies with amoxicillin may provide data to develop appropriate dosing regimens. FDA is also active in department and agency efforts to prepare for other emergencies, such as natural disasters and pandemics. In FY 2009, the target remains at 4 countermeasures.

Performance: In FY 2008, CDER facilitated the development of and access to medical countermeasures for counterterrorism and emerging infections through these actions:

- FDA extended the expiry of **Tamiflu (oseltamivir)** capsules from 5 years to 7 years.
- FDA assisted the HHS/PHEMCE Radiological/Nuclear Integrated Program Team (R/N IPT) in preparing a White Paper for the Enterprise Executive Committee: "**Neupogen** in the Strategic National Stockpile to Address Neutropenia Associated with Acute Radiation Syndrome -- Issues Regarding Potential Use in an Emergency."
- FDA provided comments to the Department of Health and Human Services (HHS) regarding a plan for anticipated information needs to support submission of an NDA for approval of a "**home MedKit**" containing antiviral drugs as a mitigation strategy for a potential influenza pandemic.
- **Levaquin (levofloxacin)** tablets, injection, and oral solution were approved for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis* in pediatric patients. The drug previously was approved to treat adults after exposure to inhaled anthrax.
- To prepare the American population for an anthrax attack, FDA posted on its internet site revised home preparation instructions for **doxycycline** dosing for children and adults who are not able to swallow pills, at: http://www.fda.gov/cder/drug/infopage/penG_doxy/home_prep.htm.
- FDA awarded a contract for hollow fiber studies and mathematical modeling to determine the optimal dosing regimen for **amoxicillin** for anthrax post-exposure prophylaxis for pregnant women and children.

8. Improve the Safe Use of Drugs in Patients and Consumers. (222301)

Context: CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. The FDA Amendments Act of 2007 (FDAAA) recognizes FDA's critical role in assuring the safe and appropriate use of drugs after they are marketed. FDAAA gives FDA substantial new resources for medical product safety, as well as a variety of regulatory tools and authorities to ensure the safe and appropriate use of drugs. Congress, along with the recommendations made over the past two years by the Institute of Medicine, the Government Accountability Office (GAO), and a multitude of others, directed FDA to shift its regulatory paradigm to recognize that ensuring that marketed products are used as safely and effectively as possible is equally as important as getting new safe and effective drugs to market quickly and efficiently. With increased focus and resources on post-marketing, CDER is establishing procedures and tools for tracking, managing, and monitoring safety issues in much the same way CDER tracks pre-market issues according to PDUFA requirements. Activities in FY 2006 and FY 2007 to standardize communications policies and procedures and to develop a tracking system to capture information about known and emerging safety issues established a foundation upon which CDER can now begin to build the capacity and capability to more effectively manage safety issues in a timely fashion. In FY 2009 the target is to act on 50% of the issues within timelines.

Performance: In FY 2008, CDER met its target of acting upon at least 50 percent of the identified priority postmarket safety issues within an established timeframe. During the first year of this new process, CDER focused its efforts on increasing its staff resources for tracking, managing, and monitoring postmarket safety issues. CDER conducted a pilot for prioritizing postmarket safety issues, developing action plans and timelines for those issues, and monitoring and managing progress toward those plans.

9. Reduce the Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database. (222201)

Context: The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product to identify unexpected safety risks associated with the use of a human drug that could not have been predicted by clinical trials and biostatistical analysis. Reports of these unexpected safety problems, called adverse events, are captured in the Adverse Event Reporting System (AERS), a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. Information captured in AERS allows FDA scientists and statisticians to search for patterns that may indicate an emerging safety hazard, which is the first step in analyzing the potential causes and formulating an effective risk management response. FDA is working to make AERS more efficient by improving the data entry work processes and reengineering the system to increase the percentage of electronic submissions, to reduce the amount of manual re-keying, along with other efficiencies. These system improvements will allow the FDA to reduce the average cost and time associated with turning a submitted Adverse Event Report into a verified record in the database. This improvement in efficiency will allow scientists and statisticians to access safety information sooner, and will free up resources that can be redirected to risk analysis activities that directly improve our ability to recognize and respond to drug safety problems.

Performance: The average cost associated with turning a submitted Adverse Event Report into a verified record in the database has been decreasing since FY 2003 due to FDA efforts to streamline its business processes and improve the information systems that are used to process records. In FY 2003, the cost per report was $21.91/per report. In FY 2004, the cost per report was $19.30/per report. In FY 2005, the cost per report was $17.35/per report. In FY 2006, the cost per report was $16.47/per report. In FY 2007, the cost per report was $13.64/per report. In FY 2008, the actual cost per report was $10.59/per report. The proposed FY 2009 target of $12 per report is an increase over the FY 2008 value due to the expected addition of periodic reports that have not been previously entered in the past. The cost decrease for the FY 2008 actual of $10.59 per report as compared to the target value of $13 per report is due mainly to the high volume of electronic submissions, thereby offsetting the cost per report. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports. In the absence of electronic submissions, the program costs for manual data entry would be nearly double what they are today.

10. Reduce medication errors in hospitals through increased adoption of bar code medication administration technology. (222202)

Context: In November 1999, the Institute of Medicine released a report estimating that as many as 98,000 patients die from medical errors in hospitals alone. Many of these deaths, as well as additional non-fatal illnesses, are associated with errors involving FDA regulated medical products, especially medications. A significant percentage of drug related mortality and

morbidity results from errors that are preventable. In addition to their human cost, these errors impose significant economic costs on the U.S. health care system. The total cost of preventable adverse events has been estimated at $17 billion. Preventing some of the adverse drug events related to medication errors in U.S. hospitals will significantly reduce related morbidity, mortality and health care costs. Research to date has demonstrated the ability of bar code scanners at the point of care to intercept errors in dispensing and administration of medications and thereby prevent related adverse events. Consequently, this measure tracks the adoption rate of bar code medication administration technology in hospitals, with the expectation that increased adoption rates will be directly related to decreased medication error-related adverse events.

Performance: The results of the American Society of Health-System Pharmacists (ASHP) national survey of pharmacy practice in hospital settings: prescribing and transcribing-2007 were published in 2008. Over the last few years the adoption rate of bar code medication administration technology has grown each year, up to 19.6% overall in 2007.

11. Number of foreign and domestic high-risk human drug inspections. (224201)

Context: FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2010. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way. For FY 2010, the target has been increased to 700 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 high-risk foreign and domestic drug manufacturers.

CDER Program Activity Data (PAD)

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
New Drug Review				
Workload – Submissions/Filings/Requests				
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	104	135	110	110
Efficacy Supplements	176	132	185	185
Manufacturing Supplements	2031	1784	2220	2350
Active INDs (Drugs and Biologics—Commercial and Research)	14,820	15,745	15,270	15,500
Sponsor Requests: IND-Phase Formal Meetings	2502	2059	2575	2600
Sponsor Requests: Review of Special Study Protocols	456	347	485	500
Submissions of Promotional Materials	68,288	70,509	72,500	75,000
Outputs – Reviews/Approvals				
Reviews: Priority NDA/BLA	31	31	32	30
Reviews: Standard NDA/BLA	140	118	140	135
Approvals: Priority NDA/BLA	21	20	22	22
Approvals: Standard NDA/BLA	67	60	70	70
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	9.9	10.4	10.0	10.0
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	15.3	23.3	15.0	15.0
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	6.0	6.0	6.0	6.0
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10.0	16.1	10.0	10.0
Reviews: NDA Supplementals	3,147	3,167	3,250	3,250
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	1,730	1,880	1,780	1,780
Biologic Therapeutics Review				
Workload – Submissions/Filings/Requests				
Receipts: Commercial IND/IDE (Biologics Only)	98	100	99	100
Receipts: IND/IDE Amendments (Biologics Only)	8,325	13,727	14,023	14,023
Outputs – Reviews/Approvals				
Reviews: Total Original License Application (PLA/ELA/BLA)	5	7	7	7
Approvals: PLA/BLA	1	5	2	2
Reviews: License Supplement (PLA/ELA/BLA)	232	240	250	250
Generic Drug Review				
Workload – Submissions/Filings/Requests				

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Receipts: Abbreviated New Drug Applications (ANDA)	882	830	850	800
Outputs – Reviews/Approvals				
Actions – ANDA	1779	1934	1900	1900
Approval Actions - ANDA (both Tentative and Full Approvals)	682	598	650	700
Median Review Time from ANDA Receipt to Approval (months)	18.89	21.65	17.5	17.5
Actions - ANDA Supplementals (Labeling and Manufacturing)	3720	5562	3000	3000
Over-the-Counter Drug Review				
OTC Monographs Under Development*	15	12	12	12
OTC Monographs Published*	5	3	5	5
*Category includes Proposed Rules and Final Rules				
Best Pharmaceuticals for Children Act				
Labels Approved with New Pediatric Information	17	16	22	20
New Written Requests Issued	30	5	5	5
Pediatric Exclusivity Determinations made	14	18	22	20
Post Exclusivity Safety Report	13 drugs (2 A/Cs)	19 drugs (2 A/Cs)	12	12
Patient Safety				
Workload – Submissions/Filings/Requests				
Submissions: Adverse Event Reports	486,882	522,871	600,000	650,000
Electronic Submissions: % of Total Adverse Drug Reaction Reports	43%	58%	60%	65%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	70%	77%	85%	85%
Submissions: Drug Quality Reports	3371	5390	5900	6400
Outputs – Reviews/Approvals				
Safety reviews completed by Office of Surveillance & Epidemiology	1863	1,900	2,000	2,000
Number of drugs with Risk Communications	63	104	60-80	70-90
Administrative/Management Support				
Workload				
Number of Advisory Committee Meetings	25	28	35	35
Number of FOI Requests	2,984	2431	3,200	3,200
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	83	75	100	100
Number of Citizen Petitions Pending	217	237	277	317

CDER Workload and Outputs	FY 2007 Actual	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)				
Outputs				
Number of FOI Requests Processed	3676	3588	3,900	3,900
Number of Citizen Petitions Completed [1] (excluding suitability petitions and OTC monograph-related petitions)	48	55	60	60

[1] Citizen Petitions completed may include petitions filed in prior years.

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,774***	***1,960***	***1,960***
Pre-Approval Inspections (NDA)	138	120	120
Pre-Approval Inspections (ANDA)	95	51	51
Bioresearch Monitoring Program Inspections	526	490	490
Drug Processing (GMP) Program Inspections	972	1,085	1,085
Compressed Medical Gas Manufacturers Inspections	46	159	159
Adverse Drug Events Project Inspections	88	144	144
OTC Monograph Project and Health Fraud Project Inspections	33	48	48
Domestic Laboratory Samples Analyzed	1,769	951	951
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***452***	***566***	***566***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	174	192	192
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	117	69	69
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	129	210	210
Foreign Drug Processing (GMP) Program Inspections	268	382	382
Foreign Adverse Drug Events Project Inspections	6	16	16
IMPORTS			
Import Field Exams/Tests	2,863	2,870	6,197
Import Laboratory Samples Analyzed	346	586	586
Import Physical Exam Subtotal	**3,209**	**3,456**	**6,783**
Import Line Decisions	321,205	330,267	339,584
Percent of Import Lines Physically Examined	1.00%	1.05%	2.00%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***166***	***166***	***166***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	135	110	110
State Partnership Inspections: GMP Inspections	25	50	50
TOTAL HUMAN DRUG INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,392***	***2,692***	***2,692***

Estimates for FY10 Generic Drugs User Fee Inspections not reflected in the table.
Estimated timeframe for these inspections is FY 2012 and FY 2013.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT[1]

FDA's Office of Orphan Products Development summarizes the budget program requirements that justify a $20,396,034 submission for FY 2010.

The following table shows a three-year funding history for the Office of the Orphan Products Development

	FY 2008 Actual[5]	FY 2009 Omnibus	FY 2010 Estimate
Program Level	**$16,655,394**	**$18,805,394**	**$20,396,034**
Orphan Product Grants [1]	$14,035,161	$14,035,161	$14,315,864
Pediatric Consortia Grants[2]		$2,000,000	$2,000,000
Medical Product Safety and Research[3]			$1,200,000
Program Administration [4]	$2,620,233	$2,770,233	$2,880,170

[1]The Orphan Product Grants piece is part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.
[2]The Pediatric Device Consortia Grants piece is part of the aggregate amount of budget authority contained in the CDRH budget line item of the All Purpose Tables.
[3]Request for new funds to implement the Food and Drug Administration Amendments Act of 2007 (FDAAA).
[4]The Program Administration piece is part of the aggregate amount of budget authority contained in the Other Activities budget line item of the All Purpose Tables. FY 2009 and FY 2010 amounts include a $150,000 increase to support the Pediatric Consortia Grants.
[5]Includes 0.7 percent Rescission.

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

Since its inception in 1982, the Office of Orphan Products Development (OOPD), located in the Office of the Commissioner, has 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. OOPD administers the major provisions of the Orphan Drug Act (ODA) which provide incentives for sponsors to develop products for rare diseases. The ODA has been very successful – as of April 21, 2009 , 339 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 provisions under the Food Drug and Cosmetic Act – more that 48 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.

OOPD activities support FDA's strategic goals by improving the efficiency of translation of new 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 four functional mission activities: orphan product grants which provide funding for clinical research in rare diseases, orphan drug designations, humanitarian use device designations, and outreach activities.

Orphan Product Grants Activity

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 60 to 85 ongoing grant-funded projects. A major portion of the appropriated funds for a given fiscal year go towards continued funding of prior approved grants.

OOPD engages in several grant program activities. OOPD staff review solicited grant applications to ensure program requirements are met, and coordinate and convene peer review

panels to provide technical review of grant proposals to ensure that the best scientific proposals are funded. OOPD selects grant applications for funding, and conducts site visits to grantees to ensure extramural funded studies, which involve human subjects, are consistent with grant agreement terms and minimize FDA's exposure to risk of violations in human subjects protection requirements. OOPD monitors the grant-funded products to satisfy regulatory and program requirements. OOPD is modernizing the transmission of applications and other review information through full electronic submissions, and improving the OOPD database system to allow for more efficient and effective retrieval of information and other internal management practices.

There have been 43 products approved by FDA for marketing which received development support from the orphan grants program. Most are listed at http://www.fda.gov/orphan/grants/magrants.htm. Highlights of these include treatments for Fabry Disease (approved in 2003), for Mucopolysaccharidosis Type II, also known as Hunter Syndrome (approved 2006), for Cystic Fibrosis patients with Pseudomonas Aurginosa (approved 1997), for infant botulism (approved 2003), a titanium expandable rib prosthesis for Thoracic insufficiency syndrome (approved 2004), and Diaphragm Electrical Stimulator for ventilator dependent tetraplegic patients (approved 2008).

In FY 2008, OOPD funded 21 new grants and provide funding for approximately 40 other ongoing grant-funded clinical study projects totaling $14,035,161. Among the recent new applications recommended for funding are studies for the treatment of neonatal hyperinsulism and for the treatment of cholestasis, a blockage of the bile duct. A recent example of the success of the orphan grants program was the approval of the first product for the treatment of Hunter syndrome, a rare inborn disease of metabolism characterized by deficiency of the enzyme iduronate-2-sulfatase. Symptoms of Hunter syndrome, which usually become apparent at the age of one to three years, include growth delay, joint stiffness and coarsening of facial features. More advanced features include respiratory and cardiac problems, enlargement of liver and spleen, and neurologic deficits. The condition is diagnosed in approximately one out of 65,000 to 132,000 births. Another example of a successful orphan product is Elaprase, a new molecular entity that received Orphan designation on November 28, 2001. An Orphan grant to study Elaprase in the treatment of this disease was awarded in 2004. Elaprase was approved for marketing by FDA in 2006 after a randomized, double-blind, placebo-controlled study of 96 patients with Hunter syndrome showed that the treated participants had an improved capacity for walking. A more recent example of the success of the orphan grants program was the approval of the NeuRx DPS RA/4 Respiratory Stimulation System in 2008. An Orphan grant to study this device for the treatment of ventilator dependent tetraplegic patients was awarded in 2000. More information is provided in the Humanitarian Use Device (HUD) Designation Activity section below.

Orphan Drug Designation Activity

There are an estimated 6,000 rare diseases, affecting more than 25 million people in the U.S., between 85 and 90 percent of which are serious or life-threatening. In enacting the ODA in 1983, Congress sought to provide incentives to promote the development of drugs (including antibiotics and biological products) for the treatment of rare diseases. OOPD evaluates applications for orphan drug designations from sponsors who are developing medical products to

treat rare diseases or disorders that affect fewer than 200,000 persons in the U.S. 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.

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

Of the 1,994 orphan designations issued by OOPD as of April 21, 2009 , 339 have resulted in marketing approval with orphan exclusivity. During FY 2008, OOPD reviewed 192 applications for orphan designation. These include potential treatments for many kinds of cancers, multiple myeloma, sickle cell disease, and pediatric multiple sclerosis. OOPD designated 164 orphan drugs in FY 2008. FDA has approved 13 prior orphan designated drugs for marketing in FY 2008. One example is the approval of Xenazine (tetrabenazine) for the treatment of chorea associated with Huntingtons's Disease (HD), a devastating neurodegenerative disease that causes progressive movement disorders, cognitive dysfunction and behavioral changes and is ultimately a fatal condition. Chorea is the most common symptom, affecting approximately 90% of HD patients, and is characterized by excessive, involuntary and repetitive movements, which are the most visible and dangerous manifestations of HD and interfere with patients' abilities to perform activities of daily living, including dressing, bathing and caring for themselves. Until this year, patients had no FDA-approved treatments for Huntington's disease. It is estimated that 30,000 Americans are affected by Huntington's disease. This drug was first granted orphan drug designation by the FDA in December 1997. It received marketing approval August 15, 2008.

The number of requests for orphan designation has nearly doubled in the last nine years on average. 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 pharmacogenomics and individualized medicine that challenge our reviewers.

Humanitarian Use Device Designation Activity

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).

OOPD conducts activities leading to HUD designation, 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.

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 somewhat like a pre-market approval (PMA) application, but exempt from the effectiveness requirements of sections 514 and 515 of the Safe Medical Devices Act of 1990. In FY 2008, OOPD received 13 HUD applications and designated 9 of these.

A recently approved (June 2008) HDE includes a stimulator device for severe spinal cord injury patients to free the patients temporarily from their ventilator. Christopher Reeve had received the still experimental device in 2003, allowing him to breathe off a ventilator for up to eight hours at a time prior to his death caused by an unrelated bloodstream infection. Spinal cord injuries can affect the muscles of the chest and abdomen, including the diaphragm, which is a lower abdominal muscle essential for breathing. Normally, a person inhales when the diaphragm contracts and the lungs expand with air, and a person exhales when the diaphragm relaxes and the air flows back out of the lungs. The HDE approved implantable device called the NeuRx DPS RA/4 Respiratory Stimulation System electrically stimulates the muscles and nerves that run through the diaphragm. It allows some spinal cord injury patients to breathe for at least four hours a day without a mechanical ventilator. The stimulation device uses four electrodes implanted in the muscle of the diaphragm to stimulate contraction. The device does not cure paralysis of the diaphragm, but does free a patient from a ventilator to enhance their quality of life. There are about 500 ventilator-dependent spinal cord injuries in the U.S., per year.

Pediatric Consortia Grants Activity

The development of pediatric medical devices currently lags five to ten years behind those for adults. 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 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.

The FDA definition of “pediatric” for purposes of device development encompasses devices used from birth to 21 years of age. The FDA’s Center for Devices and Radiologic Health defines “pediatric use” as any use of a medical device in a pediatric population in which there is a

primary pediatric indication or a more general indication where considerable pediatric application is anticipated.

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 will facilitate the development, production, and distribution of pediatric medical devices by:

1. encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers.
2. mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing.
3. connecting innovators and physicians to existing Federal and non-Federal resources.
4. assessing the scientific and medical merit of proposed pediatric device projects.
5. providing assistance and advice as needed on business development, personnel training, prototype development, and post-marketing needs.

In 2009, an estimated 3 grants will be awarded on a competitive basis up to $2 million in total (direct plus indirect) costs per year for up to 2 years. It is anticipated that funding for the number of non-competing continuation awards in FY 2010 will be similar to FY 2009.

Medical Product Safety and Research Activity

This is a proposed new activity for FY 2010 in support of the medical product safety and research initiatives in the Food and Drug Administration Amendments Act of 2007 (FDAAA). With the $1.2 million request for FY 2010, the OOPD plans to support its ongoing activities in the following ways:

1. Encourage additional applications for orphan product grants for research on promising products beneficial to the pediatric community, especially promising pediatric medical device products.
2. Fund additional orphan product grants for research on promising products beneficial to the pediatric community, and
3. Provide additional guidance and training on safety practices and considerations to principal investigators who conduct OOPD-funded research on promising orphan products involving human subjects.

Outreach Activity

OOPD continues its 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 pharmacogenomics 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.

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.

OOPD participated in various outreach activities during FY 2008. Some of these activities include participation in international governmental conferences, patient support meetings, and meetings addressing rare medical conditions. In FY 2008**,** OOPD received more than 40 invitations/requests to speak at orphan-drug stakeholders' meetings. OOPD made presentations at over 20 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. Other OOPD accomplishments include:

1. meeting with the Chief Executive Officers of the member companies of PhRMA (the Pharmaceutical Research and Manufacturers of America) to discuss and encourage these companies to commit more effort and resources toward developing products for rare diseases
2. locating a new source of the drug uridine for a 13 year old girl when the current source stopped. This is a life-saving drug to treat Uridine Monophosphate Synthetase Deficiency, a genetic enzyme deficiency that currently affects only 20 surviving patients worldwide
3. partnering with the National Organization for Rare Disorders (NORD), a consortium of rare disease patient organizations, and the NIH, to sponsor an educational conference about rare diseases, which included international groups. This conference coincided with the 25th anniversary of the Orphan Drug Act
4. participating in a conference sponsored by Genetic Alliance, an organization devoted to promoting optimum health care for people suffering from genetic disorders, about the Federal programs and resources available for product developers and patient groups
5. meeting with representatives of the World Health Organization to discuss assistance WHO could provide in facilitating the development of potential products for neglected diseases, typically tropical diseases that are rare in the United States
6. completing the development of a common application format for the approval of orphan products to be used by both the FDA and the European Medicines Agency, FDA’s

European counterpart. This agreement was a significant accomplishment that will make it easier for drug sponsors to get their orphan products designated

7. planning a training course on the topic of small clinical trials to be held in FY 2009. The course will consist of experts and will be for FDA and NIH employees who will benefit from a rigorous look at how to apply the newest methodologies for clinical trials to small patient populations
8. meeting with stakeholders in an interagency effort to increase the availability of pediatric medical devices for children with rare diseases or conditions through both the HUD program and the Orphan Grant program.

The following table shows a five-year funding history for the Office of Orphan Product Development's program level resources.

Five Year Funding Table

The following table shows a five-year funding history for the Office of Orphan Products program level, budget authority, and user fee resources.

Fiscal Year	Program Level
FY2006 Actual	$16,644,270
FY 2007 Actual	$17,167,256
FY 2008 Actual	$16,655,394
FY 2009 Omnibus	$18,805,394
FY 2010 Estimate	$20,396,034

Budget Request

The FY 2010 President's Budget request for the Office of Orphan Products Development is $20,396,034. The request represents an increase of $1,590,640 (or almost nine percent) above the FY 2009 Omnibus level. This change represents $390,640 for pay increases and $1,200,000 for non-pay increases.

Office of Orphan Product Development
Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2008 Actual	FY 2009* Estimate	FY 2010* Estimate
GRANTS PROGRAMS			
New Orphan Product Grants Awarded	21	23	23
New Pediatric Consortia Grants		3	3
ORPHAN DRUG REQUESTS, DESIGNATIONS, AND MARKET APPROVALS			
Designation Requests	192	220	235
Designations	171	180	190
Market Approvals	13	18	20
HUD REQUESTS AND DESIGNATIONS			
Designation Requests	13	20	22
Designations	9	10	11

*preliminary estimates based on recent year

BIOLOGICS

The FY 2010 program level budget submission for the FDA Biologics Program is $305,731,000.

The following table shows a three-year funding history for the Biologics Program.

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	**$248,627,000**	**$233,508,000**	**$271,490,000**	**$305,731,000**	**$34,241,000**
Center	$212,390,000	$202,278,000	$232,308,000	$260,997,000	$28,689,000
FTE	888	858	916	959	43
Field	$36,237,000	$31,230,000	$39,182,000	$44,734,000	$5,552,000
FTE	228	209	230	238	8
Program Level FTE	**1,116**	**1,066**	**1,146**	**1,197**	**51**
Budget Authority	**$167,965,000**	**$154,831,000**	**$183,451,000**	**$206,438,000**	**$22,987,000**
Center	$135,457,000	$125,383,000	$148,134,000	$166,182,000	$18,048,000
Field	$32,508,000	$29,448,000	$35,317,000	$40,256,000	$4,939,000
Pay Increase (non add)				*$2,803,000*	*$2,803,000*
Safer Medical Products (non-add)				*$20,184,000*	*$20,184,000*
Budget Authority FTE	**795**	**725**	**810**	**836**	**26**
Center	579	526	592	615	23
Field	216	199	218	221	3
User Fees	**$80,662,000**	**$78,677,000**	**$88,039,000**	**$99,293,000**	**$11,254,000**
Center PDUFA	$66,824,000	$70,890,000	$73,206,000	$83,747,000	$10,541,000
FTE	278	304	293	313	20
Field PDUFA	$3,262,000	$1,524,000	$3,358,000	$3,489,000	$131,000
FTE	10	8	10	10	0
Center MDUFMA	$10,109,000	$6,005,000	$10,968,000	$11,068,000	$100,000
FTE	31	28	31	31	0
Field MDUFMA	$467,000	$258,000	$507,000	$507,000	$0
FTE	2	2	2	4	2
Proposed User Fees	**$0**	**$0**	**$0**	**$482,000**	**$482,000**
Field Reinspection (non-add)				$482,000	$482,000
FTE				3	3
User Fees FTE	**321**	**342**	**336**	**361**	**25**

The FDA 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*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA Biologics Program is responsible for ensuring the safety, purity, potency, and effectiveness of biological products, including vaccines and allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries. The Biologics Program also helps to defend the public against the threats of emerging infectious diseases and bioterrorism through preparedness planning, development and licensing of medical countermeasures (that are used to diagnose, treat, or prevent disease from pathogen exposure), and ensuring the availability of safe and effective medical countermeasures.

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 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, the Center for Biologics Evaluation and Research (CBER) became its own center within FDA. The program operates with both budget authority appropriations and user fees to support prescription drug and medical device review.

CBER is committed to advancing the public health through innovative regulation that ensures the safety, effectiveness, and timely delivery of biological products to patients. CBER is responsible for ensuring 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 tissue for transplantation, and an adequate and safe supply of allergenic materials and anti-toxins.

The Office of Regulatory Affairs (ORA) provides FDA leadership on enforcement, import, inspection, and laboratory policies. Through its field offices nationwide, ORA supports the Biologics Program by conducting premarket activities such as bioresearch monitoring of clinical research, preapproval inspections and laboratory method validations needed for application decisions, and inspecting manufacturing facilities to ensure their ability to manufacture the product to the specifications stated in the application. ORA also conducts risk-based domestic and foreign postmarket inspections of medical products to assess their compliance with Good Manufacturing Practice requirements. In addition to overseeing regulated products on a surveillance or for cause basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods. In

* 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. or 42 U.S.C. (Public Health Service Act and Public Health Security and Bioterrorism Preparedness Response Act of 2002).

instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. ORA's Field Biologics Program is funded by appropriated budget authority and user fee dollars that allow the Field to perform inspections.

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Biologics Program by maintaining its legacy systems and databases used for managing and tracking its premarket review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Biologics Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee and Modernization Act (MDUFMA) enable the Biologics Program to ensure the timeliness and predictability of FDA review of new products for sponsors and consumers. Under these user fee programs, FDA agreed to pursue a comprehensive set of application review performance goals. During FY 2007, the latest completed performance period, the Biologics Program met or exceeded all of its user fee performance commitments.

The Biologics Program has also continued to meet all of the targets in FY 2007 for all of the non-user fee Government Performance and Results Act (GPRA) goals. Thus far, CBER has successfully achieved the FY 2008 targets for which completed performance data is available and expects to continue to meet the performance targets when data becomes available in FY 2009. In FY 2008 CBER also achieved the 2003 Program Improvement Plan long-term outcome goal to reduce the approval time for the fastest 50 percent of standard New Molecular Entities/Biologics Licensing Applications for the FY 2005- 2007 cohort.

The Biologics Program executes its regulatory responsibilities in three major program areas: Blood and Blood Products, Vaccines and Allergenics, and Cell, Tissues and Gene Therapies. The activities conducted in these program areas are as follows:

<u>Blood and Blood Products – Center Activities</u>
CBER is responsible for ensuring the safety of the nation's blood supply by minimizing the risk of infectious disease transmission and other hazards while facilitating the maintenance of an adequate supply of blood and blood products. The scope of the blood program is far reaching, with over 14.4 million human whole blood and red blood cell components and over 15 million transfusions of other blood components transfused annually, according to *The 2007 National Blood Collection and Utilization Survey*. The responsibility to keep the blood supply safe is especially important in the face of an emerging infectious disease, pandemic or terrorist event. CBER regulates blood and blood components used for transfusion and for manufacture into products such as plasma derivatives and their resulting blood products, including clotting factors,

concentrates, immune globulins, albumin and protease inhibitors. CBER also establishes product standards and performs lot-release testing for products. CBER works closely with many partners, including the Department of Health and Human Services' (DHHS) Office of the Secretary, the Centers for Disease Control and Prevention (CDC), and industry to ensure the safety and availability of blood products.

CBER also regulates related products, including blood establishment computer software, cell separators, and blood collection containers, as well as tests to screen blood donors for human immunodeficiency virus-type 1 (HIV1) and other viruses, including hepatitis B and C viruses (HBV and HCV), West Nile virus (WNV), human T-lymphotropic virus types I and II, and for syphilis. The testing of donors for infectious agents is a critical safeguard for blood safety. To further enhance blood safety, CBER facilitates the development and implementation of sensitive tests to detect infectious agents in blood. CBER also continues the development of donor screening questionnaires to reduce risk by identifying and deferring high risk donors. In the postmarket arena, CBER develops and enforces quality standards, and monitors, analyzes, and acts on reports of errors, accidents and adverse clinical events.

In FY 2007, CBER exceeded all of its performance goals by completing review and action on at least 99 percent of all complete blood bank and source plasma Biologic License Application (BLA) submissions, and BLA supplements within 12 months. Some FY 2009 highlights include the approval of two orphan drugs for patients with potentially fatal, rare conditions to help prevent bleeding and the formation of blood clots, and the approval of the first nucleic acid test that screens for the presence of two divergent types of HIV in donated blood plasma and tissue.

Blood and Blood Products – Field Activities

Under the provisions of both the Public Health Service Act and the Federal Food Drug and Cosmetic Act, ORA field investigators conduct inspections of blood establishments that manufacture or participate in the manufacture of blood and blood components for human use. The Field conducts inspections to ensure that blood establishments manufacture biological products that are safe and are in accordance with current good manufacturing practices. FDA implemented the inspection of blood establishments in 1972.

The inspection of a blood establishment is based on a multi-layered set of safeguards related to blood and blood component collection, manufacturing, and distribution. Inspections verify that firms institute proper procedures to screen donors, test blood for required infectious diseases, and follow-up on blood donor and recipient adverse reactions.

Blood and blood products are vitally important products in medical treatment. ORA Field efforts focus on two main areas: performing inspections of blood establishments engaged in the collection, manufacturing, preparation or processing of human blood or blood products and inspecting laboratories that perform testing on blood products and donors to confirm donor screening for communicable disease agents. In FY 2008, ORA conducted 1,014 inspections of highest priority registered domestic blood banks, source plasma operations, and biologics manufacturing establishments, exceeding the FY 2008 GPRA performance target of 870 establishments.

Vaccines and Allergenics – Center Activities

CBER regulates vaccine and allergenic products. Many vaccine products are pediatric vaccines that have contributed to the dramatic reduction or elimination of life-threatening childhood diseases in the U.S., such as diphtheria, measles, and polio. Newer vaccines play an increasing role in protecting and improving the lives of adolescents and adults and include vaccines to prevent meningococcal disease, shingles, and cervical cancer. In addition, there are vaccines under development that offer the promise of preventing serious infectious diseases, such as pandemic influenza viruses and severe acute respiratory syndrome (SARS), HIV-1, and malaria. As with all medical products, highly-trained scientists and clinicians rigorously review laboratory and clinical data in assessing the safety, effectiveness, and quality of vaccines.

CBER reviews additional studies after some vaccines are approved to further evaluate their safety and effectiveness (for example, in broader population groups). Both before and after a vaccine is licensed, FDA inspects vaccine manufacturing facilities to help ensure continued high quality and safe production. Due to the complexity of the manufacturing process, CBER activities also include lot-release testing to ensure vaccines are potent, safe, and sterile before the manufacturer distributes the product in interstate commerce.

CBER regulates allergenic products: patch tests and extracts. Allergen patch tests are diagnostic tests applied to the surface of the skin that are used by physicians to determine the specific causes of contact dermatitis. Allergenic extracts are used for the diagnosis and treatment of allergic diseases such as allergic rhinitis ("hay fever"), allergic sinusitis, allergic conjunctivitis, bee venom allergy and food allergy. CBER maintains reference standards for allergenics, used by physicians to detect allergies in patients. CBER distributes the reference standards to manufacturers and evaluates novel technological approaches to improve allergenic product development, standardization, and characterization of these complex biological products.

In the postmarket area, the CDC and FDA jointly manage the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety. VAERS is a postmarketing safety surveillance program that collects information about adverse events (also known as side effects) potentially related to vaccination and reported after the administration of U.S. licensed vaccines. In collaboration with CDC, state health departments, and other partners, CBER uses VAERS to monitor vaccine adverse event reports for possible indicators of vaccine safety concerns.

CBER plays a leadership role to prepare for and respond to the risks of a pandemic influenza outbreak. Working with industry, agencies in DHHS, and global partners, CBER facilitates the development and availability of pandemic influenza vaccines in the shortest time possible to protect the largest number of people using a vaccine that is safe, effective, and easy to deliver.

CBER accomplished its annual performance targets under its performance goal for increasing manufacturing diversity and capacity for pandemic influenza vaccine production in FY 2008. These targets included ensuring all six influenza vaccine producers were licensed before the start of the influenza season, creating an influenza A reference strain for manufactures to make an effective vaccine, and engaging in pre-BLA discussions with a manufacturer on a pandemic vaccine, and holding workshops with the World Health Organization (WHO) to develop and post guidelines for regulatory preparedness regarding pandemic influenza vaccines on the web. Additionally, CBER approved the first vaccine available in the United States to protect against

Japanese encephalitis virus which is transmitted to people by mosquitoes, and is evaluating vaccine postmarket safety information from a large managed care organization.

Vaccines and Allergenics – Field Activities

ORA provides significant inspection oversight, technical assistance, and outreach to manufacturers to help assure the adequate preparation and rapid availability of safe and effective vaccines. ORA's activities include annual inspections of influenza virus vaccine manufacturing facilities and appropriate compliance follow-up with manufacturers when inspections reveal issues that could compromise a safe, plentiful supply of influenza vaccine, and bioresearch monitoring inspections in support of FDA's review of new applications submitted by flu vaccine manufacturers. ORA also provides technical support to CBER, HHS agencies and flu vaccine manufacturers during product development.

Cell, Tissue and Gene Therapy – Center Activities

CBER is responsible for regulating many different types of human tissue and cells that are transplanted during various types of medical procedures, including skin replacement following severe burns, tendons and ligaments used to repair injuries, bone replacement, and corneas used to restore eyesight. Tissue transplantation is a rapidly growing industry. The number of musculoskeletal tissue transplants increased from approximately 350,000 in 1990, to more than 1.5 million transplants annually.

Transplantation of human tissues presents unique safety challenges in light of the risks of transmitting infectious diseases from donor to recipient and the contamination of tissues during processing. Since 1993, CBER has required tissue establishments to screen and test donors, and since 1997 required tissue establishments to prepare, validate, and follow written procedures to prevent contamination and cross-contamination during processing. In response to the increased use, role, and complexity of tissue transplants, CBER developed a comprehensive regulatory framework, which went into effect in May 2005, for the regulation of human cells, tissues, and cellular- and tissue-based products. The new framework promotes the use of the most up-to-date tools and methods to reduce risks of infectious disease transmission and contamination.

CBER also regulates cellular and gene therapy products. Somatic cells, vectors expressing certain gene products, and genetically manipulated cells offer the promise of harnessing the power of different cell types to fight disease, restore normal function, repair injuries, replace lost cells, or regenerate failing organs. CBER is aware of both the promise of gene therapy and its potential to cause serious adverse events, and works closely with NIH, academia, and industry on these products. For example, CBER and NIH have collaboratively developed a Web-accessible database on human gene transfer to enable faster reporting of adverse events in human gene transfer trials.

CBER has provided proactive scientific and regulatory advice through meetings, guidance and regulations to biologic manufacturers in areas of novel product development. Focusing on how best to evaluate essential issues of safety and efficacy while facilitating product development, CBER is also committed to protecting human-study subjects. CBER's involvement in broad public interactions helps CBER and product developers address important issues involving the development of novel gene and cellular therapy products.

Some FY 2009 accomplishments include issuing recommendations for developing tests to measure potency of therapies, participation in many outreach activities such as workshops, and the issuance of draft guidance on Current Good Tissue Practices for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) manufacturing establishments to help prevent the introduction, transmission, or spread of communicable disease during the manufacturing process.

Cell, Tissue and Gene Therapy – Field Activities

FDA's risk-based approach to assure the safety of HCT/Ps is being implemented to prevent infectious disease transmission and contamination and to increase the quality and consistency of products. ORA's efforts are concentrated in two main areas. The first area includes ensuring that tissues are recovered, processed, stored and distributed in a manner that reduces the risks of serious infectious diseases and contamination with infectious agents. The second area includes performing inspections to monitor the recovery and processing of HCT/Ps and the testing and screening of donors, and assuring that HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing. During FY 2008, ORA inspected 383 highest priority human tissue establishments, exceeding the FY 2008 performance target of 325 establishments.

Five-Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Biologics Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$197,709,000	$138,518,000	$59,191,000	979
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 Omnibus	$271,490,000	$183,451,000	$88,039,000	1,146
FY 2010 Estimate	$305,731,000	$206,438,000	$99,293,000	1,197

Budget Overview and Supported Activities

The FY 2010 President's Budget requests $305,731,000 in program level funding for the Biologics program, including the support of 1,197 FTE. The Field portion of this request is $44,734,000, supporting 238 FTE.

The request represents an increase of $34,241,000 (or 12.6 percent) over the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009 in budget authority and user fee amounts. The overall increase provides additional resources for pay increases, strengthening the information technology systems, increasing safety of blood and tissues, maintaining user fee goals and strengthening the science behind CBER's regulatory decisions.

The budget authority for the FY 2010 President's Budget is $206,438,000, an increase of $22,987,000 over the FY 2009 FDA appropriation in the Omnibus Appropriations Act, 2009. The CBER portion of the submission is $166,182,000 and the Field amount is $40,256,000.

The user fee collection authority includes a total of $99,293,000 for the Biologics Program, an increase of $11,254,000 over the FY 2009 FDA appropriation in the Omnibus Appropriations Act. The Biologics program collects user fees for human drug review (PDUFA) and medical device review (MDUFMA). The CBER portion of the current law user fees is $94,815,000 and the Field amount is $3,996,000. The proposed user fee for the Field to conduct additional reinspections and export certification is $482,000 in new fees.

Safer Biologics Initiative

The FY 2010 budget requests an increase over the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009 of $22,987,000 for the safer biologics initiative. Of this amount, $2,803,000 is for the pay raise and $20,184,000 is the Biologics portion of the initiative that will fund enhancements to the biologics safety programs, including information technology. The CBER portion of the pay raise is $2,041,000 and the Field portion of the pay raise is $762,000. The cost of living pay raise will contribute towards allowing the Biologics program to maintain their GPRA performance targets and other workload outputs at the FY 2009 levels.

Base funding for this initiative encompasses the entire Biologics program. This increase along with the base funding will work to ensure the safety and effectiveness of biological products, including the nation's blood supply and the products derived from it. It will contribute to the production and approval of safe and effective adult and childhood vaccines, the oversight of human tissue for transplantation, cell and gene therapies, biological related devices, and an adequate and safe supply of allergenic materials and anti-toxins. It will also continue to ensure preparedness to help defend against the threats of emerging infectious disease and bioterrorism.

With the requested increases, CBER will continue to implement the pediatric and postmarket safety requirements of the 2007 Food and Drug Administration Amendments Act (FDAAA). To improve safety in the pediatrics arena, CBER will review pediatric plans, assessments, waivers, and deferrals and conduct a retrospective review. In the postmarket safety arena, CBER will develop a system and standards to track and review safety information for prescription biologics to help report regularly on potential risks identified through the system.

The requested increase will continue enhancements to modernize the human tissue, blood safety, and vaccine programs, including the supply, quality, and availability of these products, and innovative technologies to deal with terrorism and emerging public health threats. Enhancements will include conducting safety investigations, modernizing tissue, blood and vaccine standards, testing assays, disease models, methods, sample panels, and review capacity.

CBER will increase the capacity and expertise of their blood, tissue and vaccine safety teams to proactively monitor and analyze outcomes and potential adverse events, including data gained though increased partnerships with healthcare organizations and other federal agencies. Additionally, CBER will develop enhanced guidance for evolving technologies and provide early interactions, outreach and training on product development and safety. Support for inspections, the enhancement of risk analysis tools and help for manufacturers to implement and expand a quality systems approach that will contribute to safer biologic products.

CBER plans to meet its pandemic influenza vaccine production performance goal by completing an evaluation of a pilot vaccine adverse-effects program. This includes developing and evaluating new methods to detect possible adverse effects of newly licensed vaccines and to participate in at least one international workshop or conference.

In FY 2010, ORA is continuing to progress towards the GPRA goal to increase tissue inspections to 518. Additionally, ORA will continue to establish its workforce for inspections and import exams and to increase laboratory capacity with the FY 2010 Budget Request. Specifically, ORA will increase inspections for the Biologics Program:

- to 25 domestic tissue inspections above the FY 2010 levels by the end of 2012
- to 23 foreign tissue inspections above the FY 2010 levels by the end of 2013.

These inspections are planned to for 2012 and 2013 because it will take two years to hire and train new field staff so they can conduct inspections.

User Fees Authority and Increases

The current law and proposed user fees will provide an increase of $11,254,000 for the Biologics Program. This amount includes increases for the current PDUFA and MDUFMA user fees and a proposed user fee for reinspection. The base funding for the current user fees is $88,039,000.

The Biologics Program is submitting an increase in PDUFA user fee collection authority that will provide an additional $10,672,000. Of this amount, CBER will receive an increase of $10,541,000 and the Field portion will be $131,000. The PDUFA increase provides for inflation and workload adjustments. These increases will help FDA meet the agreed upon performance goals negotiated with industry when PDUFA IV was passed in FY 2007. For the FY 2010 performance, the Biologics Program will maintain or exceed performance targets to review and complete action on standard and priority original PDUFA NDA/BLA submissions within 10 months and 6 months respectively. It will also maintain or exceed performance targets to review and complete action on standard PDUFA efficacy supplements within 10 months.

This submission also includes an increase in MDUFMA user fee collection authority that will provide CBER an additional $100,000 for Biologics medical device review program. The MDUFMA increase provides for inflation and workload adjustments. These increases will help FDA meet the agreed upon performance goals negotiated with industry in MDUFMA.

Proposed User Fees

The FY 2010 request also includes $482,000 for a proposed mandatory reinspection user fee. The Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

Biologics Performance Measures Table

Long Term Objective: Increase the number of safe and effective new medical products available to patients

Measure	FY	Target	Result
233201: Complete review and action on standard original PDUFA NDA/BLA submissions within 10 months of receipt. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	100% (Target Exceeded)
	2006	90%	100% (Target Exceeded)
	2005	90%	100% (Target Exceeded)
233202: Complete review and action on priority original PDUFA NDA/BLA submissions within 6 months of receipt. *(Output)*	*2010*	90%	Apr 30, 2011
	2009	90%	Apr 30, 2010
	2008	90%	Apr 30, 2009
	2007	90%	100% (Target Exceeded)
	2006	90%	100% (Target Exceeded)
	2005	90%	100% (Target Exceeded)
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	100% (Target Exceeded)
	2006	90%	100% (Target Exceeded)
	2005	90%	100% (Target Exceeded)
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	100% (Target Exceeded)
	2006	N/A	100% (Target Not In Place)
	2005	N/A	100% (Target Not In Place)

Measure	FY	Target	Result
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. *(Output)*	*2010*	90%	Nov 30, 2011
	2009	90%	Nov 30, 2010
	2008	90%	Nov 30, 2009
	2007	90%	99% (Target Exceeded)
	2006	N/A	100% (Target Not In Place)
	2005	N/A	100% (Target Not In Place)

Long Term Objective: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

Measure	FY	Target	Result
234101: Increase manufacturing diversity and capacity for pandemic influenza vaccine production. *(Output)*	*2010*	See goal-by-goal section below.	Nov 30, 2010
	2009	See goal-by-goal section below.	Nov 30, 2009
	2008	See goal-by goal section, below.	Accomplished targets. See goal-by-goal section below. (Target Met)
	2007	See goal-by goal section, below.	Accomplished targets. See goal-by-goal section, below. (Target Met)
	2006	N/A	Accomplished targets. See goal-by goal section, below. (Target Met)
	2005	N/A	N/A

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure	FY	Target	Result
234202: Number of high risk registered domestic blood bank and biologics manufacturing inspections. *(Output)*	*2010*	1,000	December, 2010
	2009	870	December, 2009
	2008	870	1,014 (Target Exceeded)
234203: Number of highest priority human tissue establishment inspections. *(Output)*	*2010*	518	December, 2010
	2009	380	December, 2009
	2008	325	383 (Target Exceeded)
	2007	325	427 (Target Exceeded)

Measure	FY	Target	Result
	2006	N/A	354 (Historical Actual)

1. Complete review and action on standard original PDUFA NDA and BLA submissions within 10 months of receipt. (233201)

Context: The Prescription Drug User Fee Act (PDUFA) authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. Standard original BLAs are license applications for biological products, not intended as therapies for serious or life-threatening diseases. In FY 2010, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year, and complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 9 standard applications within 10 months of receipt, and has met or exceeded this performance goal since 1994. The FY 2008 performance data for this goal will not be available until November 2009.

2. Complete review and act on priority original PDUFA NDA/BLA submissions within 6 months of receipt. (233202)

Context: PDUFA authorizes the FDA to collect fees from the prescription drug and biologic drug industries to expedite the review of human drugs and biologics so they can reach the market more quickly. A BLA will receive priority review if the product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. In FY 2010, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 6 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 6 priority applications within 6 months of receipt, and has met or exceeded this performance goal since 1994. The FY 2008 performance data for this goal will not be available until April 2009.

3. Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (233203)

Context: PDUFA authorizes the FDA to collect fees from the prescription drug and biologic industries to expedite the review of human drugs and biologics so they can reach the market more quickly. An efficacy supplement is a change to an approved licensed product to modify the "approved effectiveness" of a product such as a new indication, and normally requires clinical data. In FY 2010, FDA continues to maintain the target set for this goal in the PDUFA legislation.

Performance: FDA tracks PDUFA performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 10 months after receipt, is expired. In FY 2007, CBER exceeded its goal by completing review and action on 100 percent of 9 standard PDUFA efficacy supplements within 10 months of receipt, and has met or exceeded most of these performance goals since 1994. The FY 2008 performance data for this goal will not be available until November 2009.

4. Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (233205)

Context: In FY 2010, CBER has established the goal of reviewing and acting upon complete blood bank and source plasma BLA submissions within 12 months after submission. Since so few complete blood bank and source plasma submissions are received by CBER, the actual performance may be significantly different than the target. User fee resources are not available for blood bank and source plasma application review.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 12 months after receipt, is expired. In FY 2007, CBER exceeded its goal by reviewing and acting on 100 percent of 5 submissions within 12 months of receipt. The FY 2008 performance data for this goal will not be available until November 2009.

5. Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (233206)

Context: In FY 2010, CBER has established the performance goal of reviewing and acting upon complete blood bank and source plasma BLA supplement submissions within 12 months after submission. User fee resources are not available for blood bank and source plasma application review.

Performance: CBER tracks performance by year-of-receipt, which FDA calls the cohort year and complete performance data are not available until the prescribed review time, i.e., 12 months after receipt. In FY 2007, CBER exceeded its goal by reviewing and acting on 99 percent of 371 supplements within 12 months of receipt. The FY 2008 performance data for this goal will not be available until November 2009.

6. Increase manufacturing diversity and capacity for pandemic influenza vaccine production. (234101)

Context: During FY 2006, the Biologics Program received appropriated funding under P.L. 109-148 to establish the infrastructure and surge capability to react to a potential disease pandemic. Influenza pandemics are explosive global events in which most, if not all, persons worldwide are at risk for infection and illness. Pandemic influenza strains, such as avian influenza, can rapidly change. Vaccines will need to be produced for pandemic influenza strains on a short notice, and FDA needs to provide new and accelerated pathways to facilitate their rapid production and evaluation. This goal changes on a yearly basis to ensure continued progress in preparation for a pandemic outbreak. In FY 2007, the targets included: Issue one guidance or concept paper to

facilitate development of non-egg-based influenza vaccines; evaluate the potency of monovalent influenza vaccines from at least three manufacturers by using quality systems guidelines; demonstrate two new or improved methods for improved influenza vaccine manufacture; and develop at least four influenza virus vaccine strains optimized for growth in non-egg culture systems by using quality systems guidelines.

In FY 2008, the pandemic preparedness targets were to: facilitate rapid development, evaluation and availability of at least one new pandemic influenza vaccine and one new trivalent (seasonal influenza) vaccine; demonstrate one improved method for evaluating the safety, potency or immunogenicity of influenza vaccines; and establish international regulatory cooperation, harmonization and information sharing in vaccine evaluation and safety activities by participating in one international workshop or conference. The FY 2009 pandemic preparedness targets include: starting a pilot program to develop and evaluate new methods to detect possible adverse effects, both pre-specified and non-pre-specified, of newly licensed vaccines, including pandemic influenza vaccines, in large population databases and participating in at least one international workshop or conference. The FY 2010 pandemic preparedness targets will be to complete and evaluate the pilot vaccine adverse-effects program and to participate in at least one international workshop or conference.

Performance: In FY 2006, CBER accomplished all of it targets for this goal. The targets include: developing a concept paper on clinical data needed to support license of new trivalent vaccines and of pandemic vaccines; drafting a guidance on cell substrates to facilitate development on non-egg based influenza vaccines and co-sponsoring two workshops with WHO an pandemic vaccines. In FY 2007, CBER met all of its pandemic targets. The targets include: issuing the guidance “Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines” to facilitate development of non-egg-based influenza vaccines; evaluating the potency of five influenza vaccines (four inactivated and one live) using quality systems guidelines; and demonstrating four methods for improved influenza manufacture and develop four influenza virus vaccine strains optimized for growth in non-egg culture systems by using reverse genetics to rescue reassortants based on the A/Puerto Rico/8/34 virus backbone.

In FY 2008, CBER accomplished all of it targets for this goal. CBER facilitated rapid development and evaluation of a new pandemic vaccine through multiple activities including:

- Completing production of an H5 reassortant, "Influenza A virus reassortant A/Duck/Laos/3295/2006 (H5N1), DUCK/LAOS-PR8/CBER-RG1 reference strain" and distributing it to the recipients including the National Institute for Biological Standards and Control (NIBSC) in the UK and Taiwan-CDC in China;
- Characterizing attenuated reassortant of A/duck/Laos/3295/06 with modified internal gene;
- Completing collaborative calibration (with National Biological Standards Board-UK) for A/Anhui/2/2005

CBER posted guidelines on the WHO website of The WHO Guidelines on regulatory preparedness for pandemic influenza vaccines. The guidelines, co-authored by WHO, FDA and Health Canada, resulted from three technical workshops that were convened with representation of national regulatory authorities (NRAs) from a broad range of countries. The goals of these

workshops were to build a global network of key regulatory authorities engaged in and responsible for pandemic influenza vaccine regulation and to develop regulatory guidelines for preparedness of human pandemic influenza vaccines. The guidelines are intended to provide, both NRAs and vaccine manufacturers, state of-the art advice concerning regulatory pathways for human pandemic influenza vaccines; regulatory considerations to take into account in evaluating the quality, safety and efficacy of vaccine candidates; and requirements for effective postmarketing surveillance of human pandemic influenza vaccines.

7. Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202)

Context: FDA will increase risk-based compliance and enforcement activities by inspecting the highest priority registered manufacturers of biological products. The highest priority firms will be those whose operations are determined to be the highest risk, new product types in need of an inspectional history to evaluate and stratify risk, and emergency response situations. Inspections for the goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure, as appropriate, the safety, purity and potency of biological products. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target has been increased to 1,000 inspections to reflect historical accomplishments.

Performance: In FY 2008, FDA exceeded the high risk inspection goal of 870 by inspecting 1,014 blood banks and biologics manufacturing establishments.

8. Number of highest priority human tissue establishment inspections. (234203)

Context: Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections.

Performance: In FY 2008, FDA exceeded the human tissue goal of 325 by conducting 383 inspections under new regulations.

BIOLOGICS PROGRAM ACTIVITY DATA (PAD)

Premarket Review Applications	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
NDA/BLA Submissions			
Applications received			
Standard:	26	29	29
Priority:	4	5	5
Applications completed [1/]			
Standard:	82	82	82
Priority:	2	3	4
Applications approved [2/]			
Standard:	59	35	37
Priority:	0	1	2
Applications pending [3/]			
Standard:	46	51	50
Priority:	7	8	6
Efficacy Supplements			
Applications received			
Standard:	7	8	8
Priority:	2	3	3
Applications completed [1/]			
Standard:	4	5	7
Priority:	1	2	3
Application approved [2/]			
Standard:	8	9	10
Priority:	1	2	3
Applications pending [3/]			
Standard:	15	17	15
Priority:	1	2	1
Original Manufacturing Supplement			
Applications received	1,689	1,858	1,860
Applications completed [1/]	528	581	585
Applications approved [2/]	1,458	1,604	1,610
Applications pending [3/]	1,031	1,134	1,100

Device Premarket Applications – PMAs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Applications received	0	1	1
Supplements received	33	36	40
Applications completed [1/]	0	1	1
Supplements completed [1/]	5	6	6
Applications approved [2/]	1	1	1
Supplements approved [2/]	30	33	33
Applications pending [3/]	0	1	1
Supplements pending [3/]	5	6	6
Device 510(k)s			
Applications received	53	58	60
Applications completed [1/]	43	47	50
Applications approved [2/]	45	50	55
Applications pending [3/]	23	25	20
Investigational Applications			
Commercial IND/IDE Receipts [4/]	137	151	151
IND/IDE Amendment Receipts [4/]	10,779	11,857	11,860
Active INDs/IDEs [4/]	2,894	3,183	3,190

Other Activities	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Patient Safety			
Adverse Event Report Received [5/]	36,410	40,000	44,000
Biological Product Deviation Report Received	44,723	44,000	44,000
Sponsor Assistance/Outreach			
Meetings	408	450	455
Final Guidance Documents	30	28	28
Admin/Management Support			
Advisory Committee meetings held	7	9	14
FOI requests processed	562 [6/]	401	425

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/ Increase due to an Agency-wide effort to reduce the FOI backlog.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,678***	***2,010***	***2,034***
Bioresearch Monitoring Program Inspections	104	183	183
Blood Bank Inspections	991	1,093	1,093
Source Plasma Inspections	149	205	205
Pre-License, Pre-Approval (Pre-Market) Inspections	38	24	24
GMP Inspections	25	17	17
GMP (Device) Inspections	3	10	10
Human Tissue Inspections	381	494	518
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***50***	***52***	***66***
Bioresearch Monitoring Program Inspections	6	6	6
Foreign Human Tissue Inspections	2	0	13
Blood Bank Inspections	8	12	12
Pre-License Inspections	7	10	10
GMP Inspections	23	20	20
IMPORTS			
Import Field Exams/Tests	36	100	100
Import Line Decisions	63,302	81,864	105,868
Percent of Import Lines Physically Examined	0.06%	0.12%	0.09%
TOTAL BIOLOGICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,728***	***2,062***	***2,100***

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ANIMAL DRUGS AND FEEDS

The FY 2010 program level budget submission for the FDA Animal Drugs and Feeds Program is $171,022,000.

The following table shows a three-year funding history for the Animal Drugs and Feeds Program.

FDA Program Resources Table

(dollars in thousands)

	FY 2008		FY 2009	FY 2010 President's	FY 2010 +/- FY
	Enacted	Actuals	Omnibus	Budget Request	2009 Omnibus
Program Level	**$114,617,000**	**$109,625,000**	**$134,344,000**	**$171,022,000**	**$36,678,000**
Center	$75,224,000	$72,150,000	$90,515,000	$105,198,000	$14,683,000
FTE	383	378	424	456	32
Field	$39,393,000	$37,475,000	$43,829,000	$65,824,000	$21,995,000
FTE	226	211	238	311	73
Program Level FTE	**609**	**589**	**662**	**767**	**105**
Budget Authority	**$103,094,000**	**$97,365,000**	**$116,471,000**	**$135,475,000**	**$19,004,000**
Center	$63,701,000	$59,890,000	$73,035,000	$82,452,000	$9,417,000
Field	$39,393,000	$37,475,000	$43,436,000	$53,023,000	$9,587,000
Pay Increase (non add)				*$1,990,000*	*$1,990,000*
Protect America's Food Supply (non-add)				*$13,312,000*	*$13,312,000*
Safer Medical Products (non-add)				*$3,702,000*	*$3,702,000*
Budget Authority FTE	**551**	**530**	**573**	**620**	**47**
Center	325	319	338	361	23
Field	226	211	235	259	24
User Fees	**$11,523,000**	**$12,260,000**	**$17,873,000**	**$35,547,000**	**$17,674,000**
Center ADUFA	$11,523,000	$12,260,000	$13,362,000	$15,290,000	$1,928,000
FTE	58	59	66	66	0
Field ADUFA			$250,000	$250,000	**$0**
FTE			2	2	0
Center AGDUFA			$4,118,000	$4,382,000	$264,000
FTE			20	20	0
Field AGDUFA			$143,000	$143,000	$0
FTE			1	1	0
Proposed User Fees	**$0**	**$0**	**$0**	**$15,482,000**	**$15,482,000**
Field Reinspection				**$2,408,000**	**$2,408,000**
FTE				19	19
Center Export Certification				**$74,000**	**$74,000**
FTE				0	0
Inspection and Facility Registration	**0**			**13,000,000**	**$13,000,000**
Center				$3,000,000	$3,000,000
FTE				9	9
Field				$10,000,000	$10,000,000
FTE				30	30
User Fees FTE	**58**	**59**	**89**	**147**	**58**

The FDA Animal Drugs and Feeds Program operates 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)

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The FDA Animal Drugs and Feeds Program ensures that only safe and beneficial veterinary drugs to treat and prevent diseases in animals and improve the production of food-producing animals are approved for marketing. 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. In addition, the Center for Veterinary Medicine (CVM) works to protect the health of companion animals. CVM accomplishes its program responsibilities through premarket review, surveillance, and compliance monitoring activities designed to prevent marketing of products that are toxic and by coordinating enforcement actions against products associated with adverse events that threaten public and animal health.

The authority to regulate animal drugs and medicated feeds derives from the Food, Drug, and Cosmetic Act, which Congress amended in 1968 to include new authorities relating to animal drugs. 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 and reauthorized in FY 2008. The new Animal Generic Drug User Fee Act (AGDUFA) was enacted in FY 2008.

CVM conducts the activities of the Animal Drugs and Feeds program with assistance from the Office of Regulatory Affairs (ORA). ORA provides FDA leadership on enforcement, inspections (domestic and import), and laboratory policies. Through its Field offices nationwide, ORA supports the Animal Drugs and Feeds Program by conducting pre- and postmarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products. ORA also monitors and samples imports to ensure the safety of the animal drug and feeds supply. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force.

The Field Animal Drugs and Feeds Program is funded by appropriated dollars, ADUFA, and AGDUFA. Appropriated budget authority and user fee revenue allow the Field to perform inspections and fund inspections through State contracts.

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing 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.

platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Veterinary Program by maintaining its legacy systems and databases used for managing and tracking its review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with Veterinary Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The Animal Drugs and Feeds Program executes its regulatory responsibilities in three areas: Premarket and Medical Product Safety, Food and Feed Protection, and Other Postmarket Safety and Effectiveness Activities.

Premarket and Medical Product Safety – Center Activities

Under Premarket and Medical Product Safety, the Animal Drugs and Feeds Program is responsible for bringing innovative, high quality, and safe medical products to market for consumers and animals. Premarket and Medical Product Safety supports important public health priorities by transforming health through improved regulatory processes that safely make new drugs, procedures, and technology available in less time.

During the premarket review, the program reviews premarket applications of pioneer and generic animal drugs for safety and effectiveness. In addition, under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, CVM reviews conditional drug approval requests, indexing requests, and new requests for designation to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species.

On August 14, 2008, the Animal Drug User Fee Amendments of 2008 (ADUFA) was authorized. ADUFA was originally passed in 2003 and was set to expire on September 30, 2008. The new amendments extend ADUFA until 2013. ADUFA permits collection of application, product, establishment, and sponsor fees to enhance the animal drug review process. The ADUFA reauthorization maintains the FY 08 review timeframes for key submissions, in addition to enhancements to the program. The most significant of these is the “end review amendment” process which enables the FDA to work with a drug manufacturer to make corrections to address deficiencies at the end of the review process, rather than restarting the review clock. This will improve efficiency by significantly reducing the number of submission review cycles. In addition, this reauthorization encourages increased communications between FDA and industry, and also provides for improvements to the information technology infrastructure of animal drug review, providing a tool which enables industry to submit drug applications electronically and gives reviewers the ability to evaluate those applications online. Under the first five years of ADUFA, FDA agreed to pursue a comprehensive set of six review performance goals. For example, the review and action time on 90 percent of original new animal drug applications and reactivations decreases from 295 days in FY 2004 to 180 days in FY 2008. FDA’s overall performance to date for the FY 2004 through FY 2008 submission cohorts indicates FDA met or exceeded those ADUFA performance goals. In FY 2008, CVM approved 11 original new animal

drug applications and 15 significant supplemental applications. An example includes Cefovecin sodium, a new antimicrobial for use in dogs and cats for the treatment of skin infections.

Passage of the first ever generic drug user fee program, the Animal Generic Drug User Fee Act (AGDUFA) of 2008, made user fees available to enhance review performance. This program provides consumers with alternative lower cost medications available sooner, better ensuring an adequate supply of animal drugs. Under AGDUFA, FDA agreed to meet review performance goals intended to achieve progressive yearly improvements, shortening the time for FDA to review and act on submissions with each fiscal year. For example, the review and action time on 90 percent of non-administrative original abbreviated new animal drug applications and reactivations decreases from 700 days in FY 2009 to 270 days in FY 2013. In FY 2008, CVM approved four significant generic animal drug applications.

Under MUMS, CVM reviews conditional approval requests for minor species drugs, new requests for designation, and requests for indexing of legally marketed unapproved new animal drugs. In March 2008, CVM issued a notice of proposed rule making to amend the implementing regulations of the MUMS Act to define a small number of animals for minor use designation. In 2009, appropriations allowed for implementation of a grant program for designated products authorized by the Act. In addition, CVM added the first drug to the "Index of Legally Marketed Unapproved New Animal Drugs for Minor Species," commonly referred to as the "Index". The MUMS Act created the Index to permit the marketing of some drugs that would not otherwise be made available, because the potential market is too small to support the costs of the drug approval process. The product added to the index is Ovaprim, a spawning hormone for ornamental fish. Also, as of March 2009, CVM has granted 64 listed drug designations. An example includes Aquaflor® (florfenicol) Type A medicated article for the control of mortality in freshwater-reared salmonids due to a skin condition characterized by the development of recurring boils. This is the first new antimicrobial approved for use during furunculosis outbreaks in more than 20 years.

Another growing area is the application of genetically engineered animals. Producing animals through genetic engineering raises potential food and animal safety issues, and CVM needs to act based on a thorough understanding of the scientific and risk issues that are involved. In FY 2008, CVM continued to work with developers of genetically engineered (GE) animals to ensure that research animals did not enter the food supply. CVM helped them develop data to lead to potential approval for commercialization. In addition, CVM worked on developing a coordinated, science-based approach to regulating genetically engineered animals and their products in CVM and across FDA. On January 15, 2009, FDA issued a final guidance for industry, "The Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs," on the regulation GE animals. The guidance clarifies the FDA's statutory and regulatory authority, and provides recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law. On February 6, 2009, FDA approved the first rDNA construct in a GE animal, a goat used to produce a human biologic in its milk.

CVM reviews new applications and previously approved new animal antimicrobial drug applications with respect to antimicrobial resistance and human safety. CVM issued Guidance For Industry #152 as a possible process for evaluating the potential effects of antimicrobial new

animal drugs on non-target bacteria as part of the new animal drug application process. On July 10, 2008, FDA announced approval of Terramycin® 200 for Fish, an antimicrobial drug for two new aquaculture indications. Terramycin® is the second drug approved for use during outbreaks of coldwater disease and the first ever drug approved for the control of mortality due to columnaris disease, a bacterial infection.

On July 3, 2008, CVM published a final rule in the Federal Register that prohibits the extralabel use of cephalosporin antimicrobial drugs in food-producing animals, including, but not limited to, cattle, swine, chickens, and turkeys. This rule will help further protect consumers against antimicrobial-resistant strains of zoonotic foodborne bacterial pathogens and preserve the effectiveness of cephalosporin-class drugs for the treatment of human infections. On November 25, 2008, FDA revoked the order so that it may fully consider the many substantive comments it received.

CVM conducts regulatory research to support premarket and medical product safety. Regulatory research activities allow CVM to validate the safety and efficacy of animal-derived food and animal health products to ensure approved products are safe for humans and animals to eat. In FY 2008, CVM scientists initiated laboratory work aimed at improving methods for detecting veterinary drug residues from approved uses and to replace older official methods that are becoming outdated due to advances in technology. In addition, CVM scientists have completed or initiated several studies in food animals to investigate biomarkers of inflammation, or genetic and protein markers, that may be used in the premarket evaluation of anti-inflammatory claims made for new animal drugs. Also, CVM scientists have provided antimicrobial susceptibility data obtained through the National Antimicrobial Resistance Monitoring System (NARMS) to pharmaceutical sponsors seeking new animal antimicrobial drug approvals.

Premarket and Medical Product Safety – Field Activities

ORA's Field force conducts preapproval inspections to support CVM's review of New Animal Drug Applications (NADA). The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA also 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.

Food and Feed Protection – Center Activities

The Animal Drugs and Feeds Program ensures animal drugs and feed products currently on the market remain safe and effective for consumers by monitoring animal drug and feed products, manufacturers, and adverse events. Seventy-percent of CVM's work is devoted to the safety of the food supply. A key to food safety is reducing the risk of foodborne illnesses that sicken millions of people each year. Some foodborne illnesses are due to harmful or illegal residues in animal products, while others result from microbiological infection. Food and feed protection safeguards the public from the spread of infectious, occupational, and environmental diseases, and terrorist threats.

In November 2007, FDA released its Food Protection Plan. The Plan encompasses three core elements: prevention, intervention, and response. Consistent with the Food Protection Plan, CVM is incorporating an enhanced modeling capability for relative risk ranking into CVM surveillance and compliance programs, which will better ensure the safety of animal feed and animal-derived food supplies. CVM supports the Food Protection Plan to better detect food system signals that indicate contamination by developing a centralized database for veterinarians that captures data on food safety incidents and causes. CVM is also developing an early warning surveillance and notification system to identify adulterated pet food products and outbreaks of pet illness, and to provide notice to veterinarians and other stakeholders during pet food recalls. In addition, CVM is improving risk communications to the public, industry, and other stakeholders by developing a program for disseminating timely and accurate information through a variety of methods such as articles and brochures.

Reducing the risk of Bovine Spongiform Encephalopathy (BSE, also known as "mad cow disease") in the food supply is also a CVM priority. In April 2008, FDA issued a final regulation that strengthened the existing 1997 rule, "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" by prohibiting the tissues that have the highest risk for carrying the agent thought to cause BSE in animal feed, including pet food. These high risk cattle materials are the brains and spinal cords from cattle 30 months of age and older. The 2008 rule also prohibits the use of the entire carcass of cattle not inspected and passed for human consumption, unless the cattle are less than 30 months of age, or the brains and spinal cords have been removed. In addition, the revisions augment the current animal feed regulation by further reducing the risks of BSE associated with cross-contamination and on-farm mis-feeding of animals. On April 6, 2009, FDA announced a proposed delay in the implementation of the 2008 BSE final rule. The final rule, which would have gone into effect on April 27, 2009, is proposed to be delayed 60 days to June 26, 2009. The agency is taking this action in response to comments from affected parties expressing concerns about their ability to fully comply with the rule by the April 27, 2009 effective date. The original 12-month implementation period was to allow time for the livestock, meat, rendering, and animal feed industries to adapt their practices to comply with the new regulation.

Another highly publicized area in FY 2008 was producing animals through cloning. On January 15, 2008, FDA issued three documents on animal cloning outlining FDA's regulatory approach. The three documents were a risk assessment, a risk management plan, and guidance for industry. FDA concluded that meat and milk from clones of cattle, swine, and goats, and the offspring of all clones, are as safe to eat as food from conventionally bred animals.

CVM also monitors antimicrobial drugs used in food-producing animals to identify the development of resistance among bacterial foodborne pathogens. CVM serves as the leader for the NARMS program, which monitors changes in susceptibility or resistance of select zoonotic bacterial organisms recovered from animals, humans and retail meats On July 16, 2008, the second NARMS-Enteric Bacteria Executive Report (2004) was published, summarizing data on *Salmonella* and *Campylobacter* isolates recovered in 2004 from food animals at federally inspected plants, in retail meats, and in humans in an integrated format. The report also includes susceptibility data on *Escherichia coli* isolates recovered from retail meats and chickens in 2004.

This information is needed to monitor potential public health impacts of antimicrobial use in food producing animals. The 2005 NARMS Executive Report was published in February 2009.

In addition, CVM expanded the number of DNA fingerprinting profiles of *Salmonella* and *Campylobacter* isolated from retail meats. All DNA profiles are submitted to the Centers for Disease Control and Prevention (CDC) PulseNet national database at CDC. On October 2008, FDA released the 2006 NARMS Retail Meat Annual Report providing 2006 data on the prevalence of antimicrobial resistant foodborne pathogens and commensal bacteria among retail meat and poultry samples, comprising results from nearly 4,800 samples. In addition, CVM has added a second reporting requirement that requires analysis and summary of data from all these monitoring components. This added requirement necessitates the need for improved testing, data review and reporting timeframes of our partner agencies with more efficient data sharing and increased interagency communication.

CVM plays a vital role in pandemic influenza preparedness because of uncontrolled use of antiviral drugs in agriculture. In FY 2008, CVM worked with counterparts in the U. S. Department of Agriculture to draft guidance for animal feed that applies to certain situations where bird flocks containing Influenza A (commonly known as "bird flu") may be rendered. CVM scientists developed a method to analyze antiviral drugs in poultry tissues so that CVM may detect prohibited use of these drugs in poultry.

CVM's mission also includes protecting the food supply from deliberate contamination, including terrorist activities. CVM works with other Federal agencies to help the country prepare for a biological emergency, natural disaster, or terrorist attack by making sure there is a safe animal feed supply system. In 2008, CVM enhanced the protection of homeland security by assembling experts on imported animal feed that may be at risk for deliberate contamination and by establishing new criteria that is now being applied to all inspections.

Related to regulatory research in the area of BSE, a real-time polymerase chain reaction, or PCR-based method, to detect ruminant materials such as cattle, sheep, goat, and deer in feed is being subjected to a peer-verification trial prior to release for general use by federal and state laboratories. This method, which CVM scientists developed, is capable of analyzing 15 feed samples for ruminant materials in just over 2 hours, compared to 8 hours using the current PCR-based method used by these same laboratories.

Food and Feed Protection – Field Activities

ORA works to ensure that animal drugs and feed products currently on the market remain safe and effective for consumers by monitoring animal drug and feed products and manufacturers. The Field conducts BSE inspections and follow-up investigations and inspections of findings of illegal drug residues in meat and poultry. ORA works to identify the source of adulteration and supports CVM in taking corrective actions against repeat violators to prevent the problem from reoccurring.

During FY 2008, ORA inspected 244 high risk animal drug and feed establishments to ensure the safety of marketed animal drugs and animal feeds. By conducting appropriate and effective pre-

and post-approval monitoring and surveillance activities, the Field seeks to mitigate the effects of harmful products entering into the supply chain.

ORA works with State counterparts on safety activities. ORA funds grants and cooperative agreements to perform State inspections in areas such as BSE and Tissue Residue. State inspection staffs also attend ORA-sponsored training courses, which allow these partners to more effectively contribute to FDA's mission.

Other Postmarket Safety and Effectiveness Activities – Center Activities

The Animal Drugs and Feeds Program is responsible for monitoring adverse events and addressing zoonotic diseases, animal diseases that can be transmitted to humans. These efforts support the goal of protecting the public from infectious, occupational, and environmental threats and preventing the spread of infectious disease.

CVM maintains an early warning system by collecting and reviewing information from Drug Experience Reports (DER) that list Adverse Drug Events (ADE). The primary purpose for maintaining the FDA/CVM ADE database is to provide an early warning or signaling system to CVM for adverse effects not detected during pre-market testing of FDA-approved animal drugs and for monitoring the performance of drugs not approved for use in animals. CVM scientists use the ADE database to make decisions about product safety, which may include changes to the label or other regulatory action. For FY 2008, CVM received approximately 41,403 ADEs, and was able to review 16,832 of these complaints. During the fiscal year, CVM reviewed approximately 3,800 DERs regarding promotional labeling and advertising. As a result, the Center in FY 2008 issued three Warning Letters and two untitled letters requesting discontinuation of violative labeling and advertising materials. The issues ranged from unsubstantiated claims for prevention of zoonotic disease to omission of pertinent information and inappropriate minimization of risk.

Under the Public Health Service Act, CVM has responsibility for controlling the spread of zoonotic diseases transmitted from pets and exotic animals to humans. In January 2008, FDA updated a previous consumer article on the danger of contracting Salmonella from pet turtles to reflect new information from the CDC. CVM, through the Animal Health Literacy Campaign, also created education materials such as a brochure, poster and book cover. CVM continues to work with turtle growers, states, and CDC to address public health concerns. On September 9, 2008, FDA announced that it would remove its restrictions of the Interim Final Rule banning certain African rodents and prairie dogs that can carry or spread monkeypox because it has been determined that such measures are no longer needed. There have been no new cases of monkeypox in the United States since an outbreak in 2003 through diseased African rodents. The CDC has a rule which prohibits the importation of all African rodents.

CVM conducts regulatory research to support other postmarket safety and effectiveness activities. CVM scientists published two manuscripts, one describing a new liquid chromatography/mass spectrometry surveillance method for detecting multiple drug residues in honey and another on the determination of albendazole and its metabolites in the muscle tissues of hybrid striped and large mouth bass, to identify the marker residue for which analytical

methods are developed for regulatory monitoring. In addition, CVM scientists developed methods for detecting melamine in feeds and drugs in distillers grains.

Other Postmarket Safety and Effectiveness Activities – Field Activities

ORA supports the Center's evaluation of adverse event reports. The Field conducts 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 (i.e., salmonella from pet turtles) ORA will assist CVM by conducting any appropriate investigations.

Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Animal Drugs and Feeds program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$97,844,000	$89,580,000	$8,264,000	592
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 Omnibus	$134,344,000	$116,471,000	$17,873,000	662
FY 2010 Estimate	$171,022,000	$135,475,000	$35,547,000	767

Budget Request

The FY 2010 President's Budget requests $171,022,000 in program level funding for the Animal Drugs and Feeds Program, including the support of 767 FTE. CVM's portion of the request is $105,198,000, supporting 456 FTE. The Field's portion is $65,824,000, supporting 311 FTEs. The request represents an increase of $36,678,000 (or twenty-seven percent) over the FY 2009 Enacted Budget in budget authority and user fee amounts. The overall increase provides additional budget authority to cover a targeted increase to improve animal drug review and safety activities, food and feed protection activities, and a cost of living pay increase for the entire Animal Drugs and Feed Program.

This total funding level meets the required trigger for the Animal Drugs and Feeds Program, enabling FDA to collect the ADUFA and AGDUFA user fees that supplement the appropriated portion of the new animal drugs review program. The Program will be able to retain more than 89 user fee supported FTE to continue its efforts to improve the quality and timeliness of the new animal drug and animal generic drug review processes.

Protecting America's Food Supply Initiative

The FY 2010 budget request for the Protecting America's Food Supply Initiative for the Animal Drugs and Feeds program is $13,312,000. With the additional funding, the Animal Drugs and Feeds program will increase performance in protecting America's food supply by investing in the FDA Food Protection plan supporting an approach consisting of prevention, intervention and response to the lifecycle of food protection.

Additional funding for CVM's efforts to protect America's food supply will focus on three areas: risk assessment, detection of food system "signals", and emergency response. Under the risk assessment area, CVM will develop mechanisms to protect animal feeds from becoming

contaminated with harmful ingredients. CVM will also improve its risk-based safety framework by developing and publishing new processing and ingredient standards and definitions for animal feeds, and updating feed labeling standards. CVM will improve its detection of food system "signals" by working with the states and veterinary associations to develop and implement a Pet Event Tracking Network to track early reporting of contaminated feed and food. This will help improve the response time to animal disease outbreaks associated with pet food. CVM plans to improve its emergency response area by developing a network of state and federal laboratories that integrate resources and expertise for timely and accurate reporting, identification, and analysis of animal feed contamination events through examination of animal tissues for infectious agents, toxins and other causes of disease. This will enhance the ability to conduct root cause analysis and develop the data, information and protective measures needed to help prevent future outbreaks.

Under the Protect America's Food Supply Initiative, the ORA's FY 2010 budget request for the Field Food Protection Program is $107,952,000, which includes a $100,733,000 increase in the Field Foods Program and a $7,219,000 increase in the Field Animal Drugs and Feeds Program over FY 2009 funding levels.

FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners. FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Field Feeds Programs in the following four areas:

- Develop a National Workplan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples;
- Ensure that programmatic objectives and implementation are coordinated;
- Continue to develop uniform, national standards for such subjects as manufacturing, inspections, and enforcement;
- Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners;
- Increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for Federal, State, local, tribal and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

Furthermore, ORA is requesting funding in FY 2010 to continue building its workforce for more field food and feed work and support for the field food and feed work. In order to do so, ORA is

requesting funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work such as:

- Increase of 20,000 food and feed import exams by the end of 2011
- Increase of 50 foreign food and feed inspections by the end of 2012.

Safer Medical Products Initiative

The FY 2010 budget request for the Safer Medical Products Initiative for the Animal Drugs and Feeds Program is $3,702,000. With the additional funding, the Animal Drugs and Feeds program will increase performance in two major areas: new science and analysis to improve the safety of medical products and enhancing science programs across FDA.

Additional funding for CVM's efforts to modernize medical product safety and development will be targeted in two areas: safer drugs, including regulating animal biotechnology, and modernizing science. Under the safer drugs area, the increase will permit CVM to partner with state control organizations to implement targeted sample analysis of animal feeds and develop the infrastructure and laboratory capacity to support critically needed directed feed sampling surveillance programs. This will improve sampling strategies for imported animal drugs and animal feeds for chemical and microbiological contaminants and sampling of animal feeds related to bovine spongiform encephalopathy (BSE). In addition, to help ensure food and drug health concerns produced through genetically engineered animals is addressed, CVM will hire cross-disciplinary staff for scientific and risk evaluation of animal biotechnology products. These staff will implement final guidance, review safety questions and review approvals for new animal biotechnology products, and coordinate related U.S. and foreign regulation and trade. Under the modernizing science area, CVM will strengthen its capacity to support emerging areas of science and manufacturing that are essential to regulation FDA products by using genomics, proteomics, and metabolomics technologies as a source of biomarkers to individualize or personalize medical and veterinary treatment.

Under the Safer Medical Products Initiative, the ORA's Field Animal Drugs and Feeds program, the FY 2010 budget request for the Field Medical Product Safety and Development Program is $26,986,000, which includes a $13,868,000 increase in the Field Drugs Program, a $4,177,000 increase in the Field Biologics Program, a $1,554,000 increase in the Field Animal Drugs and Feeds Program, and a $7,387,000 increase in the Field Device and Radiological Products Program over FY 2009 funding levels.

Cost of Living Pay Increase

The Animal Drugs and Feeds Program's portion of FDA's requested pay increase is $1,990,000. Of this amount, CVM's portion of this increase is $1,176,000 and the Field portion is $814,000.

User Fees Inflationary Increases:

The ADUFA collection estimate is $17,280,000 for FY 2010, an increase of $2,020,000 over the FY 2009 Enacted level, with the Animal Drugs and Feeds program portion totaling $15,540,000. Of this amount, CVM's portion of this increase is $15,290,000 and the Field portion is $250,000.

provides a cost-efficient, high quality animal drug review process that is predictable and performance driven.

The AGDUFA collection estimate is $5,106,000 for FY 2010, an increase of $275,000 over the FY 2009 Enacted level. The Animal Drugs and Feeds program portion totals $4,525,000 and will generate resources that will allow FDA to improve product review performance.

Authorized in August 2008, AGDUFA provides revenue for FDA plans to increase review staff, provide training and development, and refine business processes, including development of policies targeted at more efficient review. AGDUFA shortens the time to approval, thereby making lower cost medications available sooner to the food animal production industry, veterinary practitioners, companion animal owners, and the general public.

Proposed User Fee Increase

The Animal Drugs and Feeds program proposed receiving user fee resources for Food Inspections and Facility Registrations generating resources that will allow FDA to further protect America's food supply. FDA is requesting an increase for user fee collection authority that will provide an additional $13,000,000 and 39 FTE for the Animal Drugs and Feeds program. With these resources, CVM will provide contract support to state feed control laboratories to increase the activity levels of current programs and greatly enhance FDA's feed safety program by coordinating feed surveillance activities of states with FDA's programs, further strengthening FDA's ability to prevent the occurrence of future feed safety problems. In addition, these resources would fund FDA inspections at food facilities.

Finally, the Animal Drugs and Feeds Program proposed receiving user fees resources for Reinspection and Export Certification User Fees. FDA is requesting and increase for user fee collection authority that will provide an additional $2,408,000 and 19 FTE for the Animal Drugs and Feeds program. These resources will support reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

The FY 2010 budget also proposes a new user fee to support export certification activities. FDA collects user fees of up to $175 per certificate issued for export certificates for animal drugs as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collection user fees for export certificates for animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations.

Animal Drugs and Feeds Performance Measures Table

Long Term Objective: Increase the number of safe and effective new medical products available to patients.

Measure	FY	Target	Result
243201: Complete review and action on original NADAs & reactivations of such applications received during the fiscal year. *(Output)*	*2010*	90% w/in 180 days	Jan 2012
	2009	90% w/in 180 days	Jan 2011
	2008	90% w/in 180 days	Jan 2010
	2007	90% w/in 200 days	100% of 7 w/in 200 days (Target Exceeded)
	2006	90% w/in 230 days	100% of 7 w/in 230 days (Target Exceeded)
	2005	90% w/in 270 days	100% of 4 w/in 270 days (Target Exceeded)
243202: Complete review and action on Non-administrative original ANADAs and reactivations of such applications received during the fiscal year. *(Output)*	*2010*	90% w/in 680 days	Jan 2012
	2009	90% w/in 700 days	Jan 2011
	2008	N/A	NA

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure	FY	Target	Result
244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)*	*2010*	250	December, 2010
	2009	233	December, 2009
	2008	233	244 (Target Exceeded)
244203: Number of targeted prohibited material BSE inspections. *(Output)*	*2010*	490	December, 2010
	2009	490	December, 2009
	2008	490	555 (Target Exceeded)
	2007	490	523 (Target Exceeded)
	2006	N/A	516 (Historical Actual)
	2005	N/A	588 (Historical Actual)

1. **Complete review and action on original NADAs & reactivations of such applications received during the fiscal year.** (243201)

Context: The FY 2009 and FY 2010 goal and targets reflects reauthorization of ADUFA and continued achievement of statutory review timeframe(s) over a five-year period (FY 2009-FY 2013). The goal and targets reflect one of the ADUFA user fee goals and the Center's ability to maintain FY 2008 review time frames for specified new animal drug application reviews.

Performance: Based on the final performance update for FY 2007, FDA exceeded all ADUFA performance goals. FDA reviewed and acted on all seven (7) original NADAs and reactivations of such applications received during FY 2007 within 200 days. As of September 30, 2008, the preliminary performance assessment for FY 2008 data indicates FDA has exceeded the ADUFA goal(s).

2. Complete review and action on Non-administrative original ANADAs and reactivations of such applications received during the fiscal year. (243202)

Context: This new measure reflects the FY 2008 authorization of the new Animal Generic Drug User Fee Act (AGDUFA). The FY 2009 and FY 2010 goal and targets reflect one of the AGDUFA user fee goals to complete the review of 90% of specified abbreviated applications for the approval of generic new animal drugs within incrementally decreasing time frames over a five-year period (FY 2009-FY 2013).

Performance: AGDUFA is a new performance goal and target as of FY 2009. Performance data is not available to report in this budget submission since the program is currently undergoing implementation.

3. Number of domestic and foreign high risk animal drug and feed inspections. (244202)

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which we had no historical experience, and were unsure how the new site-selection methodology would evolve. In FY 2010, the target is being slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues.

Performance: In FY 2008, FDA exceeded this inspection goal of 233 by inspecting 244 high risk animal drug and feed establishments.

4. Number of targeted prohibited material BSE inspections (244203)

Context: FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing

products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc.

Performance: In FY 2008, FDA completed the inspection of all 555 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

Animal Drugs & Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Workload and Outputs	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
New Animal Drug Applications (NADAs)[1]			
Received	11	13	13
Completed	14	14	14
Approved	11	11	11
Pending[2]	4	3	2
New Animal Drug Application Supplements[1, 3]			
Received	510	510	510
Completed	534	534	534
Approved	447	447	447
Pending[2]	162	138	114
Abbreviated New Animal Drug Applications (ANADAs)[1]			
Received	47	12	12
Completed	27	27	27
Approved	4	4	4
Pending[2]	59	44	29
Abbreviated New Animal Drug Application Supplements[1, 3]			
Received	146	146	146
Completed	98	110	122
Approved	78	78	78
Pending[2]	205	241	265
Investigational New Animal Drug (INAD) Files[4]			
Received	2440	2464	2464
Completed	2238	2491	2491
Pending[2]	313	286	259

[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, protocols, technical sections, data sets, meeting requests, memos of conference, and other information.

Animal Drugs & Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Workload and Outputs	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
Generic Investigational New Animal Drug (JINAD) Files[4]			
Received	137	137	137
Completed	103	135	137
Pending[2]	71	73	73
Food (Animal) Additive Petitions	21	11	11
Investigational Food Additive Petitions	61	46	46
Adverse Experience Reports (AERs)			
Received	41,403	44.934	48,465
Reviewed	16,832	19,770	24,233

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,127***	***2,820***	***2,621***
Pre-Approval/BIMO Inspections	61	77	77
Drug Process and New ADF Program Inspections	190	151	205
BSE Inspections	1,794	2,594	2,306
Feed Contaminant Inspections	26	20	20
Illegal Tissue Residue Program Inspections	212	320	320
Feed Manufacturing Program Inspections	208	141	141
Domestic Laboratory Samples Analyzed	1,617	1,850	1,850
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***33***	***26***	***41***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	23	25	26
Foreign Drug Processing and New ADF Program Inspections	19	10	20
Foreign Feed Inspections	2	0	8
IMPORTS			
Import Field Exams/Tests	2,930	2,930	3,500
Import Laboratory Samples Analyzed	594	720	720
Import Physical Exam Subtotal	**3,524**	**3,650**	**4,220**
Import Line Decisions	244,591	253,956	263,680
Percent of Import Lines Physically Examined	1.44%	1.44%	1.60%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,712***	***5,160***	***5,160***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***324***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,652	4,744	4,744
State Contract Inspections: Feed Manufacturers	322	348	348
State Contract Inspections: Illegal Tissue Residue	271	550	550
State Partnership Inspections: BSE and Other	324	300	300
State Contract Animal Drugs/Feeds Funding	$2,300,000	$2,550,000	$2,725,000
BSE Cooperative Agreement Funding	$3,000,000	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$300,000	$342,801	$375,050
Total State Funding	**$5,600,000**	**$5,892,801**	**$6,100,050**
TOTAL ANIMAL DRUGS AND FEEDS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***8,196***	***8,306***	***8,122***

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DEVICES AND RADIOLOGICAL HEALTH

The FY 2010 program level budget request for the FDA Devices and Radiological Health Program is $371,414,000.

The following table shows a three-year funding history for the Devices and Radiological Health Program.

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	**$303,871,000**	**$275,284,000**	**$329,627,000**	**$371,414,000**	**$41,787,000**
Center	$225,203,000	$204,791,000	$243,975,000	$273,813,000	$29,838,000
FTE	1,141	1,130	1,204	1,275	71
Field	$78,668,000	$70,493,000	$85,652,000	$97,601,000	$11,949,000
FTE	441	434	443	485	42
Program Level FTE	**1,582**	**1,564**	**1,647**	**1,760**	**113**
Budget Authority	**$258,086,000**	**$237,734,000**	**$280,587,000**	**$315,377,000**	**$34,790,000**
Center	$192,839,000	$177,455,000	$209,061,000	$234,974,000	$25,913,000
Field	$65,247,000	$60,279,000	$71,526,000	$80,403,000	$8,877,000
Pay Increase (non add)				*$4,859,000*	$4,859,000
Safer Medical Products (non-add)				*$29,931,000*	$29,931,000
Budget Authority FTE	**1,395**	**1,365**	**1,406**	**1,475**	**69**
Center	969	945	977	1,029	52
Field	426	420	429	446	17
User Fees	**$45,785,000**	**$37,550,000**	**$49,040,000**	**$56,037,000**	**$6,997,000**
Center MDUFMA	$26,647,000	$23,289,000	$28,911,000	$32,836,000	$3,925,000
FTE	146	164	201	220	19
Field MDUFMA	$967,000	$972,000	$1,049,000	$1,049,000	$0
FTE	7	6	6	7	1
Center MQSA	$5,717,000	$4,047,000	$6,003,000	$6,003,000	$0
FTE	26	21	26	26	0
Field MQSA	$12,454,000	$9,242,000	$13,077,000	$13,077,000	$0
FTE	8	8	8	8	0
Proposed User Fees	**0**	**0**	**0**	**$3,072,000**	**$3,072,000**
Field Reinspection				$3,072,000	$3,072,000
FTE				24	24
User Fees FTE	**187**	**199**	**241**	**285**	44

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]

Allocation Method: Direct Federal/intramural

Program Description and Accomplishments

The FDA Devices and Radiological Health Program (the Devices Program) is responsible for ensuring the safety and effectiveness of medical devices and for eliminating unnecessary human exposure to products that emit radiation.

The Devices Program protects the health of the American public by assuring the safety and effectiveness of medical devices throughout their total product life cycle (TPLC) – from product conception and premarket development, through production and use of the marketed products. The Devices Program also eliminates unnecessary human exposure to man-made radiation from medical, occupational, and consumer products, such as airport scanners and microwave ovens. The scope of the medical device and radiological health industry is diverse. Products range in complexity from eye glasses to heart pacemakers and genetic tests, and from microwave ovens to medical ultrasound, mammography and x-ray equipment.

The Devices and Radiological Health Program began in 1976 with the passage of the Device Amendments to the Food, Drug, and Cosmetic Act. The program operates with appropriations and user fees. The user fee program known as the Medical Device User Fee and Modernization Act (MDUFMA) was enacted in FY 2002 and reauthorized in FY 2007 under FDAAA as the Medical Device User Fee Act (MDUFA). An additional user fee program is authorized by the Mammography Quality Standards Act (MQSA), enacted in 1992. 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.

FDA's Center for Devices and Radiological Health (CDRH), with assistance from the Office of Regulatory Affairs (ORA) Field offices nationwide, administers the Devices Program. CDRH evaluates new premarket medical devices for safety and effectiveness during the device review process. To ensure that products currently on the market remain safe and effective for patients and consumers, CDRH monitors medical products, manufacturers, and adverse events. ORA provides FDA leadership on enforcement, import, inspection, and laboratory policies. ORA conducts premarket and postmarket inspections of domestic and foreign manufacturers, performs laboratory analysis to support inspections, reviews and evaluates imports of medical devices and radiological products, and, in collaboration with CDRH, conducts enforcement activities. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. The Field Devices and Radiological Health program is funded by appropriated budget authority and user fees.

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM

[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.

works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Device and Radiological Health Program by maintaining its legacy systems and databases used for managing and tracking its review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Device and Radiological Health Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The Devices Program executes its regulatory responsibilities in three areas: Premarket Device Safety and Effectiveness, Postmarket Device Safety and Surveillance, and MQSA.

Premarket Device Safety and Effectiveness – Center Activities

Under Premarket Device Safety and Effectiveness, the Devices Program is responsible for bringing to market innovative, high quality, and safe medical products. Premarket Device Safety and Effectiveness supports the Pandemic Influenza initiative, the HIV/AIDS initiative, and the priority to transform health through improved regulatory processes that safely make technology available in less time.

CDRH conducts Premarket Device Safety and Effectiveness activities with assistance from ORA Field offices. During premarket review, the program evaluates the safe manufacturing and data integrity components of premarket applications for medical devices. With support from MDUFA user fees, the program improved the timeliness and predictability of FDA premarket review of new devices for consumers. Under MDUFMA and MDUFA, FDA agreed to pursue a comprehensive set of device review performance goals. FDA's overall review performance for the FY 2004 through FY 2008 receipt cohorts[2] indicates that FDA is meeting or exceeding most MDUFA performance goals.

CDRH reviews of safety and effectiveness in device premarket applications improves patient care and access to health care technology and innovation. CDRH recently approved and cleared many advanced, first-of-kind device technologies. Examples include

- the first total ankle replacement to give patients the ability to regain and retain some of their ankle mobility and function
- a test to diagnose common human influenza infections and the highly pathogenic avian influenza A (H5N1) viruses within four hours on multiple samples at one time, a significant achievement for public health surveillance and more timely detection of a pandemic virus
- a breast cancer gene test that is an important new tool in treatment management, providing assessment of tumor recurrence risk and long term survival

[2] MDUFA calculates performance statistics for the fiscal year in which premarket submissions are received (the "receipt cohort"), regardless of when FDA acts on the submissions. As a result, the statistics shown for a particular fiscal year may change with time as FDA continues to complete work on the submissions within a fiscal year cohort. Until all submissions in a cohort receive a final decision, only a preliminary performance assessment can be provided for that cohort.

- the first test for hepatitis B virus that measures the amount of virus in a patient's blood to provide a highly sensitive method for gauging therapy progress in patients with chronic disease.

CDRH conducts regulatory research to support Premarket Device Safety and Effectiveness. Regulatory research allows CDRH to improve the predictability, efficiency, effectiveness, and speed of premarket reviews to ensure that consumers have access to safe medical devices. Research findings improve the development of new device technologies, such as cancer imaging technologies, by developing methodology to estimate device performance after a small pilot study, before conducting a large pivotal trial. CDRH laboratory research also ensures greater understanding of future technology that CDRH must be prepared to regulate.

Concurrent with regulatory research, CDRH is working collaboratively with product developers and the scientific community on FDA's critical path initiative to identify and resolve critical product development problems and improve FDA's regulation of new device technology. Modernizing the medical product development process makes product development more predictable and less costly. Important results of the critical path initiative during FY 2008 include progress in developing an artificial pancreas for treating adult and juvenile diabetes, in cancer biomarker validation to support cancer research, and in developing and implementing feasibility trials for the treatment of breast cancer with thermal ablation devices.

To improve the quality of industry premarket submissions and health outcomes for consumers, the Devices Program conducts outreach to industry, consumers, and others. CDRH conducts industry workshops and participates in audio conferences and educational programs at national meetings. In FY 2008, CDRH participated in 42 educational programs at national and regional meetings. Clinical community outreach also includes newsletters and websites, such as CDRH Learn—the innovative new online educational tool for industry.

Premarket Device Safety and Effectiveness — Field Activities

ORA's Field force supports CDRH in the initial phases of the total product life cycle by conducting preapproval inspections of foreign and domestic establishments. ORA also conducts bioresearch monitoring of clinical research studies, laboratory method validations for premarket application decisions, and preapproval quality manufacturing facility inspections to determine if the factory is able to manufacture products according to the specifications stated in their application.

The device bioresearch monitoring program assures the quality and integrity of research data and protects human research subjects through the prompt investigations of allegations of research misconduct. In FY 2008, ORA conducted 301 inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations. By consistently meeting its performance goal targets since FY 2002, 85 percent of FDA inspections of clinical research with medical devices revealed only minor problems with research conduct. To help improve the remaining device research that may be problematic, CDRH increased outreach activities to regulated industries through meetings and by publishing articles in professional journals to improve awareness of proper clinical research practices.

Postmarket Device Safety and Surveillance — Center Activities

The Devices Program is responsible for ensuring that medical devices and radiological products currently on the market remain safe and effective for consumers by monitoring medical products, manufacturers, and adverse events. Postmarket Device Safety and Surveillance supports the HHS priority to transform health by proactively communicating with providers and patients, and sustains the HHS goal of protecting the public from infectious, occupational, environmental, and terrorist threats, and preventing the spread of infectious disease.

During FY 2008, CDRH moved forward in its transformation of Postmarket Device Safety and Surveillance by establishing a Center-wide matrix structure. Based on corporate models, the matrix formalizes interactions horizontally across the vertical CDRH Offices to improve the Center's postmarket risk identification, risk analysis, and public health response through increased collaboration. The matrix also ensures that all CDRH Offices communicate consistent, substantial, and timely information for regulatory public health decision-making within FDA and among its international counterparts.

CDRH's Unique Device Identification (UDI) initiative is another element of the transformation effort. Upon completion of this multi-year initiative, UDI will enable CDRH to track devices, facilitate recalls, and support inventory management during terrorist attacks or natural disasters.

CDRH is committed to an import safety program that meets the needs of the growing global medical device market and helps assure that medical devices shipped to the United States meet FDA standards for safety and manufacturing quality. CDRH's efforts support FDA's Action Plan for Import Safety (APIS) and include staff dedicated to Import/Export Strategic issues. CDRH collaborates with foreign governments regarding the sharing of inspection and adverse event data. CDRH continues to support commitments under the 2007 China memorandum of agreement (MOA) by providing capacity building training in China. CDRH provides medical device regulatory training in India and Panama and is fulfilling additional commitments to capacity building by training over 15 FDA staff assigned to oversee FDA offices in India, Costa Rica, Europe, China and Jordan.

CDRH established the Medical Products Surveillance Network (MedSun) in 2002 to collect information about device use problems from a sample of clinical sites nationwide. MedSun has been successful in monitoring postmarket device use. CDRH exceeded its performance targets for FY 2006 through FY 2008 to increase the number of actively participating facilities that submit reports to FDA. MedSun sub-networks within MedSun participating facilities provide FDA with increased knowledge of device problems occurring in targeted high-risk products and populations. During FY 2008, CDRH established a new subnetwork, HomeNet, to identify problems with medical devices used in the home, and recruited and oriented 22 sites into it. CDRH expanded existing subnetworks and now has 48 LabNet, 37 KidNet, 10 SightNet, and 20 HeartNet sites.

To ensure the safety of newly marketed products, CDRH monitors post-approval studies. In FY 2008, CDRH epidemiology staff monitored 150 industry-run studies. CDRH also employs a Medical Device Reporting (MDR) system for adverse event reports. In FY 2008, the system received more than 616,000 reports concerning 1,342 medical devices. FDA review of these reports led to follow-up actions, including a Public Health Notification to communicate critical

health information on life-threatening complications associated with the unapproved use of a bone protein to fuse vertebrae in the upper spine. In 2008 CDRH was awarded international recognition for the paper, "Risk of local adverse events by gender following cardiac catheterization." CDRH collaborated with the American College of Cardiology to identify factors causing women to be at substantially higher risk than men for local hemorrhage complications at the puncture site following cardiac catheterization.

CDRH provides training for industry on ways to reduce manufacturing errors and omissions. The CDRH risk communication and outreach program to health professionals and consumers provides science-based, accurate information about medical devices and radiological products to improve consumer health. CDRH develops consumer websites, publishes four audience-specific e-Newsletters, and produces the award-winning FDA Patient Safety News, a monthly television news show and web site for communicating FDA safety messages on drugs, devices, and biologics to physicians, nurses, pharmacists, risk managers, and educators. In 2008, FDA piloted a partnership with WebMD to expand access to timely and reliable consumer health information through a specific FDA page on WebMD's site. By leveraging WebMD's website readership, CDRH can now reach 34 million more visitors per month.

CDRH's research activities provide information to assess device postmarket risks and performance issues. For many medical devices, embedded software now determines much of the product's functionality and performance, and can require more than 100,000 lines of code. Managing the complexity is a huge challenge for medical device designers and regulators alike. CDRH's Software Laboratory is at the forefront of investigating the performance of embedded software. In 2008, the Software Laboratory exposed software design errors that were linked to adverse events, including deaths. Cases included devices such as an implantable cardioverter-defibrillator and wearable insulin pumps, and resulted in appropriate corrective actions. Additionally in 2008, CDRH scientists used their research knowledge to assist the Veteran's Administration (VA) in developing a plan for monitoring the health of approximately 5,000 soldiers returning from Iraq and Afghanistan with embedded fragments of improvised explosive devices (IEDs). CDRH is applying its expertise with medical implants to help assess the safety consequences of embedded fragments. IED fragments must be monitored for three carcinogenic effects: low-level radiation, toxic metals, and implanted solids. CDRH also is applying its expertise in imaging, which is a major mode of monitoring embedded fragments.

CDRH maintains pandemic and emergency preparedness, assuring compliance with federal Continuity of Operations (COOP) guidelines, the FDA Pandemic Flu Exercise, and participation in interagency groups. During 2008 CDRH participated with multiple interagency-academic-medical center organizations in the Biological Aerosol Test Method (BATM) and Personal Protective Equipment Decontamination Project. The aim of the Department of Defense-sponsored project is to develop strategies for reusing single use, disposable respirators in the event of a shortage or pandemic situation.

Postmarket Device Safety and Surveillance – Field Activities

ORA's Field force supports postmarket safety by performing risk-based domestic and foreign postmarket surveillance inspections, field exams, and sampling of medical device manufacturers to assess their compliance with Quality Systems (Good Manufacturing Practice) (QS)

requirements. 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 performance standards.

During FY 2008, the ORA Field force conducted more than 1,431 QS foreign and domestic inspections to evaluate the manufacturing processes of medical device manufacturers. The importance of postmarket surveillance is highlighted by a recent increase in Class I (most serious), II, and III recall actions. The number of recall actions for FY 2008 was 831, up from 661 in FY 2007, and these recalls involved 2,472 different products. This surveillance achievement is also shown in the resolution of significant enforcement actions involving the safety of marketed medical devices. In FY 2008, FDA reached a $1.1 M settlement with Advanced Bionics LLC, a California hearing device manufacturer, and its president and CEO over alleged violations that involved the failure to notify the FDA of a change of outside supplier or vendor, which may have exposed patients to unnecessary health risks. The FDA's complaint alleged that Advanced Bionics shipped cochlear implants to customers in the United States without first filing appropriate supplemental information with the FDA, preventing the FDA from being able to evaluate the potential impact of the changes on the safety and effectiveness of the device. FDA's complaint also stated that two devices were shipped after the firm had conducted a recall of the product in March 2006. The two devices were subsequently implanted in patients.

In accomplishing its mission, the postmarket area faces many of the same challenges as the premarket activities; however, the postmarket area faces the additional challenge of ensuring the safety of rapidly increasing imported products. By detecting and intercepting unsafe products at the manufacturing level, ORA strives toward its ultimate goal of preventing harmful and ineffective devices from reaching the consumer. ORA continues to implement improved risk-based targeting of inspection and import resources to protect the public health by ensuring both the quality and effectiveness of medical products that are available to consumers.

Mammography Quality Standards Act (MQSA) – Center Activities

The Devices Program safeguards the public health with safe and reliable mammography to detect breast cancer in its earliest and most curable stages, as authorized by MQSA. MQSA can transform the health of women through early detection strategies that increase healthy life potential.

Under MQSA, FDA collects user fees to cover the costs of inspecting non-government facilities. Congress authorizes yearly fee adjustments, as necessary, to ensure that FDA recovers the full cost of facility inspections.

CDRH's MQSA program develops national quality standards and regulations for mammography facilities and the mammography accrediting bodies. The program focuses on facility inspections to ensure that mammograms are performed only in federally compliant establishments. MQSA activities also provide accessible MQSA data to consumers. CDRH certifies new mammography facilities and annually recertifies one-third of approximately 8,800 facilities. CDRH analyzes and acts on inspection results to ensure compliance with quality standards. Through state contracts

and ORA's field force, CDRH met or exceeded its mammography performance goal in the five years ending FY 2008. This goal ensures that 97 percent of domestic facilities meet inspection standards, with less than 3 percent with Level I problems. In FY 2008 only 1.5 percent of mammography facilities had Level I violations.

Mammography Quality Standards Act – Field Activities

The Field Devices Program supports MQSA objectives by managing approximately 8,000 state-conducted inspections annually and by conducting foreign inspections to ensure the safety of mammography conducted in military facilities located in foreign countries.

Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Devices and Radiological Health Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$255,041,000	$220,563,000	$34,478,000	1,498
FY 2007 Actual	$267,543,000	$230,682,000	$36,861,000	1,544
FY 2008 Actual	$275,284,000	$237,734,000	$37,550,000	1,564
FY 2009 Omnibus	$329,627,000	$280,587,000	$49,040,000	1647
FY 2010 Estimate	$371,414,000	$315,377,000	$56,037,000	1760

Budget Request

The FY 2010 budget request for the Devices and Radiological Health Program is $371,414,000. It is an increase of $41,787,000 above the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009.

The total budget request provides user fees and budget authority to continue FDA's advances in medical product safety and development. Budget authority funding encompasses all the Devices Program activities for ensuring the safety and effectiveness of medical devices and the safety of radiological products. These activities include premarket review, postmarket surveillance, inspection, research, and outreach-coordination. The funding request supports many ongoing CDRH initiatives such as the Action Plan for Import Safety (APIS), which helps to protect the American public from unsafe imported medical products. The request continues support for CDRH's Critical Path initiative work to modernize medical product development, accelerate innovation, and enhance product safety. Funding also supports the ongoing UDI initiative, enabling CDRH to work toward the completion of a highly effective system to track devices, facilitate recalls, and support inventory management during terrorist or natural disasters. Resources in the request fund CDRH's continued implementation of Title III of FDAAA, including establishment of the Demonstration Grants Program to Improve Pediatric Device Availability. With budget authority support for continued work on additional initiatives, such as strengthening science capacity to support nanotechnology, genomics and personalized medicine, CDRH advances new therapies for disease prevention, detection, diagnosis, and treatment.

<u>Budget Authority Increase</u>

For FY 2010, the Devices and Radiological Health Program requests increases in budget authority for two areas. The Program requests an additional $4,859,000 in Pay, Rent and Infrastructure to support cost of living increases. This increase provides an additional $3,369,000

for CDRH and $1,490,000 for Field activities. These resources ensure that the Program has the capacity to fully carry out all mission-critical activities.

The Program also requests an additional $29,931,000 to support its Safer Drug, Devices and Biologics initiatives. This increase provides an additional $22,544,000 for CDRH and $7,387,000 for Field activities. The additional resources enable CDRH to strengthen its ongoing initiatives by increasing staff who will:

- strengthen the foreign and domestic inspection program
- enhance development and incorporation of risk-based monitoring criteria into the screening of imported devices
- strengthen enforcement of electronic product radiation control requirements to ensure product safety
- develop the capacity to gather unique information about device problems through web interaction, which will accelerate problem identification
- enhance CDRH's development of strategies for monitoring radiation exposure from medical imaging
- increase awareness of the public health importance of reducing radiation exposure for children.

Additional resources also enable the Devices Program to further the multi-year effort to fully implement provisions of FDAAA by increasing staff levels, which will allow CDRH to

- develop high-priority guidance relating to medical devices and global initiatives
- enhance implementation of FDAAA third party inspections program provisions
- increase the number and quality of hospital reports on device problems in pediatric and other high-risk areas so problems are addressed quickly
- increase capacity to address pediatric premarket and postmarket issues and improve children's health nationwide
- advance the safety and effectiveness of medical products through expert review of device software
- ensure that medical devices developed and marketed globally adhere to standardized levels of reasonable quality, safety and effectiveness
- enhance efforts to ensure the safety and effectiveness of medical devices by assessing the impact of Center activities on clinical outcomes for patients
- improve device regulation and risk communication through development of a Center-wide, risk-based decision making process.

With additional funding, the Devices Program also plans to strengthen its science capacity, including support in the areas of nanotechnology, genomics and personalized medicine. Experts in these fields will

- increase CDRH's capacity to regulate the diagnostic technology used to develop drugs and dosing based on an individual's genetic make-up (personalized medicine)
- advance CDRH's guidance for producing safe and effective devices by defining key nanotechnology issues involving devices.

The requested budget authority increase plus existing base funding allows the Devices Program to reach the budget authority statutory trigger mandated under MDUFA. Meeting the trigger authorizes FDA to collect the MDUFA user fees that supplement the appropriated portion of the medical device review program. The user fees enable the Devices Program to maintain its cadre of 220 user fee-supported FTE and continue its efforts to improve the quality and timeliness of the device review process and to promote the delivery of new technologies to the public. As a result of the FY 2010 budget authority request, plus the MDUFA supplemental resources, the Devices Program can achieve its Results Act performance goals and targets for FY 2010. The Devices Program's Activity Data show a similar level of performance for CDRH workload targets for FY 2010 as compared to the Omnibus Appropriations Act, 2009 level.

In FY 2010, ORA will continue to establish its workforce for inspections and import exams and to increase laboratory capacity. Specifically, ORA will increase inspections for the Medical Devices Programs:

- Increase of 41 domestic Quality Systems (QS) -GMP medical device inspections above the FY 2010 levels by the end of 2012.,
- Increase of 41 QS-GMP foreign medical device inspections above the FY 2010 levels by the end of 2013.

These inspections are not planned to be completed until 2012 and 2013 because ORA will invest the next one to two years in hiring and training new field staff.

User Fee Increases

The FY 2010 request includes a total of $52,965,000 in existing user fee authority for the Medical Devices Program, an increase of $3,925,000 over the level of the Omnibus Appropriations Act, 2009. FDA is requesting an increase in MDUFA user fee collection authority, which will provide an additional $3,925,000 for CDRH's medical device review program. The supplemental MDUFA user fees support Device Program staff increases to ensure ongoing improvement in the review process.

Proposed User Fees

The FY 2010 request also includes $3,072,000 for a proposed mandatory reinspection user fee. The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the full cost of reinspection and associated follow up work. FDA currently funds this activity through discretionary appropriations. The request provides $3,072,000 in user fee authority for Field activities.

Medical Devices and Radiological Health Performance Measures Table

Long Term Objective: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

Measure	FY	Target	Result
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)*	*2010*	60% in 180 days and 90% in 295 days	Jan 31, 2012
	2009	60% in 180 days and 90% in 295 days	Jan 31, 2011
	2008	60% in 180 days and 90% in 295 days	Jan 31, 2010
	2007	90% in 320 days	96% of 33 (Target Met)
	2006	NA	81% of 40 (Target Met)
	2005	NA	N/A
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. *(Outcome)*	*2010*	85% in 180 days and 95% in 210 days	Jan 31, 2012
	2009	85% in 180 days and 95% in 210 days	Jan 31, 2011
	2008	85% in 180 days and 95% in 210 days	Jan 31, 2010
	2007	90%	97% of 132 (Target Met)
	2006	N/A	95% of 136 (Target Met)
	2005	N/A	95% of 101 (Target Met)
253205: Percentage of 510 (k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. *(Outcome)*	*2010*	90% in 90 days and 98% in 150 days	Jan 31, 2012
	2009	90% in 90 days and 98% in 150 days	Jan 31, 2011
	2008	90% in 90 days and 98% in 150 days	Jan 31, 2010
	2007	80% in 90 days	92% of 3,531 (Target Met)
	2006	N/A	91% of 3,530 (Target Met)
	2005	N/A	91% of 3,382 (Target Met)
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	*2010*	300	December, 2010
	2009	300	December, 2009
	2008	300	301 (Target Exceeded)
	2007	295	323 (Target Exceeded)

Measure	FY	Target	Result
	2006	N/A	336 (Historical Actual)
	2005	N/A	335 (Historical Actual)
253206: Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. *(Outcome)*	*2007*	290 days	Feb 28, 2010
	2006	N/A	Oct 31, 2009
	2005	N/A	322 days (Historical Actual)

MDUFMA, and MDUFMA as amended review goals (Goals 253203, 253204, and 153205) are based on FDA review time only, and do not include time that elapses when the sponsor is responding to questions or issues raised by FDA. This means that FDA cannot determine exactly when all the applications in a review cohort will be completed. The actual results reported for this goal are as of the times noted, and as the final applications in the cohort are resolved, small changes to previously reported results may occur.

Long Term Objective: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

Measure	FY	Target	Result
254101: Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	*2010*	97%	December 31, 2010
	2009	97%	December 31, 2009
	2008	97%	97% (Target Met)
	2007	97%	97% (Target Met)
	2006	N/A	97% (Historical Actual)
	2005	N/A	97% (Historical Actual)
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	*2010*	1,365	December, 2010
	2009	1,340	December, 2009
	2008	1,270	1,431 (Target Exceeded)
	2007	1,195	1,468 (Target Exceeded)
	2006	N/A	1,506 (Historical Actual)
	2005	N/A	1,495 (Historical Actual)

Long Term Objective: Improve information systems for problem detection and public communication about product safety.

Measure	FY	Target	Result
252201: Participation rate of facilities in the MedSun Network. *(Outcome)*	*2010*	95%	December 31, 2010
	2009	95%	December 31, 2009
	2008	95%	98% (Target Exceeded)
	2007	90%	90% (Target Met)

1. Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 and 295 days. (253203)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. PMAs involve potentially high-risk devices with the most chance of significantly improving the treatment of patients. The steps taken in MDUFMA, and MDUFMA as amended, that will reduce approval times for PMA applications are expected to reduce approval times for all filed applications, while recognizing that some applications may not ultimately meet FDA's standards for safety and effectiveness and that performance measures based on all applications will take more time to observe. Due to the renegotiation of MDUFMA, the Performance targets for Original PMA applications will be to arrive at a decision on 60% of Original PMA applications within 180 days and 90% within 295 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by arriving at a decision on 96% of Original PMA applications within 320 days. The current baseline for FDA decision time for standard PMAs is 295 days. The FY 2008 performance data for this goal will not be available until January 2010.

2. Percentage of 180 day PMA supplements reviewed and decided upon within 180 and 210 days. (253204)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: approval, approvable, approvable pending GMP inspection, not approvable, denial. PMAs involve potentially high-risk devices that have the highest likelihood of significantly improving the treatment of patients. Supplemental applications are generally submitted for changes in already approved products such as technology changes or the addition of a new indication. It is essential that FDA complete the review process for these products quickly and thoroughly. Due to the renegotiation of MDUFMA, the Performance targets for 180 day PMA Supplements will be to arrive at a decision on 85% of applications within 180 days and 95% within 210 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by reviewing and arriving at a decision on 97% of PMA Supplements applications. The FY 2008 performance data for this goal will not be available until January 2010.

3. Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 and 150 days. (253205)

Context: Complete decision constitutes the comprehensive review of the application package initially received by FDA and FDA's decision letter. A decision will result in one of the following designations for each application: substantially equivalent or not substantially equivalent. This goal for review and decision on 510(k)s within 90 days addresses the statutory requirement to review a 510(k) within 90 days**.** Due to the renegotiation of MDUFMA, the Performance targets for 510(k)s will be to arrive at a decision on 90% of applications within 90 days and 98% within 150 days. This target will remain stable from FY 2008 through FY 2012.

Performance: CDRH has exceeded performance for this goal in FY 2007 by reviewing and arriving at a decision on 92% of 510(k)s. The FY 2008 performance data for this goal will not be available until January 2010.

4. Number of Medical Device Bioresearch Monitoring (BIMO) inspections. (253201)

Context: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2010.

Performance: In FY 2008, FDA exceeded this goal of 300 by conducting 301 medical device related Bioresearch Monitoring inspections.

5. Reduction in FDA's total approval time for the fastest 50 percent of expedited PMAs approved, using the submission cohort for FYs 2005-2007. The baseline for this goal is the three year average of total FDA approval time for the fastest 50 percent approved for the applications filed during FYs 1999-2001. (253206)

Context: MDUFMA commits FDA to significant improvements in device review performance. This is important to the entire device industry, which is expanding in size and technical complexity. The industry is relying on FDA to take a leadership role in regulating a rapidly emerging frontier of medical device technology with timeliness, quality, scientific consistency, and international harmonization. Most of the device industry is small and rapidly changing. Many small and new start-up firms rely heavily on FDA for guidance and outreach, and the reviews from these firms take extra FDA time and energy.

- About 25 percent of PMAs are for breakthrough technologies; and

- Over 25 percent of PMAs are from first-time submitters.

The area of expedited devices is particularly important because they are the most complex, raise new medical and scientific issues, and FDA often works with first time or small device sponsors. These devices are for uses that have not been approved yet, and could have great clinical impact. Our expedited program is the area where we have the most improvements to make.

Standard PMAs are also for the most complex (Class III) devices, and also have significant clinical impact. For example, a drug-eluting cardiac stent could, if used properly, reduce repeat angioplasty of bypass surgery by 15-30 percent.

Performance: The FDA approval time for the fastest 50 percent of Original PMAs approved for the FY 2003-2005 cohort is 322 days compared to 360 days for the baseline FY 1999-2001 submission cohort.

6. Percentage of an estimated 8,800 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (254101)

Context: This goal will ensure that mammography facilities remain in compliance with established quality standards and improve the quality of mammography in the United States. Under the Mammography Quality Standards Act (MQSA), which was reauthorized in 2004, annual MQSA inspections are performed by trained inspectors with FDA, with State agencies under contract to FDA, and with States that are certifying agencies. State inspectors conduct approximately 90 percent of inspections. Inspectors perform science-based inspections to determine the radiation dose, to assess phantom image quality, and to empirically evaluate the quality of the facility's film processing. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections. FDA also employs an extensive outreach program to inform mammography facilities and the public about MQSA requirements. These include: an Internet website, collaboration with NIH to provide a list of MQSA-certified facilities, and a toll-free facility hot line.

Performance: FDA met this goal in FY 2008 by ensuring that 97 percent of an estimated 8,800 mammography facilities met inspection standards with less than 3 percent level 1 (serious) problems. Inspection data continue to show facilities' compliance with the national standards for the quality of mammography images. Improving the quality of images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. FDA works cooperatively with the States to achieve this goal.

7. Number of domestic and foreign Class II and Class III device inspections. (254201)

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. The FY 2009 target was increased to 1,340 inspections due to FY 2008 Supplemental funding increases

in the Field Devices Program. For FY 2010, the target has been increased to 1,365 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 medical device performance goal of 1,270 by inspecting 1,431 foreign and domestic high-risk Class II and Class III medical device manufacturers.

8. Participation rate of facilities in the MedSun Network. (252201)

Context: FDAMA gives FDA the mandate to replace universal user facility reporting with the Medical Product Surveillance Network (MedSun) that is composed of a network of user facilities that constitute a representative profile of user reports. MedSun is a critical component in increasing the percent of the population covered by active surveillance, which will allow for more rapid identification and analysis of adverse events. FDA will ensure the active participation of 95% of Medsun facilities in FY 2009.

Performance: In FY 2008, FDA expanded actively participating sites in MedSun Network to 98% and maintained a cohort of 350 facilities.

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Expedited PMA Received	3	5	9
Expedited PMA Approved	1	3	8
Expedited PMA – Performance	90%	90%	90%
PMAs Received (PDP and PMA)	30	30	50
PMAs Approved (PDP and expedited)	22	25	45
Original PMA performance	90%	90%	90%
PMA Supplement Panel Tracks Received	7	8	12
PMA Supplement Panel Track Approved	3	6	12
Panel track PMA Supplement performance	90%	90%	90%
Humanitarian Device Exemptions Received	3	6	6
Humanitarian Device Exemptions Approved	2	5	5
Average HDE FDA Review Time (FDA days approval)	534	250	140
PMA Supplements Received	171	150	150
PMA Supplements Approved	141	135	135
510(k)s Received (Trad., Special, Abbrev., 3rd party)	3,848	3,800	3,600
510(k)s Completed (All Decisions)[3]	3,570	3,600	3,500
510(k) performance	80%	80%	80%
Investigational Device Exemptions Received	221	230	230
Investigational Device Exemptions Decisions	219	220	220
% Acted on Within 30 Days	100%	100%	100%
IDE Supplements Received	4,439	4,300	4,300
IDE Supplements (Approved/Total Decisions)	4,395	4,300	4,300
% Acted on Within 30 Days	100%	100%	100%
Total Standards Recognized for Application Review	795	815	830

[3] MDUFMA 510(k) Performance for FY 2008 is incomplete as the cohort remains open.

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***1,996***	***2,322***	***2,404***
Bioresearch Monitoring Program Inspections	289	300	300
Pre-Approval Inspections	60	75	75
Post-Market Audit Inspections	42	58	58
GMP Inspections	1,271	1,476	1,560
Inspections (MQSA) FDA Domestic (non-VHA)	278	334	334
Inspections (MQSA) FDA Domestic (VHA)	31	30	30
Domestic Radiological Health Inspections	90	125	125
Domestic Field Exams/Tests	480	480	480
Domestic Laboratory Samples Analyzed	144	201	201
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***262***	***297***	***329***
Foreign Bioresearch Monitoring Inspections	14	10	10
Foreign Pre-Approval Inspections	38	34	34
Foreign Post-Market Audit Inspections	10	21	21
Foreign GMP Inspections	208	251	288
Foreign MQSA Inspections	15	14	14
Foreign Radiological Health Inspections	11	5	5
IMPORTS			
Import Field Exams/Tests	6,566	8,770	13,180
Import Laboratory Samples Analyzed	1,110	1,141	1,141
Import Physical Exam Subtotal	**7,676**	**9,911**	**14,321**
Import Line Decisions	5,567,469	6,786,886	8,273,385
Percent of Import Lines Physically Examined	0.14%	0.15%	0.17%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,272***	***8515***	***8513***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***71***	***71***	***71***
Inspections (MQSA) by State Contract	7,639	7,382	7,380
Inspections (MQSA) by State non-Contract	620	1,120	1,120
GMP Inspections by State Contract	13	13	13
State Contract Devices Funding	$75,000	$85,000	$120,000
State Contract Mammography Funding	$9,000,000	$9,500,000	$10,000,000
Total State Funding	$9,075,000	$9,585,000	$10,120,000
TOTAL DEVICES INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,601***	***11,205***	***11,317***

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

The FY 2010 program level budget request for the FDA's National Center for Toxicological Research is $58,745,000.

The following table shows a three-year funding history for the National Center for Toxicological Research Program:

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	**$47,402,000**	**$44,443,000**	**$52,511,000**	**$58,745,000**	**$6,234,000**
Center	$47,402,000	$44,443,000	$52,511,000	$58,745,000	$6,234,000
FTE	196	192	198	210	12
Program Level FTE	**196**	**192**	**198**	**210**	**12**
Budget Authority	**$47,402,000**	**$44,443,000**	**$52,511,000**	**$58,745,000**	**$6,234,000**
Center	$47,402,000	$44,443,000	$52,511,000	$58,745,000	$6,234,000
Pay Increase (non add)				*$690,000*	$690,000
Protect America's Food Supply (non-add)				*1,625,000*	1,625,000
Safer Medical Products (non-add)				*$3,919,000*	$3,919,000
Budget Authority FTE	196	192	198	210	12

The FDA's National Center for Toxicological Research 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*
Food and Drug Administration Amendments Act of 2007*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The FDA's National Center for Toxicological Research (NCTR) conducts peer-reviewed scientific research and provides expert technical advice and training that enables FDA to make sound science-based regulatory decisions that improve the health of Americans. The research conducted by the National Center for Toxicological Research provides cutting-edge technology for FDA reviewers and solutions to complex safety issues by closing the gap between discovery and practical application in determining the safety of products for patient use.

* 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.

NCTR receives federal appropriations to execute its mission under the legal authorities highlighted above. NCTR spends all of its resources to conduct scientific research in support of the FDA's mission to bring safe and efficacious products to market and to reduce the risk of adverse health effects.

NCTR was established in 1971 as a national scientific resource to conduct research that translates knowledge and technology into processes that improve the safety-assessment of FDA-regulated products. Through the efforts of highly trained scientists and contract support staff, NCTR conducts fundamental and innovative laboratory research vital to the mission of protecting public health such as:

- developing scientific processes to advance FDA towards personalized medicine (individualized therapy and disease susceptibility)
- identifying early predictors of risk of toxicity of regulated products
- developing, validating, and providing guidance for the regulatory use of new technologies
- providing regulatory tools that facilitate premarket review, postmarket safety assurance, and risk-based product safety decisions
- evaluating the biological effects of potentially toxic chemicals or microorganisms
- providing key research data for high priority safety issues
- performing research in the areas of food safety and food defense
- facilitating expedited development of regulated products 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, and promote the international standardization and global harmonization of regulatory science.

NCTR executes its research responsibilities in three program areas: Personalized Nutrition and Medicine, Food Protection, and Enhancing Product Safety.

<u>Personalized Nutrition and Medicine</u>
Under Personalized Nutrition and Medicine, NCTR aims to define and characterize individual responses to regulated products such as drugs, devices, biologics, cosmetics, and nutrients to improve the health of Americans. While the research strategies of the 20th century yielded data and knowledge that extended our average life span and improved personal and public health, much of that knowledge was based on the average response of a population to a food, nutrient, or environmental chemical or the average risk for carrying a specific allele of a gene involved in a disease. Such knowledge may or may not be applicable to an individual with different genotypes or environmental exposures. Personalization is aimed at changing the public's perception that there are good drugs and bad drugs, to a more accurate impression that certain drugs may work well for certain people, but poorly for others.

NCTR promotes Personalized Nutrition and Medicine by developing a broad range of studies involving systems toxicology assessments to characterize biomarkers of health, disease risk, and disease status. These indicators will aid the FDA in developing science-based individualized treatment therapies that will increase treatment effectiveness and reduce the rate of adverse events in patients. NCTR will explore new approaches such as nutrigenomics to better understand how individual attributes affect responses to drugs, foods, nutrients, and dietary supplements.

Under Personalized Nutrition and Medicine, NCTR supports the Department of Health and Human Services (DHHS) priority of *Personalized Health Care* and FDA's *Critical Path Initiative*. Under these programs, DHHS anticipates being able to dramatically increase the success rate in providing patients with innovative solutions that strike an optimal balance of high benefit and low risk because they are "personalized" making the goal of reducing the pain, suffering, and cost to patients and the healthcare system that result from avoidable drug side-effects more achievable.

NCTR conducts regulatory research to support Personalized Nutrition and Medicine with collaborations in the systems biology realm of research with industry, academia, and within FDA, and has identified a performance outcome related to personalized medicine. NCTR's overall performance to date for FY 2005 through FY 2008, combined with FY 2009 and 2010 goals, indicates NCTR is meeting or exceeding most personalized nutrition and medicine targets. NCTR is developing research strategies that account for genetic, environmental, and cultural diversity that influence expression of genetic make-up and produce knowledge for improving personal and public health. NCTR is also developing classification algorithms for predicting disease and health and is developing a statistical method to identify gender-based biomarkers for both toxicity and efficacy of treatments. NCTR will continue research to define the correlations between an individual's nutrition, health, and genetic profile. These new and innovative projects are conducted with local-community participation. This increased understanding can be used to develop personalized dietary recommendations which may improve the health of individuals and communities.

NCTR accomplishments in FY 2008 support the goal of personalizing nutrition and medicine. A manuscript submitted for publication described the results of a prototype pattern-recognition algorithm that detects normal and anomalous tissue developed from more than 30 non-invasive magnetic resonance spectroscopy (MRS) brain scans. The algorithm was developed to increase the ease and accuracy of interpreting complex MRS scans that are expected to detect early-stage cancers. In 2008, NCTR also expanded the study to include a training set of almost 150 brain scans representing multiple types of tumors and normal scans. Ultimately the goals of these projects are to develop and apply pattern-recognition algorithms to identify early manifestations of brain disease, to classify and grade tumors, and to use the algorithms in other clinical applications such as the detection of breast and prostate cancer markers. These projects are anticipated to lead to improved tumor diagnostic techniques and provide more affordable noninvasive tissue screening for disease.

In 2008, NCTR organized and led the eighth Microarray Quality Control (MAQC) meeting, as part of the second phase of the MAQC project, with participants from across the government, academia, and industry. MAQC I focused on the reproducibility of gene expression experiments and resulted in an FDA companion guidance document for pharmacogenomic data submissions. MAQC II aims to standardize microarray data analysis by building consensus for "best practices" in the development and validation of microarray-based predictive models. It is expected that an FDA guidance document on the appropriate use of microarray genomic data in clinical and preclinical settings will be developed based on findings from the MAQC-II project. More than fifteen manuscripts generated from the MAQC-II project have been submitted for peer-reviewed publication.

NCTR initiated a Community-Based Participatory Research (CBPR) project, in conjunction with the USDA, in the Lower Mississippi Delta as a means to capture and assess individual nutritional, environmental, and activity exposures. The project is being conducted in this area because there is a severe problem with adult obesity and the risk for obesity in children is significantly higher than the national average. The pilot project examined the effect of better nutrition on serum levels of certain vitamins and metabolites in children enrolled in a 2008 obesity prevention summer camp for youth. Data generated can improve the basis of public health policies and inform those interested in developing improved access to food and healthcare in the Delta region.

In addition, NCTR scientists applied their classification algorithms, Classification by Ensembles from Random Partitions (CERP), which integrate data from omics and environmental assessments to identify gender-specific biomarkers for individualized treatment of non gender-specific disease such as liver disease. Ideally, patient treatment should be based on an individual's disease characteristics and risk factors. The identification of gender-specific biomarkers from microarray gene expression data will aid in evidence-based and validated biomedical decision-making.

In 2008, NCTR acquired and installed a high-resolution dedicated positron emission tomography (microPET) instrument in a specialized NCTR Imaging Facility that will be used in preclinical studies on the development of toxicity. This noninvasive imaging tool allows for an increased level of data from animal models and provides a direct link to clinical applications. Biomedical imaging has the potential to play an important role in drug-development processes and the diagnosis of disease in vital organs such as the heart, liver, and brain. Imaging devices that reveal clinical and pharmacogenomic information will individualize medicine both for the diagnosis and treatment of disease, and allow for monitoring the efficacy of treatment regimens.

<u>Food Protection</u>

In support of Food Protection, the public health goals of NCTR are prevention and intervention. NCTR's Food Protection program will develop techniques to *prevent* contamination of the food supply and the environment, and to ensure timely *intervention* strategies by developing rapid, field-ready standards for the early detection of microbial or chemical threats to the food supply. New methods and risk-based techniques continue to

be developed to identify naturally occurring and intentional contamination of the food supply and the environment. To support this goal, NCTR is expanding its capability to identify, assess, rapidly respond to, and reduce food-related health threats.

NCTR develops methods to assess and manage risks associated with food products that have been adulterated, intentionally contaminated, or otherwise found to be detrimental to human health by enabling FDA and other agencies to:

- rapidly determine the source of the contaminant by providing genomic information to the traceback investigation
- closely monitor imported food products contaminated with traditional and non-traditional biological agents that have the potential to cause outbreaks in the U.S.
- more quickly issue health alerts to the state and local public-health agencies in case of an outbreak associated with consumption of contaminated food products
- improve modeling of risk assessment data in present and future food imports.

Under the Food Protection program, NCTR seeks to enhance the nation's healthcare system to respond to bioterrorism and other public health challenges. The program is also directly linked to one of FDA's key initiatives – the *Food Protection Plan*. Through food protection research, NCTR will continue to develop the tools and science necessary to better understand the location of food security vulnerabilities and the most effective ways to minimize them.

NCTR conducts Food Protection regulatory research in collaboration with industry, academia, and within FDA, and has identified a performance outcome related to food protection. NCTR's overall performance to date for FY 2005 through FY 2008, combined with FY 2009 and 2010 goals, indicates NCTR is meeting or exceeding most food-protection targets. NCTR research will lead to the development of methods or strategies to: 1) rapidly distinguish bioterror hoax material in samples containing pathogenic and nonpathogenic bacteria, 2) use microarray technology to quickly and inexpensively detect antibiotic resistance markers in *Salmonella*, and 3) reduce the frequency of multidrug-resistant microorganisms and key pathogens in the U.S. food supply. The research conducted by the NCTR contributes to FDA's goal of increasing food protection for the public.

NCTR will continue research projects to further evaluate metabolomic and bacterial signatures of drink spoilage in milk. This investment should lead to a better understanding of the interactions between bacteria in milk, which may help to reduce or eliminate organisms that lead to spoilage. NCTR will also continue the development of an integrated genomic knowledge base for *Salmonella* including identification of knowledge gaps and development of projects to address those gaps. The goal is to increase identification and understanding of food vulnerabilities.

In 2008, NCTR investigators developed a cell-based assay method and a biochemical assay to detect and measure the activity of ricin and related toxins in diverse foods such as infant formulas, fruit juices, yogurt cultures, and peanut butter. The assay methods are very

sensitive and detect many cytotoxic agents with food-safety relevance, including the Category B select agents of ricin, abrin, Shiga toxin, the mycotoxin fumonisin B_1, and the toxic transition metal ions cadmium, iron, and copper, that are found in diverse types of food. Applied studies performed using this method showed that ricin is not inactivated by the typical pasteurization conditions used in manufacturing infant formulas and fruit juices. Ultimately, the evolving progress on these studies demonstrates the need to leverage resources to develop technology that extracts toxins from contaminated produce and other solid surfaces.

To support the Food Protection Plan, NCTR completed an Interagency Agreement with USDA and Homeland Security to determine the survivability of *Bacillus anthracis* in processed liquid-egg products which includes whole eggs, egg yolks, and egg whites stored at permissive and non-permissive temperatures. The requirements for survival and inactivation of a surrogate strain of *Bacillus anthracis* (Sterne strain) in these products were determined. Data from this research will be applied to assessing risks resulting from deliberate inoculation of anthrax spores in a high-value food matrix.

In 2008, NCTR scientists applied the NCTR-developed genomic tool, Mitochip, to a mouse model to determine the mechanism by which a weight-loss dietary supplement and natural metabolic stimulant, usnic acid, causes liver toxicity. Usnic acid is an organic compound with antimicrobial properties and has been used as an active ingredient or as a preservative in several consumer products, including creams, toothpastes, mouthwashes, deodorants, shampoos, and sunscreens. Understanding the drug-induced toxic effects on mitochondria in the liver will aid researchers in determining the human risk of exposure to low levels of usnic acid that are present in dietary supplements currently being marketed as antimicrobials.

Recently, NCTR scientists developed a rapid molecular method that can identify multi-drug resistant *Salmonella* from food samples. Recent collaborations with NCTR and the Office of Regulatory Affairs (ORA) on imported seafood *Salmonella* isolates have provided new information on the prevalence of antibiotic-resistant genes. The genetic fingerprinting was helpful in identifying similar strains isolated from different seafood samples, in different countries and years. The Centers for Disease Control (CDC) and Prevention estimate approximately 1.4 million cases of Salmonellosis occur annually in the U.S. causing significant economic loss and substantial morbidity. This study provides an understanding of the frequency and mechanism of antibiotic resistance in imported seafood products and enhances the FDA's mission to increase safety in the food supply domestically and abroad.

In 2008, NCTR determined that human intestinal microflora play a key role in the metabolism of azo dyes used in cosmetics, food products, textiles, plastics, and pharmaceuticals. The metalobolism of azo dyes by the human body is important because some azo dyes are known carcinogens. The study found that the human intestinal microflora are capable of degrading azo dyes found in contaminated foods and toxic aromatic amines, which is a potential danger to the American public. This information allows FDA scientists to gain a clearer understanding of how food contaminants affect the

intestinal microflora and how changes in the microflora may affect human health. It also provides the FDA with new information to consider when assessing the risk of azo dyes in food products.

Enhancing Product Safety

Under Enhancing Product Safety, NCTR scientists conduct customized bioassessments of regulated products. The goals of Enhancing Product Safety are to translate toxicity data into a comprehensive risk-based evaluation and to develop reliable and reproducible techniques for conducting safety assessments of FDA-regulated products. Quantitative evaluation of animal data is extrapolated to humans to establish a safety assessment for regulated products. These studies bridge the gap between laboratory studies and practical application, leverage new technologies, and support collaboration with industry and academia to speed and strengthen the process of regulatory decision-making.

NCTR regulatory research in support of Enhancing Product Safety expanded the integration of animal and human data in providing improved risk assessment and has identified a performance outcome related to enhancing product safety. This supports the critical path initiative to establish new scientific tools, especially in the area of bioinformatics. NCTR's overall performance to date for FY 2005 through FY 2008, combined with FY 2009 and FY 2010 goals, indicates NCTR is meeting or exceeding most targets towards enhancing product safety. NCTR research will allow FDA to increase the number of safe and effective new products available to the public by integrating new technology and standards into the review and evaluation of FDA-regulated products at all stages of the product lifecycle.

In support of the goal to Enhance Product Safety, NCTR is conducting ongoing research on the pediatric anesthetic, ketamine, in collaboration with CDER. Ketamine is in a class of anesthetic compounds that cause neurodegeneration when administered during development in rodents. To determine the clinical relevance of the rodent studies, scientists are evaluating the neurological effects of ketamine use in developing nonhuman primates, an animal model closely related to the human infant. Ketamine-treated animals are being assessed to determine the level of safety during all stages of pregnancy and early childhood development. Obtaining data on the relationship of dose-level and anesthesia duration to cell death and the permanency of damage to brain cells, will provide pivotal information for assessing the potential public-health risk associated with the pediatric use of agents such as ketamine and other anesthetic agents. The results from these studies are not only providing fundamental insight into normal developmental processes, but are also providing important data to guide pre- and post-market regulatory decisions and guidance for future pre-clinical and clinical studies. NCTR will continue to develop noninvasive techniques using imaging systems to determine if the use of anesthetics in children is associated with memory and learning deficits or other changes in the central nervous system. Development of these techniques will help FDA better understand the risks and benefits of anesthetic use in children that can lead to improved guidelines.

NCTR has made large strides in establishing itself as the core source of nanotechnology knowledge for the FDA. NCTR will support nanotechnology studies with the newly

created NCTR/ORA Nanotechnology Core Facility (NCF) by providing analytical support, materials characterization, and electron microscopy support. Critical equipment purchases have been made and NCTR will be hiring one additional FTE, an electron microscopy technician. By conducting this research, FDA will have a better understanding of the consequences of human exposure to nanoscale materials so that FDA may provide guidelines for the safe and effective use of these materials in regulated products.

In FY 2008, NCTR implemented the Science Training and Exchange Professional (STEP) Development Program to facilitate and strengthen the sharing of scientific expertise, tools and technology across the FDA Centers through short-term training or research. In its first year of the program NCTR accepted 12 scientists from CDRH, CVM, CFSAN, and ORA. This short-term training and exchange program is designed to enhance the professional development of Agency scientists through hands-on training, encourage the exchange of technical information on new laboratory methods and technologies, and foster networking and collaborations.

NCTR also established a secure, digital-imaging and software system to be used in the formal peer review of Good Lab Practices (GLP) studies. This virtual-pathology environment significantly reduces procedural costs and facilitates the organization of global professionals producing the most expert and timely reviews possible. Using advanced digital scanners, computer networks, and sophisticated software, it is possible to make high-resolution, high-quality images of samples and send them anywhere in the world for analysis within hours rather than days. This new digital pathology technology implemented at NCTR and featured in "*Government Health IT*," enables military doctors, government scientists, and university researchers to speed diagnoses and save lives.

NCTR scientists are actively working with the CDER genomic group to review genomic data from Voluntary eXploratory Data Submissions (VXDS) using ArrayTrack™. A manuscript titled "ArrayTrack™ – An FDA and Public Genomic Tool" has been submitted describing the role of ArrayTrack™ in FDA's VXDS program. NCTR will develop a prototype that integrates an agency-wide bioinformatics data warehouse (Janus databases) with analytical tools such as ArrayTrack™ and SNPTrack in FY2010 to manage and analyze omic data voluntarily submitted through the VXDS process by industry. Because Janus is based on the same model typically used for electronic healthcare records and clinical data repositories, this information can be integrated with the VXDS data and analyzed to enable earlier detection of adverse events and to foster personalized nutrition and medicine. An efficient and integrated bioinformatics infrastructure within the agency is essential to review and understand how sponsors reach their biological conclusions and to ensure the incorporation of omics data into regulatory processes. ArrayTrack™ provides this infrastructure so that the data analysis and interpretation process is simplified and enhanced, enabling FDA to realize the public health benefits of genomic data.

In 2008, NCTR scientists developed Mold2, a software package freely available to the scientific community that rapidly calculates a large and diverse set of molecular descriptors encoded with two-dimensional chemical structure information. Comparative analysis of Mold2 descriptors with those calculated from commercial software on several published

datasets demonstrated that Mold2 produced more predictive models. Predictive modeling can reduce the likelihood that companies will develop a drug compound that fails in animal toxicology studies late in the product-development phase after a large investment of FDA and pharmaceutical resources has been spent. This important decision-support tool allows for improved predictive toxicology that can lead to significant savings of time and money for both the pharmaceutical industry and the FDA, limited testing on animals, and increased safety and effectiveness of new products available to the American public.

Five Year Funding Table

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	FTE
FY 2006 Actual	$40,739,000	$40,739,000	190
FY 2007 Actual	$42,056,000	$42,056,000	183
FY 2008 Actual	$44,443,000	$44,443,000	192
FY 2009 Omnibus	$52,511,000	$52,511,000	198
FY 2010 Estimate	$58,745,000	$58,745,000	210

Budget Request

The FY 2010 President's Budget request for NCTR is $58,745,000. It is an increase of $6,234,000 above the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009. Base funding for the NCTR supports research in each of NCTR's three program areas of Personalized Nutrition and Medicine, Food Protection, and Enhancing Product Safety. The goal of these program areas is to enable FDA to make sound science-based regulatory decisions and improve the health of the American people.

In the Personalized Nutrition and Medicine program area, new methods for establishing gender-related biomarkers critical to evaluating efficacy and toxicity of individualized treatments for diseases that are not gender-specific will be developed. The ultimate goal of this biomarker research is the development of a user-friendly classification software tool available to the research community. Community-based participatory research is another important area in this program that focuses on identifying the correlation between an individual's nutrition, genetic profile, health, and susceptibility to chronic disease. The increased understanding of gender-specific biomarkers and gene-environment interaction will aid in the proper treatment and management of disease and advance the development of effective and safe medications, dosing regimens, and dietary guidelines that are tailored to an individual's genetic make-up.

In the Food Protection program area, techniques are developed to help prevent and detect both accidental and intentional food contamination. A primary goal of Food Protection research is to develop faster and easy-to-administer methods for earlier detection of microbial or chemical contaminants in the American food supply. This initiative will allow FDA to increase its prevention and remedy of food contamination by arming reviewers and industry with an arsenal of faster microbial detection methods and techniques.

In the Enhancing Product Safety program area, studies will be initiated to identify biomarkers of exposure and toxicity resulting from the use of nanomaterials such as the heavy metal manganese in a wide spectrum of applications including medical diagnostic and treatment equipment. These studies will focus on the effects of these materials on developing neurological systems. This will enable FDA to gain a better understanding of health and safety issues related to the use of nanomaterials. The nanotechnology research will provide a framework for regulatory guidelines for the safe and effective use of nanomaterials in FDA-regulated foods, cosmetics, and medical products. NCTR will continue to conduct studies to understand the toxicological and biological impact of animal exposure to nanomaterials. It is important for FDA to understand the toxicological consequences of the administration of nanoscale drugs, intentional exposure to nanoscale devices, and unintended exposure to nanoscale materials. Improved understanding of nanomaterials, their transport, and their toxicity will provide a framework for regulatory guidelines for safe and effective use of nanomaterials to provide early recognition of potential safety issues before they become adverse events. FDA has already reviewed and approved some nanotechnology-based products, and expects a significant increase in the number of nanoscale materials in drugs, devices, biologics, cosmetics, and food.

National Center for Toxicological Research (NCTR) Performance Measures Table

Long Term Objective: Provide consumers with clear and timely information to protect them from foodborne illness and promote better nutrition.

Measure	FY	Target	Result
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)*	*2010*	Interpret data collected in the Delta Vitamin Obesity Study	December 2010
	2009	N/A	N/A
	2008	N/A	N/A

Long Term Objective: Increase the number of safe and effective new medical products available to patients.

Measure	FY	Target	Result
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)*	*2010*	1) Demonstratable tool to use in the drug-review process based upon the liver toxicity knowledge base 2) Develop translatable biomarkers for studying pediatric products (e.g. ketamine, methylphenidate)	December 2010
	2009	Analyze imaging data by application of pattern-recognition algorithms to other tissues and diseases	December 2009
	2008	1) Omics data in the review process 2) Determine limitations of the algorithms (e.g. staging disease)	1) 7 VXDS submissions reviewed using omics tools (Target Met) 2) Algorithm able to classify four disease categories (Target Met)
	2007	1) Systems biology in drug review 2) Proof-of-principle that pattern recognition can supplement MRS brain scan interpretation	1) Urinary biomarkers for kidney failure (Target Met) 2) AZT effects on mitochondria (Target Met) 3) Prototype algorithm was successfully developed from 30 MRS brain scans (Target Met)
	2006	N/A	Hepatotoxicity of Type 2 diabetes drugs (Target Met)

Measure	FY	Target	Result
	2005	N/A	1) Biomarkers of liver toxicity (Target Met) 2) PPAR effects on liver-gene expression (Target Met) 3) Age-related changes in gene expression (Target Met)
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. *(Output)*	*2010*	Add metabolomics module to ArrayTrack™	December 2010
	2009	Expand ArrayTrack™	December 2009
	2008	Bioinformatics data package	SNPTrack Version 1 developed (Target Met)
	2007	Utility of Array Track™ and training for reviewers	1) JMP® and ArrayTrack™ integration (Target Met) 2) Regulatory training on ArrayTrack™ (Target Met)
	2006	Interpret DNA study using ArrayTrack™	Microarray studies on nutritional supplements, comfrey and aristolochic acid. (Target Met)
	2005	Develop a computer-based system to integrate databases, libraries and analytical tools	ArrayTrack™ implemented (Target Met)

Long Term Objective: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

Measure	FY	Target	Result
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. *(Output)*	*2010*	Validate SOPs for detection of nanoscale materials in FDA-regulated products in collaboration with ORA/ARL	December 2010
	2009	Operational joint NCTR/ORA Nanotechnology Core Facility	December 2009

Long Term Objective: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

Measure	FY	Target	Result
264101: Develop risk assessment methods and build biological dose-response models in support of Food Protection. *(Output)*	*2010*	1) Rapid detection toolkits for foodborne pathogens applicable to fresh produce; evaluate in field situations 2) Begin research on Bisphenol A (BPA), a component in baby bottles and formula containers	December 2010

Measure	FY	Target	Result
	2009	1) Rapid pathogen detection 2) Antibiotic resistance markers	December 2009
	2008	Ricin screening assay	Cell-based assay and PCR-based biochemical assay developed (Target Met)
	2007	Flow cytometry technology	1) Test kits and methods for pathogens (Target Met) 2) Additional *Salmonella* biochip (Target Met)
	2006	N/A	Method to screen 131 antibiotic resistance markers (Target Met)
	2005	N/A	*Salmonella* biochip (Target Met)

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure	FY	Target	Result
264201: Develop standard biomarkers to establish risk measures for FDA-regulated products. (Output)	2010	1) MAQC—draft guidance document for microarray standards 2) Identify gender-specific biomarkers that enable improved risk/benefit decisions for treatments	December 2010
	2009	Biological effects of manganese nanoparticles	December 2009
	2008	Microarray data standards	MAQC-II results are in and 15 manuscripts on track for March 2009 submission (Target Met)
	2007	Carbon nanomaterials methods and ketamine research	1) Ketamine-induced neurotoxicity in primate model (Target Met) 2) Synthesis methods for nanotubes (Target Met)
	2006	N/A	1) Behavioral effects of acrylamide (Target Met) 2) Concurrent neuropathological analysis (Target Met)
	2005	N/A	1) Neuro-imaging in nonhuman primates (Target Met) 2) Data from PET technology (Target Met)

1. 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. (262401)

Context: NCTR's goal is to define the correlations between an individual's nutrition, health, and genetic profile. This research will provide baseline data that supports the FDA goal of providing consumers clear and timely information to help promote personalized nutrition and health. Identifying biomarkers of health, susceptibility to chronic disease, and gene-micronutrient interactions is essential to gaining a more complete scientific understanding of health. NCTR is implementing a novel research program for personalized nutrition and health that relies on the "challenge homeostasis" concept for identifying markers of health and susceptibility. This approach implements a safe, but acute, challenge to the body's ability to regulate and maintain balance. NCTR will use its current omics capabilities, in conjunction with its expanded genomic analyses capabilities, to conduct this research. The intervention design proposed by NCTR establishes a model that may be used by the emerging International Micronutrient Genomics Project that will compare gene-micronutrient interactions across populations and cultures.

Performance: The NCTR Division of Personalized Nutrition and Medicine (DPNM) developed a community-based participatory research strategy for personalizing healthcare. The approach is to analyze genetic and nutrition interactions involved in the predisposition, development, and severity of obesity. The Delta Vitamin pilot study was conducted in 2008 at the Boys, Girls, and Adults Community Development Center Summer Camp in collaboration with the USDA–Agricultural Research Service Delta Obesity Prevention Research Unit. This study introduced the concept of biomedical research to the local community. The research compared the participating children's serum vitamin levels before and after a five week improved diet of healthier foods. The proposed research program for the 2009 Delta Vitamin Study expands the study to include genetic and metabolomic analyses of the local community participants. The FY 2010 goal is to begin to define the correlations between an individual's diet and genetic profile to develop personalized dietary recommendations which may improve the health of individuals and communities.

2. 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. (263101)

Context: With the advent of new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, and the expanding capabilities of noninvasive imaging technologies, FDA has the necessary tools to detect disease at an earlier stage and to better understand how an FDA-regulated compound or product interacts with the human body. The accelerated rate at which technological advances are being made in the marketplace dictates that FDA accelerate its rate of innovation in the regulatory-research arena. Combining genomic knowledge with microPET imaging is expected to facilitate the search for genetic predictors of drug response. Devices such as microPET that reveal clinical and

pharmacogenomic information will serve to individualize medicine both for the diagnosis and treatment of disease, and allow for monitoring the efficacy of treatment regimens.

Performance: In FY 2008, NCTR scientists expanded a pattern-recognition algorithm that was developed to increase the ease and accuracy of interpreting complex magnetic resonance spectroscopy (MRS) scans from more than 30 brain scans to include a set of almost 150 brain scans. In FY 2009, the goal is to develop and apply pattern-recognition algorithms to identify early biomarkers of brain disease and to use algorithms to analyze imaging data of other tissues and diseases such as breast and prostate cancer. NCTR's FY 2010 goal in this area, to develop translatable biomarkers for studying pediatric products, is especially critical as advances in pediatric and obstetric surgery have resulted in an increase in complexity, duration, and number of anesthetic procedures. To minimize risks to children resulting from the use of anesthesia, it is necessary to understand the effects of anesthetic drugs on the developing nervous system by determining the time-course of neuronal-cell death induced by ketamine administered repeatedly in living animals. NCTR will conduct studies using noninvasive microPET imaging to determine clinical relevance to the pediatric population.

3. Develop computer-based models and infrastructure to predict the health risk of biologically active products. (263102)

Context: To effectively support large datasets generated using new technologies such as toxicoinformatics, proteomics, metabolomics, and genomics, NCTR scientists develop and enhance scientific analytical software in collaboration with colleagues from government, academia, and industry to advance the incorporation of this data analysis into the regulatory process. NCTR's key objective is to develop computer-based models and infrastructure to predict the health risk of biologically active products. ArrayTrack™ is software invented by NCTR scientists that allows for the management, analysis, and interpretation of vast amounts of omics data, and is an important tool for the American public to benefit from the vast amount of bioinformatic data being generated from the new technologies. The expanded use of ArrayTrack™ and other bioinformatic tools allows FDA to support the rapid translation of scientific research into reliable and safer treatments, and better risk evaluations by improving the analysis and management of available data**.**

Performance: In FY 2008, NCTR developed a bioinformatics infrastructure, SNPTrack Version 1, for genotyping-data management, analysis, and interpretation which has been used in VXDS reviews. The FY 2009 and FY 2010 goals to expand ArrayTrack™ to accommodate the analysis of other omics data such as proteomics and metabolomics will even further simplify and enhance FDA's data analysis and review process. Another important accomplishment in FY 2008 is the selection of ArrayTrack™ by Eli Lilly for their clinical gene-expression data storage and baseline analysis. ArrayTrack™ was chosen as Eli Lilly's data management and analysis tool because of its architectural structure, quality, security, and its ability to support their gene-expression studies.

4. Develop science base for supporting FDA regulatory review of new and emerging technologies. (263201)

Context: NCTR's goal to develop a science base to support the FDA regulatory review of new and emerging technologies by establishing a joint NCTR/ORA Nanotechnology Core Facility will strengthen the FDA's ability to prevent potential health-endangering products from entering the marketplace. It is anticipated that NCTR's nanotechnology research program will expand as the number of nanoscale products the regulated community seeks to market increases. The FDA has already reviewed and approved some nanotechnology-based products, and expects a significant increase in the use of nanoscale materials in drugs, devices, biologics, cosmetics, and food. Improved understanding of nanomaterials, their transport, and their toxicity will provide a framework for regulatory guidelines for safe and effective use of nanomaterials in FDA-regulated foods, cosmetics, and medical products and provide early recognition of potential safety issues before they become adverse events in the patient population.

Performance: In FY 2008, NCTR identified collaborations, funding, and resource requirements to facilitate the establishment of the NCTR/ORA Nanotechnology Core Facility. NCTR is currently conducting studies in FY 2009, which will extend into FY 2010, to understand the toxicological and biological impact of animal exposure to nanomaterials. It is important for FDA to understand the toxicological consequences of the administration of nanoscale drugs, intentional exposure to nanoscale devices, and unintended exposure to nanoscale materials. Research plans in this area for FY 2010 include studies to quantify the migration of nanosilver from food-contact materials, and determine the conditions under which migration will occur.

5. Develop risk assessment methods and build biological dose-response models in support of Food Protection. (264101)

Context: To address research needs and build the FDA's capability to assess and reduce food-related health threats, NCTR researchers evaluate key regulatory issues of food safety, conduct multidisciplinary studies to develop risk-assessment methods, and develop biological dose-response models vital to food security. Identifying the prevalence of antibiotic-resistant genes and the genetic fingerprinting of these genes will help identify similar strains isolated from different samples. Another food-related health threat, especially for infants and children, is the presence of Bisphenol A (BPA), an endocrine disruptor that can mimic hormones and a compound used in a wide variety of household items including baby bottles, drinking bottles, and liners for canned food. NCTR will be initiating studies in collaboration with the NIEHS National Toxicology Program to address the health concerns associated with exposures to low doses of BPA during critical periods of perinatal development. Effects reported include alterations in central nervous system (CNS) anatomy, lesions in prostate and mammary glands, urinary tract abnormalities, and the early onset of puberty.

Performance: NCTR will support the implementation of the Food Protection Plan by hiring five researchers and providing equipment to develop test systems for neurotoxins

(including Class B select agents) and develop tests to rapidly identify and characterize strains of the foodborne microbial pathogen *Salmonella*. NCTR's development of a ricin-screening assay and a PCR-based biochemical assay in FY 2008 resulted in three manuscripts being submitted for publication and five presentations given at national meetings, including the annual Society of Toxicology meeting in March 2008. Both assay systems developed at NCTR will be applied in FY 2009 to validate new technologies for rapid identification of contaminants and intervention strategies to reduce threats to human health. In FY 2010 NCTR will work toward the development of rapid- detection toolkits for foodborne pathogens. The goal is for these toolkits to be applicable to fresh produce and also be usable in the field. These goals and the goal to identify antibiotic-resistant markers will allow the FDA to reduce the spread of foodborne outbreaks and enable the development of intervention strategies to reduce the frequency of multi-drug resistant pathogens in the U.S. food supply.

6. Develop standard biomarkers to establish risk measures for FDA-regulated products. (264201)

Context: NCTR's research to develop standard biomarkers to establish risk measures for FDA-regulated products prevent potential health-endangering products from remaining in and continuing to enter the marketplace. NCTR's research increases the number of safe and effective medical products available to the public by integrating new automated tools and standards into the review and evaluation of FDA-regulated products at all stages of the product lifecycle. FDA's ability to identify gender-specific biomarkers will provide improved risk/benefit decisions for treatments. The resulting treatments that focus on specific population needs will help provide personalized nutrition and medicine to the American public. By increasing the understanding of the biological effects and toxicity of nanomaterials, FDA will be able to identify biomarkers of toxicity, thus providing early recognition of potential safety issues before they become adverse events in the general population. In addition, the regulatory guidelines for nanomaterials will assist industry in identifying the most promising uses of this technology resulting in more cost-effective product development.

Performance: In FY 2008, NCTR organized and led the eighth Microarray Quality Control (MAQC) meeting as part of the second phase of the MAQC project, which is focused on the reproducibility of gene expression experiments and the standardization of microarray data analysis. A document outlining "best practices" in the development and validation of microarray-based predictive models, published in 2008, will provide the research and regulatory communities with a foundation to confidently use microarrays in clinical practice and regulatory decision-making. The goal of this project is to ensure that accurate and reliable predictions can be made based on an individual's microarray profile and that companies will bring more effective diagnostic tools to market. It will also help in the FDA review process as more array-based data is included with industry's voluntary exploratory data submissions (VXDS). The FY 2009 goal to study the biological effects of manganese nanoparticles will help FDA to understand the toxicological consequences of exposure to nanomaterials. The FY 2010 goal in this area, to identify gender-specific biomarkers that enable improved risk/benefit decisions for treatments, is expected to substantially reduce error rates when compared to using standard biomarkers which apply to both sexes.

NCTR Program Activity Data (PAD)

NCTR WORKLOAD AND OUTPUTS	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
Research Publications	125	155	155
Scientific Presentations	165	180	180
Patents (Industry)	5	6	6
Leveraged Research			
Federal agencies (Interagency Agreements)	6	9	9
Nongovernmental organizations (CRADAs)	21	22	22
Active Research Projects			
Personalized Nutrition & Medicine	59	78	62
Food Protection	51	54	52
Enhancing Product Safety	64	57	47

FIELD ACTIVITIES – OFFICE OF REGULATORY AFFAIRS

Introduction

The FY2010 program level budget request for FDA's Field Activities – Office of Regulatory Affairs (ORA) Program is $953,731,000.

The following table shows a three-year funding history for the Office of Regulatory Affairs Field activities:

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals			
Program Level	**$650,712,000**	**$573,181,000**	**$725,115,000**	**$953,731,000**	**$228,616,000**
FTE	3,552	3,314	3,775	4,336	561
Budget Authority	**$626,646,000**	**$555,450,000**	**$699,611,000**	**$848,404,000**	**$148,793,000**
Pay Increase (non add)				*12,856,000*	*12,856,000*
Protect America's Food Supply (non-add)				*$107,952,000*	*$107,952,000*
Safer Medical Products (non-add)				*$26,986,000*	*$26,986,000*
Drug Importation (non-add)				*$1,000,000*	*$1,000,000*
Budget Authority FTE	**3,485**	**3,258**	**3,706**	**3,977**	**271**
User Fees	**$24,066,000**	**$17,731,000**	**$25,504,000**	**$105,327,000**	**$79,823,000**
PDUFA	$10,178,000	$7,259,000	$10,478,000	$11,795,000	$1,317,000
FTE	50	40	50	59	9
MDUFMA	$1,434,000	$1,230,000	$1,556,000	$1,556,000	$0
FTE	9	8	8	11	3
ADUFA	$0	$0	$250,000	$250,000	$0
FTE	0	0	2	2	0
AGDUFA			$143,000	$143,000	$0
FTE			1	1	0
MQSA	$12,454,000	$9,242,000	$13,077,000	$13,077,000	$0
FTE	8	8	8	8	0
Proposed User Fees	**0**	**0**	**0**	**$78,506,000**	**$78,506,000**
Generic Drugs				$6,045,000	$6,045,000
FTE				12	12
Reinspection				$14,446,000	$14,446,000
FTE				112	112
Export Certification				$3,015,000	$3,015,000
FTE				19	19
Inspection and Facility Registration				$55,000,000	$55,000,000
FTE				135	135
User Fees FTE	**67**	**56**	**69**	**359**	**290**

Authorizing Legislation:

ORA operates under the following legal authorities that allow the Office of Criminal Investigations (OCI) to conduct criminal investigations, execute Search Warrants, make arrests, and carry firearms:

1944 – Public Health Service Act (42 USC 262)*
1965 – Food, Drug, and Cosmetic Act (21 USC 372)*
1983 – Federal Anti-Tampering Act (18 USC 1365)*
2007 – Food and Drug Administration Amendments Act (21 USC 505)*

Allocation Method: Direct Federal/intramural; contract

Program Description and Accomplishments

The FDA's Office of Regulatory Affairs is the lead office for all FDA Field activities as well as providing FDA leadership on imports, inspections, and enforcement policy. ORA's Field Program supports the five FDA Product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement, executes FDA's Import Strategy and Food Protection Plans, and directs and coordinates FDA's emergency preparedness and response programs.

ORA supports 4,366 FTE that are dispersed throughout the United States. Over 85 percent of ORA's staff works in 5 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, which are located throughout the U.S. FDA maintains offices and staff in Washington, D.C., the U.S. Virgin Islands, Puerto Rico, and in all States except Wyoming.

Besides executing its mission through its Federal workforce, ORA also works with its State, Local, Tribal, and Territories counterparts to further FDA's mission. ORA funds grants and cooperative agreements to perform State inspections and provide technical assistance to the States 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) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT

*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.

projects and resources in 2008, OIM supports the Regulatory Affairs Program by maintaining its legacy systems and databases used for managing and tracking its review programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Regulatory Affairs Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

While ORA's Field Programs are presented in the five product programs (Foods, Drugs, Biologics, Animal Drugs and Feeds, and Devices and Radiological Health), the ORA program description and accomplishment section will highlight several ORA's cross-cutting areas addressing imported products, enforcement activities, leveraging with the States, public health emergencies, and laboratory capability.

Assuring the Safety of Imported Products – Field Activities

ORA coordinates import activities with the Department of Homeland Security's Customs and Border Protection (CBP) Agency. The number and complexity of FDA-regulated imported products is increasing exponentially. Even if security concerns were not taking an ever increasing role, this would challenge FDA's ability to provide an appropriate response. In FY 2010, FDA projects a total of 20.5 million import lines, which will be comprised of 47 percent food products, 9 percent cosmetic products, 2 percent human drugs and biologic products, 1 percent animal drugs and feed products, and 41 percent medical device and radiological health products. ORA uses a combination of electronic information technology for risk-based screening and staff intensive surveillance, physical examinations, and laboratory analysis to make import entry decisions.

ORA conducted 5,926 import field examinations of FDA refused entries in FY 2008. These are performed to ensure that FDA refused articles are being exported to eliminate the potential of these goods making their way into domestic commerce. This is an agency-wide goal and includes activities and resources from all five Program areas.

To support the Field Import Program, the Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. In FY 2008, the PNC performed 80,543 import security reviews on food and animal feed entries considered to be at risk for bioterrorism and/or to present the potential of a significant health risk.

In July 2008, FDA published a Federal Register notice seeking volunteers for a pilot program regarding third-party certification of aquacultured shrimp. The objective of the pilot is to assess whether third-party certification can augment FDA's ability to ensure that products imported into the United States meet FDA safety and security standards. In Phase I of the pilot, FDA is evaluating documentation submitted by Certification Bodies wishing to participate in the pilot and visiting their offices to ask follow-up questions and review records. Those Certified Bodies whose programs satisfy criteria specified in Federal Register will move on to Phase II of the

pilot. During Phase II, FDA will observe the Certified Bodies as they inspect aquacultured shrimp processors and assess the operations of laboratories that sample and test the product before it is shipped. ORA field personnel who are certified as Level 2 Seafood Investigators will visit shrimp processors and ORA Laboratory Analysts experienced in analyzing seafood samples will visit laboratories used by the processors**.** If the pilot establishes that third-party Certification Bodies are able to certify aquacultured shrimp for compliance with FDA requirements, FDA could better target its resources on products from non-certified processors. FDA expects to complete the pilot in FY 09.

OCI has initiated a system to record and track import related criminal cases by noting the country where the product or item was manufactured and the country of shipment. Compiling this data allows OCI to better target investigative efforts and focus limited resources. Since the inception of this tracking system in March 2007 through FY 2008, OCI opened 371 investigations that have an import nexus.

Enforcement of FDA Laws – Field Activities

A strong, effective, and efficient enforcement of FDA laws and regulations is essential to FDA's mission of protecting and promoting public health. OCI was officially established in March of 1992 in response to the growing caseload of criminal activities involving FDA regulated products. The role of OCI is to provide an additional enforcement resource to enhance ORA's regulatory efforts. OCI concentrates its resources on investigations of significant violations of the Federal Food, Drug, and Cosmetic Act and Federal Anti-Tampering Act which pose a danger to the public health.

The following table shows a three-year funding history for OCI:

FISCAL YEAR	TOTAL
2008 (Actual)	**41,309,714**
2009 (Omnibus)	**46,559,507**
2010 (Estimate)	**48,138,768**

In FY 2008, OCI initiated 56 counterfeit drug investigations and had 25 arrests and 45 convictions with fines and restitutions approaching $4,000,000. In addition, OCI continued to coordinate 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 will continue 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 OCI also aggressively investigates potential criminal violations regarding the nation's food supply. During 2008, OCI initiated 140 food safety related cases and had 48 arrests and 61 convictions. An example of such a case occurred in FY 2008, when a dairy farmer in Louisiana

pled guilty to distributing adulterated milk. The OCI investigation disclosed that the farmer added salt and water to milk that was then sold to the Dairy Farmers of America (DFA). Adding the water and salt to the milk made the load heavier, which caused DFA to pay more for the adulterated milk. Another case involved a Florida business owner who was sentenced to 15 months incarceration and ordered to pay a $5,000 fine for distributing adulterated and misbranded foods such as lobster dip, salmon cream cheese, chicken salad, salmon spread, and others which contained the harmful bacterium listeria monocytogenes.

Leveraging With the States – Field Activities

ORA awards and manages State contract programs that provide resources to States to conduct inspections and report their findings to FDA. These contract programs benefit States with technical training, familiarity with federal requirements, and more uniform enforcement of consumer laws through cooperation and coordination with FDA. The State contract program has food safety contracts with 40 States and allows ORA to increase inspectional coverage and redirect resources to other priority activities.

ORA awarded 218 contracts/grants and Cooperative Agreements to State and local governments to perform MQSA, feed/BSE, tissue residue, food, and medical device inspections and Food Emergency Response Network (FERN) laboratory projects. Twenty five States are enrolled in the Manufactured Food Regulatory Program Standards (MFRP) initiative, which strengthens their food safety programs by striving toward standardization and equivalency. To better share inspection data with our State partners, ORA made its electronic State Access to FACTS (eSAF) database available to all 41 State food programs and conducted training for FDA and State personnel to learn the system. In addition, 36 States share the eSAF data base in the BSE program. These efforts improve eSAF's ability to communicate with State IT programs so that ORA can access all available State inspection data rather than being limited to contract inspection data. State inspection data complements FDA's food protection efforts and today over 10,000 State food contract inspections have been added into the eSAF system.

Training remains a top priority of the Field to ensure expertise and encourage collaboration with external stakeholders. In FY 2008, one hundred thirty nine (139) courses were conducted with more than 3,731 participants. Courses were offered to FDA, State, local, tribal and Indian Health Service regulators in the following commodity areas: Biologics; Bioresearch; Compliance; Computers; Devices; Drugs; Food; Imports; Laboratory; Management; Multi-program areas; and Veterinary Medicine. In addition, innovative video conference technology was used to connect three different States with six different locations for a three day training event. A three-year contact with the Western Institute of Food Safety and Security (WIFSS) at the University of California/Davis went into effect during FY08 for the development and maintenance of food and feed Rapid Response Teams (RRT) composed of States and their corresponding FDA District Office personnel. A draft team development and training plan has been created along with components of the curriculum, model Standard Operating Procedures (SOPS) to assist RRT development, and self assessment tool to be rolled out as a permanent part of the program. The first teams to be trained under this model will be the six states and districts involved in pilot RRT cooperative agreements awarded in fiscal year 2008. After this pilot, the (RRT) process is expected to be introduced to the other States and their FDA District Offices.

Response to Public Health Emergencies – Field Activities

ORA is working to increase FDA presence beyond our borders by opening offices in other countries and implementing Memorandums of Agreements with other countries. ORA conducted an international investigation to identify and determine the source of an unknown contaminated in Heparin Sodium USP, the active pharmaceutical ingredient in a critical drug compound used in 1,000s of US medical facilities for a host of medical procedures. Through forensic techniques, the contaminate was identified as over-sulfated chondroitin sulfate. Multiple drug and device recalls involving approximately 74 million vials/syringes were conducted by several firms as a result of this investigation. The contaminated product was imported as an API from China and used by several different domestic manufacturers. The investigation of the cause and source of the contamination included both domestic and foreign investigations. The investigation prompted recalls which ensured that distribution of contaminated product was halted, thereby preventing additional patient exposure to contaminated product and established needed standards for manufacturers to insure that their API sources were free of contamination.

Enhancing ORA Laboratory Capability – Field Activities

The laboratory analytical function of ORA is conducted in 13 laboratories located throughout the country. The ORA laboratory structure consists of five Regional Labs, four District Labs, and four Specialty Labs. Regional Labs are large general purpose laboratories that participate in most major analytical programs. District Labs participate in several analytical programs and have specialties in specific areas. Specialty labs conduct analyses in specific areas of laboratory service including; engineering, biological, and chemical hazards associated with medical devices, electronic products, and radiopharmaceuticals; and, forensic analysis of samples related to criminal activities that fall under FDA jurisdiction; including drug counterfeiting.
ORA made improvements to laboratories and regulatory science during FY 2008 including developing, manufacturing and implementing the Alternative Light Source (ALS), a Field analysis kit used to conduct visual examinations to aid in screening and sampling of suspected counterfeit drug products. Preliminary results generated by ALS Field analysis help to streamline and better prioritize lab analyses. ORA also implemented a computerized National Sample Distributor system (NSD) that analyzes laboratory capacity and routes a sample to the laboratory with the capacity and capability for analysis. The NSD directed over 35,000 samples in FY 2008, and has improved lab facility usage overall and efficiency in analytical response to emergencies, outbreak, consumer complaints as well as routine import and domestic sample collections.

To complement the analytical work of FDA labs, 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 focused on building both capacity and capability at the State and local level by expanding to 151 laboratories representing 50 States and Puerto Rico. Three Chemical Cooperative Agreements were awarded to State FERN laboratories to begin in FY2009, adding to the eight already underway.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs during the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for both political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of State, local and tribal regulatory bodies.

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. In FY 2008, FERN laboratories added capacity for 2,500 radiological samples per week and maintained 1,200 chemical samples per week.

Five Year Funding Table

The following table shows a five-year funding history for the Office of Regulatory Health program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$499,853,000	$482,361,000	$17,492,000	3,460
FY 2007 Actual	$522,658,000	$505,753,000	$16,905,000	3,290
FY 2008 Actual	$573,181,000	$555,450,000	$17,713,000	3,314
FY 2009 Omnibus	$725,115,000	$699,611,000	$25,504,000	3,775
FY 2010 Estimate	$953,731,000	$848,404,000	$105,327,000	4,366

Budget Request

The FY 2010 President's Budget requests $953,731,000 in program level funding for the Office of Regulatory Affairs (ORA), including the support of 4,366 FTE. The request represents an increase of $228,616,000 (or thirty-two percent) over the FY 2009 Appropriation in budget authority and user fee amounts. The overall increase provides additional budget authority to implement Agency-wide initiatives established in FY 2009 aimed at improving prevention, intervention, and response activities. Such activities include targeted increases aimed at improving the safety of FDA-regulated food, feed, and medical products in order to protect consumers by minimizing associated risks.

Protect America's Food Supply

The FY 2010 budget request for the Field Food Protection Program is $107,952,000, which includes a $100,733,000 increase in the Field Foods Program and a $7,219,000 increase in the

Field Animal Drugs and Feeds Program over FY 2009 Budget Authority funding levels. This request will allow ORA to continue to provide technical assistance to foreign countries, establish a presence in foreign countries, and increase laboratory capacity.

Furthermore, ORA is requesting funding in FY 2010 to acquire support and continue building its workforce for more field food and feed work. In order to do so, ORA is requesting budget authority funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work such as:

- Increase of 20,000 food and feed import exams by the end of 2011
- Increase of 2,000 domestic food and feed inspections by the end of 2012
- Increase of 50 foreign food and feed inspections by the end of 2012.

FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners. FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Field Feeds Programs in the following four areas:

- Develop a National Workplan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples;
- Ensure that programmatic objectives and implementation are coordinated;
- Continue to develop uniform, national standards for such subjects as manufacturing, inspections, and enforcement;
- Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners;
- Increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for Federal, State, local, tribal and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

<u>Medical Product Initiatives:</u>
The FY 2010 budget request for the Field Medical Product Safety and Development Program is $26,986,000, which includes a $13,868,000 increase in the Field Drugs Program, a $4,177,000 increase in the Field Biologics Program, a $1,554,000 increase in the Field Animal Drugs Program, and a $7,387,000 increase in the Field Device and Radiological Products Program over FY 2009 Budget Authority funding levels. This request will allow ORA to continue with establishing its workforce for inspections and import exams and to increase laboratory capacity. Specifically, ORA will increase inspections for the Biologics and Devices Programs:

- Increase of 25 domestic tissue inspections and 41 domestic Quality Systems (QS) GMP medical device inspections above the FY 2010 levels by the end of 2012
- Increase of 23 foreign tissue inspections and 41 foreign QS-GMP medical device inspections above the FY 2010 levels by the end of 2012

These inspections are not planned to be completed until 2012 and 2013 because ORA will invest the next one to two years in hiring and training new field staff. For FY 2010, ORA is requesting $1,000,000 for the Field Human Drug Program. This funding will be used to begin to develop a Drug Importation User Fee for FDA.

Cost of Living Pay Increase

The Office of Regulatory Affairs portion of FDA's requested pay increase is $12,856,000 across all five Field Program areas. Without these funds ORA must reduce FTE in order to adequately cover payroll, which will lead to corresponding reductions in inspections and laboratory analyses and decrease FDA's ability to protect the public health.

User Fees Inflationary Increases

The request also includes a total of $11,795,000 in Prescription Drug User Fee Act (PDUFA) inflationary increases for ORA. This is an increase of $1,317,000 over the FY 2009 Appropriation, an increase of $1,186,000 for the Field Human Drugs Program, and an increase in $131,000 for the Field Biologics Program. In September 2007, the President signed FDAAA into law. FDAAA authorized the collection of user fees for the regulatory review of prescription drugs for the fourth time. The PDUFA IV provisions of FDAAA enhance premarket review and give FDA more resources to create a modern postmarket drug safety system that follows products across their full life cycle. For ORA, PDUFA user fees enable the Human Drugs Program to conduct premarket inspections, including bioresearch monitoring inspections.

Proposed User Fees

Generic Drugs User Fee

Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering public and private spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled. This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional $6,045,000 and 12 FTEs by the proposed generic user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

Reinspection and Food Export Certification User Fee

This proposal for $25,848,000 and 129 FTEs in Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. ORA's request is for $14,446,000 and 112 FTE for all field programs. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

The FY 2010 budget also proposes a new user fee to support export certification activities. FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collection user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the FDA in FY 2010 are $4,152,000 with $3,015,000 of the collections being allocated to the Field Foods Program.

Food Inspection and Facility Registration User Fee

The FY 2010 budget proposes a User Fee for Food Inspection and Facility Registration for $75,000,000. This proposal allocates $45,000,000 to the Field Foods Program and $10,000,000 to the Field Animal Feeds Program. Food facilities would be charged user fees for inspections and registration of their establishments. These user fees would fund FDA inspection activities such as an increase in domestic and foreign inspections, an additional 3,000 sample collections and the addition of three high throughput laboratories for sample analysis and faster testing.

Office of Regulatory Affairs (ORA) Performance Measures Table

Long Term Objective: Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.

Measure	FY	Target	Result
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	*2010*	300	December, 2010
	2009	300	December, 2009
	2008	300	301 (Target Exceeded)
	2007	295	323 (Target Exceeded)
	2006	N/A	336 (Historical Actual)
	2005	N/A	335 (Historical Actual)

Long Term Objective: Detect safety problems earlier and better target interventions to prevent harm to consumers.

Measure	FY	Target	Result
214201: Number of prior notice import security reviews. *(Output)*	*2010*	80,000	December, 2010
	2009	80,000	December, 2009
	2008	80,000	80,543 (Target Exceeded)

Measure	FY	Target	Result
	2007	60,000	84,088 (Target Exceeded)
	2006	N/A	89,034 (Historical Actual)
	2005	N/A	86,187 (Historical Actual)
214202: Number of import food field exams. *(Output)*	*2010*	140,000	December, 2010
	2009	120,000	December, 2009
	2008	85,000	100,718 (Target Exceeded)
	2007	71,000	94,743 (Target Exceeded)
	2006	N/A	94,545 (Historical Actual)
	2005	N/A	84,997 (Historical Actual)
214203: Number of Filer Evaluations. *(Output)*	*2010*	1,000	December, 2010
	2009	1,000	December, 2009
	2008	1,000	1,356 (Target Exceeded)
	2007	1,000	1,355 (Target Exceeded)
	2006	N/A	1,441 (Historical Actual)
	2005	N/A	1,407 (Historical Actual)
214204: Number of examinations of FDA refused entries. *(Output)*	*2010*	5,000	December, 2010
	2009	5,000	December, 2009
	2008	4,000	5,926 (Target Exceeded)
	2007	3,000	5,510 (Target Exceeded)
	2006	N/A	5,846 (Historical Actual)
	2005	N/A	5,655 (Historical Actual)
214205: Number of high risk food inspections. *(Output)*	*2010*	6,750	December, 2010
	2009	6,100	December, 2009
	2008	5,700	6,230 (Target Exceeded)
	2007	5,625	6,421 (Target Exceeded)
	2006	N/A	6,795 (Historical Actual)

Measure	FY	Target	Result
	2005	N/A	7,568 (Historical Actual)
214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)*	*2010*	5 data exchange additions/conversions	December, 2010
	2009	5 data exchange additions/conversions	December, 2009
	2008	5 data entry labs	11 data entry labs (Target Exceeded)
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	*2010*	700	December, 2010
	2009	600	December, 2009
	2008	500	534 (Target Exceeded)
	2007	500	583 (Target Exceeded)
	2006	N/A	510 (Historical Actual)
	2005	N/A	600 (Historical Actual)
234202: Number of high risk registered domestic blood bank and biologics manufacturing inspections. *(Output)*	*2010*	1,000	December, 2010
	2009	870	December, 2009
	2008	870	1,014 (Target Exceeded)
234203: Number of highest priority human tissue establishment inspections. *(Output)*	*2010*	518	December, 2010
	2009	380	December, 2009
	2008	325	383 (Target Exceeded)
	2007	325	427 (Target Exceeded)
	2006	N/A	354 (Historical Actual)
244202: Number of domestic and foreign high risk animal drug and feed inspections. *(Output)*	*2010*	250	December, 2010
	2009	233	December, 2009
	2008	233	244 (Target Exceeded)
244203: Number of targeted prohibited material BSE inspections. *(Output)*	*2010*	490	December, 2010
	2009	490	December, 2009
	2008	490	555 (Target Exceeded)
	2007	490	523 (Target Exceeded)
	2006	N/A	516 (Historical Actual)

Measure	FY	Target	Result
	2005	N/A	588 (Historical Actual)
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	*2010*	1,365	December, 2010
	2009	1,340	December, 2009
	2008	1,270	1,431 (Target Exceeded)
	2007	1,195	1,468 (Target Exceeded)
	2006	N/A	1,506 (Historical Actual)
	2005	N/A	1,495 (Historical Actual)
214206: Maintain accreditation for ORA labs. *(Outcome)*	*2010*	13 labs	December, 2010
	2009	13 labs	December, 2009
	2008	13 labs	13 labs (Target Met)
	2007	13 labs	13 labs (Target Met)
	2006	N/A	13 labs (Historical Actual)
	2005	N/A	6 labs (Historical Actual)
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	*2010*	2,500 rad & 2,100 chem	December, 2010
	2009	2,500 rad & 1,650 chem	December, 2009
	2008	2,500 rad & 1,200 chem	2,500 rad & 1,200 chem (Target Met)
	2007	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem (Target Met)
	2006	N/A	1,200 chem (Target Met)
	2005	N/A	0

1. Number of Medical Device Bioresearch Monitoring (BIMO) inspections. (253201)

Context: FDA's mission includes assuring the protection of human research subjects, the quality and integrity of research, and the advancement of new medical technologies. A FDA-regulated research community that consists of Clinical Investigators, Sponsors and Monitors, and Institutional Review Boards has a shared responsibility to oversee this research in a truthful and ethical manner. For FY 2009, this performance goal continues to reflect the FY 2007 change in the selection of firms for inspection to a more risk based approach. There are no projected changes to this goal in FY 2010.

Performance: In FY 2008, FDA exceeded this goal of 300 by conducting 301 medical device related Bioresearch Monitoring inspections.

2. Number of prior notice import security reviews. (214201)

Context: FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

Performance: During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

3. Number of import food field exams on products with suspect histories. (214202)

Context: The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than 18.7 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA used Food Protection Resources to increase the number of import food field exams by 20,000 exams which brings the FY 2009 Target to 120,000 exams over the FY 2008 accomplishments. In FY 2010, FDA will use the FY 2009 resources to increase the number of import food field exams by 20,000 exams which brings the FY 2010 Target to 140,000 exams.

Performance: In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that

affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

4. Number of Filer Evaluations of import filers. (214203)

Context: The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices. The FY 2010 target is being maintained.

Performance: In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

5. Number of examinations of FDA refused entries. (214204)

Context: FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. For FY 2010, the target will be maintained.

Performance: In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. This goal is an agency wide goal and performance data will include

activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

6. Number of high risk food inspections. (214205)

Context: High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on a firm's compliance history. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target has been increased to 6,750 to reflect the FY 2009 Appropriations.

Performance: In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 inspections of high-risk domestic food establishments.

7. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. (214303)

Context: The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2008, 151 laboratories representing multiple government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

Performance: In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

8. Number of foreign and domestic high-risk human drug inspections. (224201)

Context: FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. In the FY 2007 model, the Agency developed several enhancements and improvements and will continue to explore ways to enhance calculations of process risk and facility sub-scores in FY 2010. As enhancements are made to FDA's data collection efforts and to the Risk-Based Site Selection Model, FDA will improve its ability to focus inspections on the highest-risk public health concerns in a cost-effective way. For FY 2010, the target has been increased to 700 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 goal of 500 by inspecting 534 high-risk foreign and domestic drug manufacturers.

9. Number of high risk registered domestic blood bank and biologics manufacturing inspections. (234202)

Context: FDA will increase risk-based compliance and enforcement activities by inspecting the highest priority registered manufacturers of biological products. The highest priority firms will be those whose operations are determined to be the highest risk, new product types in need of an inspectional history to evaluate and stratify risk, and, emergency response situations. Inspections for the goal are conducted to ensure compliance with Current Good Manufacturing Practices (CGMPs), and to ensure, as appropriate, the safety, purity and potency of biological products. The biologics inventory includes high-risk establishments such as blood collection facilities, plasma fractionator establishments, and vaccine manufacturing establishments, especially seasonal and pandemic influenza vaccines. In FY 2010, the target has been increased to 1,000 inspections to reflect historical accomplishments.

Performance: In FY 2008, FDA exceeded this high risk inspection goal of 870 by inspecting 1,014 blood banks and biologics manufacturing establishments.

10. Number of highest priority human tissue establishment inspections. (234203)

Context: Beginning in FY 2006 as a result of new regulations, the human tissue inspection goal was created. FDA's responsibility for enforcing the new regulations and the need to quickly assess compliance makes tissues one of the highest priorities. Two new rules took effect regarding human tissue: one requiring tissue facilities to register with FDA became effective January 2004; while the "Donor Eligibility Rule" became effective May 2005. The Field conducts tissue inspections to determine if human tissues for transplantation are in compliance with FDA tissue regulations and to assure consumer protection from unsuitable tissue products and disease transmission which may endanger public health. In FY 2009, FDA increased this goal by 55 additional tissue inspections, over the FY 2008 target, in order to cover more of the firms that registered as a result of the new regulations. In FY 2010, the target was increased by 138 inspections to reflect the FY 2009 Appropriations.

Performance: In FY 2008, FDA exceeded the human tissue goal of 325 by conducting 383 inspections under new regulations.

11. Number of domestic and foreign high risk animal drug and feed inspections. (244202)

Context: Important features of the risk-based strategy for this revised goal are to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal focused on pre-market approval inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that utilized risk modeling to identify the highest risk firms to be inspected. The FY 2008 target was maintained in FY 2009 because this was a new, risk-based goal for which we had no historical experience, and were unsure how the new site-selection methodology would evolve. In FY 2010, the target is being slightly increased as a result of the FY 2009 Appropriation while evaluation of the new methodology continues.

Performance: In FY 2008, FDA exceeded this inspection goal of 233 by inspecting 244 high risk animal drug and feed establishments.

12. Number of targeted prohibited material BSE inspections (244203)

Context: FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc.

Performance: In FY 2008, FDA completed the inspection of all 555 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

13. Number of domestic and foreign Class II and Class III device inspections. (254201)

Context: The ultimate goal of preventing unsafe and ineffective devices from reaching the consumer will be advanced by detecting and intercepting unsafe and ineffective product at the manufacturing level. By utilizing risk-based inspection strategies and focusing on surveillance throughout a products life-cycle FDA will be better able to protect the public health by ensuring both the quality and effectiveness of medical devices available in the U.S. marketplace. The FY 2009 target was increased to 1,340 inspections due to FY 2008 Supplemental funding increases in the Field Devices Program. For FY 2010, the target has been increased to 1,365 to reflect the FY 2009 Appropriations.

Performance: FDA exceeded the FY 2008 medical device performance goal of 1,270 by inspecting 1,431 foreign and domestic high-risk Class II and Class III medical device manufacturers.

14. Establish and maintain accreditation for ORA labs. (214206)

Context: FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena.

Performance: In FY 2008, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

15. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305)

Context: A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which will increase the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA will add three additional FERN

chemical labs in FY 2009 which will increase the surge capacity in FY 2010 to 2,100 chemical samples per week.

Performance: In FY 2008, FDA met this performance goal surge capacity target of 2,500 rad samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 rad samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***6,562***	***7,263***	***7,467***
Domestic Food Safety Program Inspections	3,611	3,850	4,100
Imported and Domestic Cheese Program Inspections	391	400	400
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	438	450	450
Domestic Fish & Fishery Products (HACCP) Inspections	1,827	1,850	1,850
Import (Seafood Program Including HACCP) Inspections	359	500	500
Juice HACCP Inspection Program (HACCP)	377	300	300
Interstate Travel Sanitation (ITS) Inspections	1,042	1,555	1,555
Domestic Field Exams/Tests	2,638	2,425	2,425
Domestic Laboratory Samples Analyzed	12,043	14,500	14,500
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***152***	***200***	***600***
All Foreign Inspections	152	200	600
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***6,714***	***7,463***	***8,067***
IMPORTS			
Import Field Exams/Tests	100,718	120,000	140,000
Import Laboratory Samples Analyzed	23,052	26,200	26,200
Import Physical Exam Subtotal	**123,770**	**146,200**	**166,200**
Import Line Decisions	9,441,024	9,526,745	9,613,245
Percent of Import Lines Physically Examined	1.31%	1.53%	1.73%

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	80,543	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,777***	***11,076***	***11,575***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***786***	***500***	***500***
State Contract Food Safety (Non HACCP) Inspections	7,791	9,797	10,297
State Contract Domestic Seafood HACCP Inspections	914	1,148	1,148
State Contract Juice HACCP	50	75	75
State Contract LACF	37	75	75
State Partnership Inspections	786	500	500
State Contract and Grant Foods Funding	$9,100,000	$9,775,000	$10,400,000
Number of FERN State Laboratories	16	19	19
Annual FERN State Cooperative Agreements/Operations Funding	$11,535,000	$13,450,000	$10,988,000
Total State & Annual FERN Funding	**$20,635,000**	**$23,225,000**	**$21,388,000**
TOTAL FOOD INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***16,277***	***19,039***	***20,142***

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***92***	***100***	***100***
All Inspections (Domestic and Foreign)	92	100	100
IMPORTS			
Import Field Exams/Tests	1,892	2,000	2,000
Import Laboratory Samples Analyzed	301	230	230
Import Physical Exam Subtotal	**2,193**	**2,230**	**2,230**
Import Line Decisions	1,588,082	1,721,372	1,865,849
Percent of Import Lines Physically Examined	0.14%	0.13%	0.12%
TOTAL COSMETICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***92***	***100***	***100***

Field Drugs Program Activity Data (PAD)

Field Drugs Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,774***	***1,960***	***1,960***
Pre-Approval Inspections (NDA)	138	120	120
Pre-Approval Inspections (ANDA)	95	51	51
Bioresearch Monitoring Program Inspections	526	490	490
Drug Processing (GMP) Program Inspections	972	1,085	1,085
Compressed Medical Gas Manufacturers Inspections	46	159	159
Adverse Drug Events Project Inspections	88	144	144
OTC Monograph Project and Health Fraud Project Inspections	33	48	48
Domestic Laboratory Samples Analyzed	1,769	951	951
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***452***	***566***	***566***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	174	192	192
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	117	69	69
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	129	210	210
Foreign Drug Processing (GMP) Program Inspections	268	382	382
Foreign Adverse Drug Events Project Inspections	6	16	16
IMPORTS			
Import Field Exams/Tests	2,863	2,870	6,197
Import Laboratory Samples Analyzed	346	586	586
Import Physical Exam Subtotal	**3,209**	**3,456**	**6,783**
Import Line Decisions	321,205	330,267	339,584
Percent of Import Lines Physically Examined	1.00%	1.05%	2.00%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***166***	***166***	***166***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	135	110	110
State Partnership Inspections: GMP Inspections	25	50	50
TOTAL HUMAN DRUG INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,392***	***2,692***	***2,692***

Estimates for FY10 Generic Drugs User Fee Inspections not reflected in the table.
Estimated timeframe for these inspections is FY 2012 and FY 2013.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,678***	***2,010***	***2,034***
Bioresearch Monitoring Program Inspections	104	183	183
Blood Bank Inspections	991	1,093	1,093
Source Plasma Inspections	149	205	205
Pre-License, Pre-Approval (Pre-Market) Inspections	38	24	24
GMP Inspections	25	17	17
GMP (Device) Inspections	3	10	10
Human Tissue Inspections	381	494	518
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***50***	***52***	***66***
Bioresearch Monitoring Program Inspections	6	6	6
Foreign Human Tissue Inspections	2	0	13
Blood Bank Inspections	8	12	12
Pre-License Inspections	7	10	10
GMP Inspections	23	20	20
IMPORTS			
Import Field Exams/Tests	36	100	100
Import Line Decisions	63,302	81,864	105,868
Percent of Import Lines Physically Examined	0.06%	0.12%	0.09%
TOTAL BIOLOGICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,728***	***2,062***	***2,100***

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2008 Actuals	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,127***	***2,820***	***2,621***
Pre-Approval/BIMO Inspections	61	77	77
Drug Process and New ADF Program Inspections	190	151	205
BSE Inspections	1,794	2,594	2,306
Feed Contaminant Inspections	26	20	20
Illegal Tissue Residue Program Inspections	212	320	320
Feed Manufacturing Program Inspections	208	141	141
Domestic Laboratory Samples Analyzed	1,617	1,850	1,850
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***33***	***26***	***41***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	23	25	26
Foreign Drug Processing and New ADF Program Inspections	19	10	20
Foreign Feed Inspections	2	0	8
IMPORTS			
Import Field Exams/Tests	2,930	2,930	3,500
Import Laboratory Samples Analyzed	594	720	720
Import Physical Exam Subtotal	**3,524**	**3,650**	**4,220**
Import Line Decisions	244,591	253,956	263,680
Percent of Import Lines Physically Examined	1.44%	1.44%	1.60%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,712***	***5,160***	***5,160***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***324***	***300***	***300***
State Contract/Coop Agreement Inspections: BSE	5,652	4,744	4,744
State Contract Inspections: Feed Manufacturers	322	348	348
State Contract Inspections: Illegal Tissue Residue	271	550	550
State Partnership Inspections: BSE and Other	324	300	300
State Contract Animal Drugs/Feeds Funding	$2,300,000	$2,550,000	$2,725,000
BSE Cooperative Agreement Funding	$3,000,000	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$300,000	$342,801	$375,050
Total State Funding	**$5,600,000**	**$5,892,801**	**$6,100,050**
TOTAL ANIMAL DRUGS AND FEEDS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***8,196***	***8,306***	***8,122***

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***1,996***	***2,322***	***2,404***
Bioresearch Monitoring Program Inspections	289	300	300
Pre-Approval Inspections	60	75	75
Post-Market Audit Inspections	42	58	58
GMP Inspections	1,271	1,476	1,560
Inspections (MQSA) FDA Domestic (non-VHA)	278	334	334
Inspections (MQSA) FDA Domestic (VHA)	31	30	30
Domestic Radiological Health Inspections	90	125	125
Domestic Field Exams/Tests	480	480	480
Domestic Laboratory Samples Analyzed	144	201	201
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***262***	***297***	***329***
Foreign Bioresearch Monitoring Inspections	14	10	10
Foreign Pre-Approval Inspections	38	34	34
Foreign Post-Market Audit Inspections	10	21	21
Foreign GMP Inspections	208	251	288
Foreign MQSA Inspections	15	14	14
Foreign Radiological Health Inspections	11	5	5
IMPORTS			
Import Field Exams/Tests	6,566	8,770	13,180
Import Laboratory Samples Analyzed	1,110	1,141	1,141
Import Physical Exam Subtotal	**7,676**	**9,911**	**14,321**
Import Line Decisions	5,567,469	6,786,886	8,273,385
Percent of Import Lines Physically Examined	0.14%	0.15%	0.17%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***8,272***	***8515***	***8513***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***71***	***71***	***71***
Inspections (MQSA) by State Contract	7,639	7,382	7,380
Inspections (MQSA) by State non-Contract	620	1,120	1,120
GMP Inspections by State Contract	13	13	13
State Contract Devices Funding	$75,000	$85,000	$120,000
State Contract Mammography Funding	$9,000,000	$9,500,000	$10,000,000
Total State Funding	$9,075,000	$9,585,000	$10,120,000
TOTAL DEVICES INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)			
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,601***	***11,205***	***11,317***

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HEADQUARTERS AND OFFICE OF THE COMMISSIONER

The FY 2010 program level budget request for FDA Headquarters and Office of the Commissioner Program is a $205,061,000.

The following table shows a three-year funding history for Headquarters and Office of the Commissioner Program.

FDA Program Resources Table

(dollars in thousands)

	FY 2008				
	Enacted	Actuals	FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
Program Level	**$146,342,000**	**$123,320,000**	**$160,271,000**	**$205,062,000**	**$44,791,000**
Center	$146,342,000	$123,320,000	$160,271,000	$205,062,000	44,791,000
FTE	722	733	737	867	130
Budget Authority	**$110,402,000**	**$97,606,000**	**$120,560,000**	**$143,712,000**	**$23,152,000**
Center	$110,402,000	$97,606,000	$120,560,000	$143,712,000	$23,152,000
Pay Increase (non add)				*$1,983,000*	*$1,983,000*
Protect America's Food Supply (non-add)				*13,351,000*	*$13,351,000*
Safer Medical Products (non-add)				*$6,818,000*	*$6,818,000*
Drug Importation (non-add)				*$1,000,000*	*$1,000,000*
Budget Authority FTE	**559**	**541**	**573**	**644**	**$71**
User Fees	**$35,940,000**	**$25,714,000**	**$39,711,000**	**$61,350,000**	**21,639,000**
PDUFA	$29,531,000	$21,936,000	$32,710,000	$35,270,000	$2,560,000
FTE	135	166	135	144	9
MDUFMA	$5,450,000	$2,967,000	$5,914,000	$5,914,000	$0
FTE	22	21	22	22	0
ADUFA	$732,000	$563,000	$656,000	$693,000	$37,000
FTE	4	4	4	4	0
AGDUFA			$193,000	$204,000	$11,000
FTE			1	1	0
MQSA	$227,000	$248,000	$238,000	$238,000	$0
FTE	2	2	2	2	0
Proposed User Fees	**$0**	**$0**	**$0**	**$19,031,000**	**$19,031,000**
Generic Drugs				$1,189,000	$1,189,000
FTE				0	0
Reinspection				$8,342,000	$8,342,000
FTE				17	17
Inspection and Facility Registration User Fee				$9,500,000	$9,500,000
FTE				33	33
User Fees FTE	163	192	164	223	59

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)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Foods Additives Amendments of 1958*

* 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.

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*

Allocation Method: Direct Federal/Intramural

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

* 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.

Commissioner consists of six subordinate offices that provide policy making, program direction, coordination and liaison, and expert advice to FDA leadership and programs.

The following table provides a description of each office's functions.

OC Office	Description
Office of the Chief Counsel	Provides expert legal advice and review on statutory and regulatory interpretations affecting FDA enforcement and administrative actions.
Office of Food Protection	Provides advice and council on strategic and substantive FDA-wide domestic and imported food related matters.
Office of the Chief of Staff	Advises FDA leadership on activities and issues affecting FDA programs, projects, and strategies impacting on various constituencies – including the public, consumer groups, industry and trade associations, stakeholders, and governmental bodies.
Office of International and Special Programs	Serves as FDA's primary focal point on international activities, including negotiating and managing bilateral agreements; coordinating and participating in international harmonization activities; and coordinating and supporting multilateral organizations. Administers the combination products and pediatric therapeutics programs.
Office of Operations	Provides advice and direction for day-to-day operational activities and the interaction and execution of initiatives across all FDA Centers, Field Offices, Regions and Headquarters. Provides administrative and program support services, assures strategic and operational management of information technology, financial management, and administrative programs. Serves as FDA's focal point for coordinating emergency and crisis response activities, interagency and intra-agency coordination of emergency and crisis planning and management, and internal and external security.
Office of Policy, Planning and Preparedness	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; ensures that internal and external stakeholders clearly understand FDA's challenges, achievements, and future directions.
Office of the Chief Scientist	Advises key officials on scientific issues that impact policy, direction, and long-range goals; and coordinates the responsibilities for women's health issues, good clinical practices program, orphan product development program, as well as provides support for the Commissioner's Fellowship Program.

Office of the Chief Counsel

The Office of the Chief Counsel (OCC) provides legal advice and policy guidance, acts as liaison to the Department of Justice and other Federal agencies or programs.

In FY 2008, OCC provided legal advice or 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, and

correspondence. OCC provided key advice on numerous complex legal issues related to implementation of a variety of new laws, including the extensive changes brought about by the Food and Drug Administration Amendments Act (FDAAA) of 2007, on medical product approvals and safety issues, food safety and nutrition issues, animal health issues, and public health emergencies. OCC conducted over 700 reviews of draft letters from FDA to firms that were believed to have violated the Federal Food, Drug, and Cosmetic Act.

In FY 2008, OCC also conducted defensive and enforcement litigation on behalf of FDA. OCC successfully defended the FDA's product approval decisions in the Abigail Alliance, Rempfer (anthrax), and Moms against Mercury (dental amalgam) cases, and played significant roles in the successful criminal prosecutions for violations of the Federal Food, Drug, and Cosmetic Act. The prosecutions include Caputo/Abtox (devices), Faust (devices), Puckett (raw milk), Leiner (drug manufacturing) and Abrano (non-sterile drugs). OCC defended the integrity of FDA's generic drug approval decisions in numerous cases such as NuPharm, Teva, Cobalt Labs, Mylan, and Valeant. OCC also gave substantial support to the FDA's enforcement actions initiated to ensure the quality of the medical device manufacturing process in the Shelhigh (consent decree governing adulterated heart valves; company now out of business) and Medtronic/Physio (consent decree governing adulterated defibrillators; company stopped shipping devices until compliance was achieved) cases, and in the Temporamandibular Joint, Inc. (TMJI) civil money penalty action (company and CEO paid $1.175 million in penalties).

Office of Food Protection

The Office of Food Protection (OFP) provides advice and council on strategic and substantive FDA-wide domestic and imported food related matters.

OFP has been charged with developing and implementing an agency-wide, visionary strategy for food protection and an agency-wide approach to promoting health via foods. In November, 2007, FDA released the Food Protection Plan, an integrated strategy for protecting the nation’s food supply. In FY 2010, OFP will continue to provide strategic council and support for the implementation FDA food protection activities through FDA’s Supply Chain Safety and Security initiative, which builds upon the foundations of food protection identified in the Food Protection Plan.

OFP plays an integral role in coordinating cross-agency food protection efforts by ensuring communication, tracking progress, and providing leadership on policy and program decisions. In addition, OFP conducts outreach with federal, state and local and international agencies, academic and non-profit organizations, professional and trade associations, industry, and the public to communicate FDA food safety and defense vision and the related actions and initiatives to create a climate for corporative work relations, and support and understating of the FDA’s food protection program objective.

OFP provides agency-wide leadership in all areas of foods, including health promotion and nutrition. OFP, in collaboration with other FDA centers, government agencies, and industry, coordinates efforts to promote the health benefits of food and raise the visibility of FDA’s role in this area

Office of the Chief of Staff

The immediate Office of the Chief of Staff (OCoS) 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 agency programs, projects and initiatives. This office provides leadership, coordination and management of the Commissioner's priority policies and issues across the Office of the Commissioner and FDA-wide. In addition, OCoS is the main point of contact on emerging public health issues requiring strategic coordination. The Office of the Chief of Staff serves as a point of contact between the FDA Centers and Offices and the Commissioner; and serves as liaison to HHS.

Office of Executive Secretariat (OES)

During the past year, OES served as FDA's liaison to the Government Accountability Office and the HHS Office of the Inspector General on several highly visible studies. OES also coordinated numerous high level briefings for the Commissioner and managed the FDA's review and clearance process for executive correspondence, memoranda of understanding, reports to Congress, consumer correspondence, and many other items.

Office of External Relations (OER)

In FY 2008, OER orchestrated several one-on-one meetings between the Commissioner and senior consumer leaders, arranged the first-ever visit of an FDA Commissioner to the headquarters of Consumers Union, and organized Consumer Briefings on such crucial FDA issues as the Reagan-Udall Foundation and the Sentinel Initiative. OER managed FDA's high-level outreach to various stakeholder groups on all major FDA announcements, and pioneered a series of innovative "Listening Sessions" between the Commissioner and major stakeholders, including a session with industry on the Salmonella outbreak. OER launched FDA's newly designed home page. Within three months, the number of "hits" increased by 33 percent over the previous year. OER refined and strengthened its web-based consumer information program, producing some 70 articles to support FDA's public health mission, establishing new distribution channels for this material, and tripling subscribers between October 2007 and August 2008.

Office of Legislation (OL)

In FY 2008, OL worked with Agency experts and Congressional staff to ensure reauthorization of the Animal Drug User Fee Act (ADUFA) and authorization of the Animal Generic Drug User Fee Act (AGDUFA). OL also worked with Members of Congress and staff to develop legislative proposals to implement the sections of the Food Protection Plan and the Action Plan on Import Safety that require new Agency authority. In addition, OL provides Congress with information requested on FDA programs and policies. In FY 2008, OL staffed over 25 Congressional hearings and provided over 1,000 responses to inquiries from Members of Congress.

Office of Public Affairs (OPA)

In FY 2008, OPA conducted numerous announcements on agency actions, including drug, biologics and device approvals and food recalls as well as implementing requirements under the Food and Drug Administration Amendments Act of 2007. OPA also announced major agency initiatives, including improvements to rules governing advisory committees, the Sentinel Initiative, Cough and Cold medications for infants, and the Safety of Food from Animal Clones.

This past year, OPA conducted one of the largest crisis communications events in recent history with the nationwide intensive investigation into the outbreak of Salmonella Saintpaul. In addition, OPA staffed all public meetings, Congressional hearings and advisory committees and answered numerous inquiries from members of the media.

Office of International Programs
The Office of International Programs (OIP) serves as the FDA focal point for all international matters.

Office of International Programs (OIP)
In FY 2008 through present, OIP continues to lead FDA's efforts to advance the Commissioner's Beyond Our Borders Initiative. Activities include increasing FDA's portfolio of international agreements, increasing capacity building initiatives, and furthering focused scientific and regulatory collaborations with key regulatory partners.

One of the highlights of the FDA Beyond Our Borders Initiative was the establishment of FDA's first-ever presence abroad. FDA successfully opened two Country Offices in China and India, and two Regional Offices in Europe and Latin America. The opening of a Regional Office in the Middle East is underway. The resident staff will carry out the full range of activities FDA normally does with its foreign counterparts, including basic regulatory cooperation, capacity building, inspections, and will foster the relationships that are instrumental to successful collaboration. As we continue with the staffing of these offices, OIP is working to expand activities associated with its Africa and Asia Office, Quads and Trilateral Office, as well as making efforts to strategically link FDA presence abroad with colleagues in headquarters in OIP, the Centers, ORA, and OC Offices in the most efficient and effective manner. While the recruitment activities for the initial phase of the China, India, Latin America, Europe, Middle East in-country and at headquarters are nearly completed, further recruitment efforts and activities are planned to assure coverage of the countries/regions from which the great majority of FDA-regulated products are sourced overseas.

In FY 2008, OIP also led FDA's efforts to contribute to FDA's obligations to key Administration initiatives, including the Strategic Economic Dialogue, a U.S. - China forum, under which implementation of FDA's agreements with China's Administration of Quality, Supervision, Inspection, and Quarantine (AQSIQ) and State Food and Drug Administration (SFDA) fall; the Transatlantic Economic Council, a U.S. and European Union (EU) forum under which FDA's bilateral work with the European Union European Medicines Agency (EMEA) falls; and the Security and Prosperity Partnership of North America, where the FDA, Canada, and Mexico have committed to revise our Trilateral Cooperation Charter to better reflect our shared concerns and commitment to product safety.

Office of Operations
The Office of Operations (OO) provides executive direction, leadership, coordination, and guidance for the overall day-to-day operations of FDA, assuring the timely and effective implementation of operations and high quality delivery of services across FDA and its Centers.

Office of Management (OM)

The FDA Competitive Sourcing goal in FY 2008 was to announce the study of at least 130 commercial positions. FDA has already announced the first two of five planned streamlined studies which have a combined total of 96 positions. FDA expects to announce the remaining studies by September 30, 2008 and exceed its plan of studying 130 positions. These studies are critical to ensuring the FDA is using the most cost effective organization and staffing to accomplish its mission. By creating Most Efficient Organizations (MEO) within the administrative support structure, public health and safety professionals are better able to focus on their primary roles in protecting and advancing the public health.

Office of Financial Management (OFM)

The Office of Financial Management (OFM) supports the mission of the FDA by providing financial management services, budget execution and controls, financial policy and compliance, and financial systems support. In FY 2008 OFM expanded its scope for the Office of Management and Budget's (OMB) 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. For FY 2009, in addition to continuing the activity above, OFM will document the processes and procedures performed in OFM 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. As UFMS is an integrated system and all DHHS Operating Divisions (OPDIVs) share it, FDA remains involved and participates in all future phased implementations of other OPDIVs. In FY 2008 FDA continued its efforts to stabilize the UFMS environment now that all OPDIVs have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to Federal Managers Financial Integrity Act (FMFIA) compliance. In FY 2009 FDA will begin 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 2010 FDA plans to continue its OBIEE business intelligence reporting development, UFMS 2010 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.

Office of Information Management (OIM)

The organizational restructuring of the Office of Information Management was officially approved in May of 2008, centralizing and consolidating IT personnel and budget resources that were distributed throughout seven Centers and Offices into one cohesive organization. This organizational change is apart of a larger IT Modernization effort to enhance IT infrastructure and to create a robust foundation to enable interoperability across the FDA and allow OIM 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.

FDA's Information Technology (IT) goals for FY 2010 are to ensure strategic investment in IT so as 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 Agency science by:

- Providing early risk based information which will promote pro-active 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; and,
- Leveraging internal and external knowledge bases.

In addition, 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 be to reduce the risk of adulterated, misbranded or unapproved products entering commerce. Some business drivers for new IT development include the following:

- System duplication and lack of interoperability – for example FDA has a need for one unified registration and listing services not multiple systems that are not interoperable
- System obsolescence due to increased number of users, amount of data handled, or unsupported technology
- Need for new types of data/document storage
- Needs for increased or new computation abilities, especially in the areas of scientific computing and data analytics
- Need for increased system security
- Need to support globalization and new FDA locations beyond the USA borders

Office of Crisis Management (OCM)

OCM provided coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g., melamine contaminated infant formula, salmonella in imported produce, and flooding in the mid-west.

OCM is charged with meeting the Department of Health and Human Services (DHHS) goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents"; HSPD-8, "National Preparedness"; and HSPD-9, "Defense of United States Agriculture and Food."

In FY 2008, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.3 and will release a version in 2009 to establish a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or

animal health. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2008 hurricane season, response activities related to outbreaks involving salmonella in imported produce, flooding in the mid-west, and wildfires and earthquakes in California. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners. OCM finalized the FDA Pandemic Influenza Emergency Response Plan during FY 2008 and conducted an FDA-wide Pandemic Influenza Exercise in October 2008. OCM will also complete the updating of the FDA Emergency Operations Plan and its four incident-specific annexes as well as provide training to Agency staff on implementation of the plan. Develop an agency-wide National Incident Management System (NIMS) implementation plan in FY 2009.

OCM will enhance FDA's Incident Command System (ICS) structure and its ability to respond to food-related events in FY 2010 by improving response capabilities by incorporating subject matter expertise into strategic planning and day-to-day operations; improve Agency preparedness by conducting exercises to assess response capabilities to foodborne illness/outbreaks; and further integrate emergency policy and planning into Agency emergency operations.

Office of Policy, Planning, and Preparedness

The Office of Policy, Planning, and Preparedness (OPPP) advises the Commissioner and other key FDA officials on matters relating to policy, development of regulations and guidance, legislative issues, planning and evaluation activities, and counter-terrorism and emerging threats.

Office of Integrity and Accountability (OIA)

OIA successfully led the overhaul of FDA's advisory committee program. To this end, OIA crafted compromise language in FDAAA to address Congress's concerns regarding conflict of interests of advisory committee members; OIA published four final guidances that significantly improve the transparency, integrity, and consistency of FDA's advisory committee program; OIA ensured FDA-wide compliance with the new advisory committee provisions of the Food, Drug and Cosmetic Act (FDCA); OIA published an important new draft guidance on when FDA convenes advisory committee meetings; OIA developed internal procedures regarding security at advisory committee meetings; and OIA helped improve the FDA webpage on advisory committees, increasing the program's transparency and improving public access to important information.

In addition, OIA helps coordinate FDA's response to allegations of improper deviations from established procedures governing the FDA's regulatory conduct, including pre- and post-market product reviews, food-related assessments, enforcement actions, and congressional obligations. To this end, OIA helps FDA respond to Congressional oversight on a number of complicated issues, including Ketek and lactoferin. OIA is leading the FDA's effort to remedy its debarment program, and helped lead the development of the new Scientific Dispute Resolution program at FDA.

Office of Policy

The Office of Policy handles high-priority, cross-cutting, and novel regulatory issues and coordinates the issuance and publication of all FDA regulations, notices, and guidance documents. The Office works on a broad range of policy initiatives, whether they involve new

FDA policies on a particular issue, drafting priority regulations and guidance documents, or advising senior Agency officials on complex regulatory matters. In addition, the Office is responsible for matters relating to the clearance and publication of FDA's regulations and guidance documents, including editing documents to meet federal specifications; clearing documents through the Department of Health and Human Services, the Office of Management and Budget, and other federal agencies; and handling other rulemaking efforts.
In FY 2008, the Office of Policy led FDA's implementation of the Action Plan for Import Safety: A Roadmap for Continual Improvement. These actions included the initiation of a pilot program and the issuance of guidance that would set the stage for FDA's recognition of third-party certification programs for select foods and feeds to verify compliance with FDA safety standards.

The Office of Policy, with the Office of Planning, coordinated the implementation of the FDAAA. As part of this effort, the Office of Policy led the implementation of the clinical trials provisions of the FDAAA.

The Office of Policy led the implementation of Memoranda of Understanding with Veterans Health Administration and the Department of Defense, Office of Health Affairs, to facilitate the coordination of post-market safety actions pertaining to medical products among the three agencies. These actions are part of FDA's Sentinel Initiative.

The FY 2010 budget includes a $1 million increase for OC for drug importation efforts.. The request includes funds to allow FDA to begin working with stakeholders to develop policy options related to drug importation. In addition, the Administration will work with Congress to enact authorizing legislation to support the infrastructure required to ensure the safety of these medicines.

Office of Planning

The Office of Planning implements the Agency's responsibilities associated with the Government Performance and Results Act, the Prescription Drug User Fee Act, and Executive Orders pertaining to economic analysis of regulatory policies and OMB/HHS directives regarding strategic management. These responsibilities include the following:

- Design and develop strategic plans, performance management systems, and operational/business process plans.
- Analyze management performance trends, Agency cost structure, and use of program resources.
- Oversee the Prescription Drug and User Fee Act performance commitments and Performance Management resources.
- Analyze cost and benefits of agency regulations.
- Provide assistance to Agency components in change management, program reinvention, and managing-to-cost.
- Analyze changes in domestic health-care system and changes in international and trade issues that relate to FDA responsibilities.
- Analyze risk communication activities and assists agency components in planning to improve risk communication effectiveness.

The Office of Planning published the FDA Strategic Action Plan on the FDA web site in early FY 2008, which describes FDA's long-term strategic goals and objectives. Under the performance management program of the Prescription Drug User Fee Act (PDUFA), the Office of Planning also completed and published on FDA's web site a major independent contract evaluation study of the human drug review system, focusing on factors that contribute to first-cycle approvals. Office of Planning will be coordinating additional PDUFA performance management program evaluations and performance management projects in FY 2009 and throughout PDUFA IV.

In FY 2008, the Office of Planning coordinated the first three meetings of the new Risk Communication Advisory Committee, which FDA established to bring together national experts to advise FDA on the science and practice of improving the effectiveness of risk communications to the public, regulated industry, and health practitioners. The Office of Planning also set up an internal pilot project for testing messages prior to issuance and completed a national survey of physicians concerning their perceptions about emerging and uncertain risks of medical products, the results of which will guide communications directed toward that audience. In FY 2009, the Office of Planning is leading the process to develop the Strategic Plan for Risk Communication at the FDA, as well as a prioritized research agenda; both are designed to guide actions to ensure that FDA risk communication is both science-based and effective. The Office of Planning is coordinating the presentation of the strategic plan and research agenda to FDA's Risk Communication Advisory Committee for feedback.

The Office of Planning successfully coordinated agency-wide business process planning efforts to re-engineer post market surveillance systems. The Office of Planning led the business modeling and analytic work to document business goals and objectives and strategies to achieve the goals including business functional requirements. The business requirements supported the procurement of a modern post market surveillance system. The Office of Planning also has taken the lead to coordinate and develop agency-wide business information management requirements for key supporting and enabling processes, which includes advisory committee management; investigational drug, biologic and device review; employee management; and document management.

Office of Planning economists also successfully completed regulatory impact analysis supporting final rules on: Substances Prohibited From Use in Animal Food or Feed which protects the food supply from pathogens that cause "mad cow disease;" Current Good Manufacturing Practice and Investigational New Drugs Intended for Use in Clinical Trials; Ozone-depleting substances (CFC), revocation of essential-use designation for epinephrine; and Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling. Office of Planning economists also published articles including ones on: Economic issues with follow-on protein products; the economic returns of pediatric clinical trials of anti-hypertensive drugs; and the healthcare impact of personalized medicine using genetic testing: an exploratory analysis for warfarin.

Office of Counter Terrorism and Emerging Threats (OCET)

OCET's mission is to protect the public health through the development and implementation of policies that safeguard medical products from adulteration or disruption of supplies due to

terrorist activities or emerging threats, and that facilitate the availability of safe and effective public health emergency medical countermeasures. OCET participates in national counter-terrorism and emerging threats preparedness activities. OCET also co-chairs the FDA intra-agency Pandemic Influenza Preparedness Task Force in spearheading FDA's interagency policy coordination to develop the FDA Pandemic Influenza Preparedness Strategic Plan. The strategic plan was released in March 2007 and updated March 2008.

OCET also coordinates FDA's participation in the DHHS Public Health Emergency Medical Countermeasures Enterprise Governance Board (EGB). Board voting members include the Assistant Secretary for Preparedness and Response, the Directors of CDC and NIH, and the FDA Commissioner (or his/her representatives). Through the EGB, FDA provides recommendations to the Secretary on 1) prioritized requirements for emergency medical countermeasures;2) research, development, and procurement activities; 3) deployment and use strategies.

OCET accomplishes its mission through:

- *strategic planning*, including developing and implementing a comprehensive FDA strategy for counterterrorism, pandemic influenza, and other emerging threats;
- *policy leadership*, including promoting counterterrorism, pandemic influenza, and emerging threats goals and needs in the agency priority-setting process; and
- *coordination and communication*, including coordinating the portfolio of FDA policy initiatives, serving as the point of entry to FDA, and facilitating intra-and inter-agency communications on policies for counterterrorism, pandemic influenza, and other emerging threats. OCET maintains a close working relationship with each FDA center and office through a network of Counterterrorism Coordinators, who serve as OCET's portal into the medical countermeasures expertise in the centers and offices

Office of the Chief Scientist

The Office of the Chief Scientist (OCS) serves as the focal point for scientific, medical, and related activities within the Office of the Commissioner.

Office of Critical Path Programs (OCPP)

The Critical Path Initiative began in 2004 with a focus on modernizing medical product development. OCPP was created in the Office of the Commissioner to support the Critical Path Initiative, which has grown to encompass all FDA-regulated products. During 2008, OCPP initiated and led a number of Critical Path projects, many of which are multicenter programs and involve substantial collaboration with outside stakeholders (e.g., other Federal agencies, academia, patient groups, industry). Key OCPP projects areas include , postmarket surveillance (e.g., Sentinel, MedWatch^{Plus} ; clinical trial modernization (e.g., the Clinical Trial Transformation Initiative with Duke); multiple bioinformatics projects (e.g., Janus, FIREBIRD, e-Platform, standards development); FDA Regulated Product Development Tools (e.g., genetic basis for adverse events, Coalition Against Major Diseases); the dual antiplatelet trial effort; and development of the first FDA training program for senior clinical investigators. In addition to the specific activities, OCPP managed the FDA-wide Critical Path Steering Committee, led or participated in numerous outreach activities, published articles related to Critical Path activities, launched the annual FDA Critical Path Rounds program, and managed the Critical Path Web page and other communications efforts. OCPP will soon post the 2008 Critical Path activities

list, which describes more than 50 Critical Path projects that received Critical Path Initiative funding during 2008, involving multiple internal and external collaborations. Projects are under way in all FDA centers.

Office of Pediatric Therapeutics (OPT)

OPT's Congressional mandate ensures the safety review of products used by children and provides for the ethical and scientific review of pediatric trials across the FDA. Seventy-nine pediatric safety reviews have been managed by OPT and presented to the Pediatric Advisory Committee (PAC) between FY 2003-FY 2008; 31 will be presented in FY 2009. In FY 2010 we project 33 products will go to the PAC. The PAC and OPT were involved in the 3 committee public discussion on the safety of Long Action Beta Agonists in FY 2009. Food and Drug Administration Amendments Act (FDAAA) has now expanded our responsibility for safety reviews to Biologics and Device products which will be reviewed by the PAC in 2009.

To better inform the public of the important changes in pediatric information, OPT has increased its efforts on communications and has had 3 articles and 1 chapter published early in 2009, with 3 articles and 1 chapter accepted in peer reviewed journals or books for publication in FY 2009. We secured a monthly "FDA Pediatric Update" in the American Academy of Pediatrics Newsletter, and between August of 2008 and April 2009 have published 9 Updates and will complete 5 more by the end of the fiscal year. In addition, dozens of presentations on pediatric safety, ethics and trial issues have been presented by OPT staff. OPT has organized or contributed to scientific working groups dealing with issues such as extrapolation, device development and exposure of infants to potentially hazardous products, including Bisphenol (BPA). We work with such entities as National Institutes of Health (NIH), EMEA, Presidential Emergency Plan for AIDS Relief (PEPFAR), international regulatory agencies, external stakeholders, Drug Information Association (DIA), and World Health Organization (WHO). OPT has three mentors in the Commissioner's Fellowship program.

In FY 2008 OPT and the EMEA established a Pediatric Cluster under a confidentiality agreement and meet on a monthly basis. As of April 2009, information has been exchanged on 375 pediatric investigational plans submitted by EMEA.

The Ethics program has provided numerous internal presentations, ethical sections for a number of guidances, numerous consultations across the Agency and participated and presented at external meetings such as WHO, EMEA pediatric committee and the Canadian Regulatory Agency. In addition, the pediatric ethics program has coordinated 2 public advisory committee meetings involving the PAC and the Pediatric Ethics subcommittee. One of these meetings was a subpart D, IRB referral and was coordinated with the Department's Office of Human Research Protections. The other was a program to look at the ethical and scientific issues surrounding the dismal outlook for children with pontine gliomas and how to move this arena forward.

Designed an Microsoft (MS) Access database for reporting and analysis of the Pediatric Review Committee activities and established a database for reporting and analysis of text-based information generated from the International program.

OPT's Congressional mandate ensures the safety review of products used by children and provides for the ethical and scientific review of pediatric trials across the FDA. Of the 79 pediatric safety reviews managed by OPT and presented to the Pediatric Advisory Committee (PAC) since 2003, 12 were done in FY 2008. The PAC and OPT were involved in 3 other FY 2008 public advisory committee meetings to discuss evolving pediatric safety issues. FDAAA has now expanded our responsibility for safety reviews to Biologics and Device products. To better inform the public of the important changes in pediatric information, OPT has focused on communications in FY2008. Seven articles and two chapters were published or accepted in peer reviewed journals this year, and we secured a monthly "FDA Pediatric Update" in the American Academy of Pediatrics Newsletter, with three articles to be published by October. In addition, dozens of presentations on pediatric safety, ethics and trial issues have been presented by OPT staff. We work with such entities as National Institutes of Health (NIH), EMEA, Presidential Emergency Plan for AIDS Relief (PEPFAR), international regulatory agencies, external stakeholders, Drug Information Association (DIA), and World Health Organization (WHO). OPT has organized or contributed to scientific working groups dealing with issues such as extrapolation, device development and exposure of infants to potentially hazardous products. The Ethics program has provided 29 internal presentations, ethical sections for a number of guidances, numerous consultations, participation in the PAC and external meetings such as WHO. International work includes monthly exchanges of information with the EMEA and, in FY 2008, covered over 230 proposed pediatric investigational plans and included participation in their Pediatric Committee meetings. OPT has two mentors in the Commissioner's Fellowship program.

Office of Combination Products (OCP)

OCP, in response to Medical Device User Fee and Modernization Act (MDUFMA) 2002, ensures the prompt assignment of combination products (drug-device, biologic-device, drug-biologic, or drug-device-biologic products) to FDA Centers, the timely and effective pre-market review of such combination products, and consistent and appropriate post-market regulation of these products. OCP also: develops guidance and regulations to clarify regulatory requirements for combination products; resolves disputes regarding the timeliness of premarket review of combination products; serves as a focal point for combination product issues for internal and external stakeholders; facilitates the intercenter consultative review process; promotes consistent and appropriate postmarket regulation of combination products; and submits annual reports to Congress on the Office's activities and impact. In addition to assigning combination products to FDA Centers, OCP is also responsible for classifying non-combination medical products as drugs, devices, or biological products if their classification is unclear or in dispute.

In FY 2008, OCP continued to clarify the jurisdictional assignment of combination products and single entity non-combination medical products through the formal Requests for Designation (RFD) process. Ten formal RFDs were carried over from FY07 and an additional 34 assignment requests were filed during FY 2008. Of the total 44 RFDs, OCP issued 39 RFD assignments in FY 2008. One hundred percent of these assignments met the 60-day decision time requirement. The remaining 5 RFDs are under review and are not overdue. Also, OCP responded to nearly three times that number of informal jurisdiction inquiries. OCP also tracks a total of 371 intercenter consultations in FY 2008.

As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, FDA agreed to develop guidance for medical imaging devices with "approved contrast agents or radiopharmaceuticals." MDUFA also requires that FDA publish this draft guidance by the end of FY 2008. OCP met this requirement by publishing the draft guidance in September 2008.

Over the past years, OCP has developed two proposed rules, on current good manufacturing practice (CGMP) and postmarket safety reporting for combination products. The purpose of these two rules is to provide the regulated industry and FDA staff standards for how cGMP and postmarket safety reporting requirements for combination products should be implemented. These proposed rules have not yet been published. Both were cleared by the Agency in FY 2008. OCP also briefed DHHS on these two proposed rules in August 2008.

Office of Science and Health Coordination (OSHC)

OSHC manages and provides oversight and coordination for FDA-wide science issues. Examples are nanotechnology, pharmaceuticals in the environment, and bisphenol A. Other programs of responsibility include the oversight of FDA sponsored clinical studies, the associated quality assurance program and FDA's Institutional Review Board. During the past year, OSHC was the co-lead implementing the recommendations of the FDA Task Force report on Nanotechnology. A public meeting was held in September 2008 on FDA regulated products containing nano-engineered materials. OSHC chairs the FDA Bisphenol A (BPA) Task Force. A subcommittee of the FDA Science Board held a public meeting in September 2008 to address the use of BPA in food contact applications. Research integrity is also the responsibility of FDA and will finalize the FDA program document on this issue in FY 2009.

OSHC also manages the Science Board and the Pediatric Advisory Committee (PAC). The Science Board is the only FDA advisory committee that provides advice directly to the Commissioner of Food and Drugs on specific technical issues, as well as emerging issues within the scientific community, industry, and academia and the PAC advises and makes recommendations to the Commissioner of Food and Drugs regarding pediatric research, adverse event reports, and labeling related to pediatric therapeutics.

OSHC also directs several Offices within the Office of the Commissioner including the Office of Women's Health, Office of Orphan Products Development, and Good Clinical Practice Programs.

In FY 2008, OSHC managed two noteworthy Science Board meetings. The first meeting discussed an on-going in-depth review of the FDA's science programs and infrastructure so that FDA can prepare for future changes in science and technology. The discussion also focused on FDA's science programs, the Office of Regulatory Affairs (ORA), and the National Center for Toxicological Research (NCTR). The in-depth review of the FDA's scientific capacity is critical to assuring that FDA will continue to meet the regulatory challenges of the present and future developments in science and technology. In the second meeting, the Science Board also discussed the National Antimicrobial Resistance Monitoring System Program and activities related to melamine.

The Office of Special Health Issues (OSHI)

Office of Scientific and Medical Programs coordinates and integrates agency policy/program, scientific, and public health issues related to AIDS, cancer, neurological disorders, MedWatch and other special health issues. OSHI is responsible for engaging, collaborating and communicating with health professionals, patients and patient advocates, and other special interest populations about FDA regulatory decisions and policies. OSHI/MedWatch staff involve patient and health professional stakeholders in agency's participatory activities to address public health issues related to the review of new medical products--including managing the patient representative and patient consultant programs, organizing patient and health professional stakeholder telephone conferences/meetings and initiating major projects of interest to OSHI stakeholders.

The office also manages several websites and e-lists and responds to email and telephone inquiries from stakeholders on a variety of patient focused issues, primarily dealing with clinical trials and access to investigational drugs. Created in FY 2008, the "FDA Updates for Health Care Professionals" E-list 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 August 2008, OSHI launched a new health professional webpage to serve as a portal for FDA information, particularly safety-related information, of interest to health professionals. The MedWatch website 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 E-list, with over 135,000 subscribers broadcasts timely new safety information to both healthcare professionals and their patients. For 2008, there were a total of 1161 safety related labeling for 535 products, including 54 boxed warnings and 47 medication guides. The MedWatch E-list distributed , 124 Alerts and Updates. In 2008, the HIV/AIDS program delivered 44 timely, targeted updates to more than 15,000 subscribers to the HIV/AIDS E-list.

Notable activities related to interactions with health professionals in 2008 include an award of excellence from the National Association of Government Communicators in May 2008 for creation of a web based, interactive, accredited educational module called "An Introduction to the Improved FDA Prescription Drug Labeling." To date, more than 760 health professionals have received continuing education for this program. In August 2008, OSHI established an interagency agreement with HRSA's Office of Pharmacy Affairs to collaborate with the American Association of Colleges of Pharmacy. The collaboration will assess and evaluate the science of safety curriculum within the U.S. Colleges of Pharmacy.

OSHI/MedWatch staffs involve patient and health professional stakeholders in agency's participatory activities to address public health issues related to the review of new medical products and related therapies. For example in 2008:

- Expanded Patient Representative Program to include twenty-two new patient representatives in non-cancer disease groups/conditions as well as new cancer and HIV/AIDS representatives
- Twenty-eight Patient Representatives/Consultants (PR/C) participated in 25 Advisory Committee meetings to review/discuss 30 products/issues

- Twenty-seven PR/Cs representing a variety of serious and life-threatening diseases attended the 2008 annual workshop entitled " Patient Representatives Making a Difference" for PR/Cs.
- Facilitated and/or organized more than 25 patient and health professional stakeholder telephone conferences/meetings on topics such as Sentinel, HFA albuterol transition, ESAs, HIV/AIDS, etc.
- Hosted 16 telephone lectures for patient representatives/consultants.

Office of Women's Health (OWH)

In FY 2008, OWH provided support for 35 scientific projects specific to cardiovascular disease in women, the collection of demographic data on women in clinical trials, and the development of data standards to enable sex-specific analyses, including 20 new projects relevant to product safety and women's health. OWH completed the pilot review template standardization project in the Center for Drug Evaluation and Research (CDER) with a final written report and presentation provided to CDER senior management. OWH provided support for a public workshop to explore the participation of women in cardiovascular studies which will assist with regulatory guidance development. OWH completed Spanish language translations of all consumer health information sheets, and completed the birth control medication booklet that provides information on all FDA-approved drugs and devices for contraception. OWH conducted three stakeholder meetings with over 75 organizations.

In FY 2008 OWH also provided consumer health information through such continued efforts as Menopause and Hormones Education, My Meds, and Pink Ribbon Sunday activities, and selectively targeted special subpopulations (e.g., colleges, seniors, Spanish speaking, and chronic disease groups). OWH partnered with the Health Resources and Services Administration (HRSA) on a Medication Safety and Effectiveness Health Education Initiative targeting community and migrant health centers and individuals with special health care requirements like HIV/AIDS. OWH collaborated with The Laura W. Bush Institute for Women's Health who is using OWH publications and display stands at their 12 health centers across Texas to promote improved health for women and their families. OWH publications and display stands are being used at over 70 colleges and universities nationwide including 12 women's colleges, 16 historically Black colleges and universities, and 5 Hispanic serving institutions. OWH participated in over 100 national, regional, state and local medical, scientific, and healthcare conferences as presenters, session chairs, exhibitors, and provided funding for the Public Affairs Specialists in ORA to exhibit at an additional 43 local and regional conferences. Consumer materials on Health and Beauty were highlighted nationally in the "Dear Abby" column during Women's Health Week in May 2008 resulting in the distribution of over 125,000 kits in English and Spanish. As of August 2008, OWH distributed more than 4.1 million health information publications through the Federal Citizen Information Center FCIC alone.

Good Clinical Practice Program (GCPP)

Established in 2000, GCPP serves as the FDA focal point for Good Clinical Practice (GCP) issues related to FDA-regulated clinical trials. GCPP 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.

In 2006, FDA launched its HSP/BIMO Modernization Initiative which is led by the GCPP. Over the last year, the GCPP has developed several key documents and participated in domestic and foreign outreach activities in support of this important effort. In coordination with the Centers and ORA, the GCPP 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, GCPP issued guidance to clarify the collection of information for clinical investigators conducting studies overseas and participated in international GCP capacity building activities such as training of non-US regulators.

Other Headquarters Offices

The Office of Shared Services (OSS) provides a full portfolio of administrative services FDA-wide.

Office of Shared Services (OSS)

OSS continues to add tremendous value to FDA as a customer service support organization that focuses its professional efforts on the FDA's programs and workforce. In 2008, OSS met or exceeded over 95% of its Service Level Agreement targets, and is on target to do the same in 2009. OSS continues to lead HHS in its socio-economic and competitive contracting efforts, and has made tremendous progress in utilizing performance-based acquisition procedures. OSS continues to expand the Biosciences Library's portfolio of research titles available online and is expanding its Integrated Library System as the primary tool for employees to find critically needed research support. FDA's Equal Employment Opportunity and Diversity Management program continues to provide critical leadership and will likely expand its portfolio in 2009 to include support to additional HHS operating divisions. The Financial Services component continues to be tremendously successful, with an Accounts Payable record of over 99 percent on time payments and over 97 percent usage of Electronic Funds Transfer, and, through active management of the FDA's travel program, continues to maintain very low travel payment delinquency rates. OSS continues to actively manage FDA's real property assets (over 350 government owned or leased facilities nationwide) through increased utilization of its Real Property Management System, and is actively planning potential upgrades to several of its laboratory and other facilities. OSS operates a cost-effective consolidated call center (known as "ERIC") in support of FDA administrative and IT services, as well as supporting the Rockville Human Resources Center.

In 2009, FDA realigned its administrative services. The Office of Acquisitions and Grants Services and the Office of Equal Employment Opportunity and Diversity Management now report directly to the Chief Operating Officer, and the Office of Financial Services now reports to the Chief Financial Officer. OSS still provides overall financial and performance control over all Shared Services functions but day-to-day operational control only over the Office of Real Property Services, the Office of Public Information and Library Services (includes the Biosciences Library, the Division of Freedom of Information Act Management, and the Division of Dockets Management), and the ERIC Call Center.

Office of IT Shared Services
In FY 2008, the Office of IT Shared Services continues to consolidate and modernize the FDA's IT infrastructure and provided 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.

Five Year Funding Table

The following table shows a five-year funding history for the Office of the Commissioner's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2006 Actual	$103,886,000	$85,676,000	$18,210,000	672
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 Omnibus	$160,271,000	$120,560,000	$39,711,000	737
FY 2010 Estimate	$205,062,000	$143,712,000	$61,350,000	867

Budget Request

The FY 2010 President's budget for FDA Headquarters and the Office of the Commissioner is $205,062,000 . It is an increase of $44,791,000 above the FY 2009 FDA appropriation level in the Omnibus Appropriations Act, 2009. In addition Headquarters and the Office of the Commissioner will receive $21,639,000 in user fee increases. .

User Fees:

Prescription Drug User Fee Act (PDUFA IV): +$2,560,000
FDAAA reauthorized the PDUFA (PDUFA IV) from FY 2008 to FY 2012. PDUFA IV includes an update in the workload adjuster to reflect the Investigated New Drug (IND) workload, an adjustment for rent activities. Additionally, the reauthorization contains a change in the Consumer Price Index (CPI) factor to better correspond to FDA's budget process, and the addition of an inflation factor to reflect the five-year average of FDA's salary and benefit costs. User fees revenues under PDUFA IV are estimated for FY 2009 at $32,710,000 and estimated at $35,270,000 under the FY 2010 President's Budget request.

Medical Device User Fee and Modernization Act (MDUFMA II): No Change
In FDAAA, MDUFA was reauthorized (MDUFA II) from FY 2008 to FY 2012. MDUFA II includes the addition of an establishment registration fee to ensure a more stable revenue base, a change in the CPI factor to better correspond to FDA's budget process, and the addition of an

inflation factor to reflect the five-year average of FDA's salary and benefit costs. User fee revenues under this program are estimated at $5,914,000 under the FY 2010 President's Budget.

Animal Drug User Fee Act (ADUFA II): +$37,000
Enacted in November 2003, ADUFA helps FDA, through a strengthened animal drug premarket review program, to provide greater public health protection by ensuring that animal drug products that receive FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption. ADUFA helps to provide a cost-efficient, high quality animal drug review process that is predictable and performance driven. User fees revenues under ADUFA are estimated for FY 2009 at $656,000 and estimated at $693,000 under the FY 2010 President's Budget request.

Animal Generic Drugs User Fee (AGDUFA): +$11,000
Enacted in 2008, the Animal Generic Drugs User Fees will generate resources to allow FDA to improve product review performance and reduce review time. Increasing costs for the review of Abbreviated New Animal Drug Applications (ANADAs) along with inadequate resources has resulted in a significant increase in review times and a backlog of generic animal drug applications for review. Management initiatives that have been implemented to increase efficiency in the generic animal drug review process include dedicated review teams for evaluation of generic animal drugs, phased review of generic investigational new animal drug submissions, and establishment of periodic meetings with representatives of the generic animal drug industry to discuss issues and ideas for improvement. Despite these efforts, insufficient funding has led to a significant increase in review time for generic animal drug applications and submissions.

Adding additional staff and information technology through user fee revenues will shorten the time to approval, and decrease the delay in making lower cost medications available to the food animal production industry, veterinary practitioners, companion animal owners, and the general public. User fees revenues under ADUFA are estimated for FY 2009 at $193,000 and estimated at $204,000 under the FY 2010 President's Budget.

Mammography Quality Standards Act (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 American women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which was reauthorized in October 2004, addresses the public health necessity for safe and reliable mammography. The Act required that mammography facilities be certified by October 1994, and inspected annually to ensure compliance with national quality and safety standards. The reauthorization codified existing certification practices for mammography facilities and laid the groundwork for further study of key issues that include ways to improve physicians' ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms. User fee revenues under this program are estimated at $238,000 under the FY 2010 President's Budget.

Proposed User Fees:

Generic Drug User Fee (GDUFA): +1,189,000

Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering public and private spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled. This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. User fee revenues under this program are estimated at $1,189,000 under the FY 2010 President's Budget.

Reinspection User Fee: +8,342,000

This proposal for $25,848,000 and 129 FTEs in Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. User fee revenues under this program are estimated at $8,342,000 under the FY 2010 President's Budget.

Food Inspection and Facility Registration User Fee: +9,500,000

The FY 2010 budget proposes a User Fee for Food Inspection and Facility Registration for $75,000,000. This proposal allocates $9,500,000 to Headquarters and the Office of the Commissioner. Food facilities would be charged user fees for inspections and registration of their establishments. These user fees would fund FDA inspections at the facilities. User fee revenues under this program are estimated at $9,500,000 under the FY 2010 President's Budget.

Headquarters and the Office of the Commissioner Performance Measures Table

Long Term Objective: Strengthen FDA's base of operations.

Measure	FY	Target	Result
291401: The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". *(Efficiency)*	*2010*	0 FTE * per HHS guidance, FY09 studies are on-hold and FY10 studies are also anticipated to be on-hold.	September 2010
	2009	154 FTE by Sept 15	September 2009
	2008	130 FTE by Sept 15 (target changed by HHS)	152 FTE by Sept 15 (Target Met)
	2007	308 by Sept 15	354 FTE by 9/15/07 (Target Met)
	2006	N/A	Study cancelled in February 2007 with the approval of the CSO. (Target Met)
	2005	N/A	350 FTE (combined with FY 2004) (Target Met)

Measure	FY	Target	Result
291402: FDA's implementation of HHS's Unified Financial Management System (UFMS). *(Efficiency)*	*2010*	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.	September 2010
	2009	Begin migration to version 11-5-10 of ORACLE Federal Financials	September 2009
	2008	Stabilize UFMS environment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials	All HHS OPDIVS are now in UFMS production. Stabilization for IHS is underway (Target Met)
	2007	Finalize decision on an activity-based costing application and make it operational for its user fee programs	Finalized the decision on an activity-based costing application and made it operational for its user fee programs. (Target Met)
	2006	N/A	Goal accomplished through various activities discussed under Performance text (Target Met)

Measure	FY	Target	Result
	2005	N/A	Implemented the General Ledger and the Payroll interface (Target Met)

Long Term Objective: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.

Measure	FY	Target	Result
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	*2010*	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. Coordinate participation in inter-agency work-groups, and implement an Agency-wide National Incident Management System (NIMS) plan	September 2010
	2009	Continued enhancement of EON IMS and GIS capabilities. Coordinate FDA's participation in exercises and interagency work-groups, update remaining emergency response plans, and develop an Agency-wide National Incident Management System (NIMS) implementation plan.	September 2009
	2008	Continued enhancement of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participation in other exercises and workgroup.	EON IMS Version 3.3 implemented Aug 08. Includes significant enhancements to further its knowledge mgmt and GIS capabilities. FDA-wide Incident Command System (ICS) training conducted for Head-quarters and field offices. Finalized Pandemic Influenza Emergency Response Plan and began planning an FDA Pandemic Influenza Exercise for Oct 2008 (Target Met)
	2007	Continue Enhancement EON IMS Coordinate FDA's participation in exercises, including TOPOFF 4	EON IMS version 3.2.1 implemented December 2007 and used in the

Measure	FY	Target	Result
		Develop an FDA emergency response plan for pandemic influenza	preparation and response to natural disasters and crises and emergencies. FDA emergency response plan for pandemic influenza developed Sept 2007. (Target Met)
	2006	N/A	EON IMS Version 2.4 August 06. deployed to OCM/ OEO located in FDA field offices and used to prep and respond to emergencies (Target Met)
	2005	N/A	EON IMS version 2.2 implemented in March 2005 and used during the April 2005 TOP-OFF 3 Exercise (Target Met)

1. The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". (291401)

Context: FDA plans to study at least 154 FTE per year based on the FAIR Act Inventory of 2003. To accomplish this, FDA conducts an intensive annual review of its FAIR inventory data from functional, organizational, geographic, and business perspectives. Once the review is completed, FDA evaluates all commercial positions that have not undergone a competitive sourcing study in order to identify a sufficient number of positions that will satisfy FDA's requirement in meeting the OMB and DHHS established goals. The commercial positions are presented to FDA senior management in the form of logical business units to determine what will be reviewed that year. The selected commercial business units are publicly announced and subjected to A-76 competitive sourcing competition either as one or more standard and/or streamline cost comparisons.

Performance: FY 2006 and FY 2007 studies were combined and as a result, FDA was required to announce 308 commercial FTE positions by September 15. FDA exceeded this goal by 15%, announcing 354 commercial FTE positions. A total of thirteen streamline studies were announced. All thirteen studies resulted in an in-house win for FDA, with a projected annual savings of $3,219,000. Due to exceeding the FY 2007 target, HHS officially reduced the target and required FDA to announce 130 commercial FTE positions. However, FDA exceeded this goal by 8.6 %, announcing 152 commercial FTE positions by September 15. For FY 2009, the target remains 154 FTE positions; however, per HHS guidance, FY09 studies are on-hold and FY10 studies are also anticipated to be on-hold

2. FDA's implementation of HHS's Unified Financial Management System (UFMS). (291402)

Context: The Department announced in FY 2001 that it intended to establish a unified financial management system to replace its operating division's individual financial management systems. The goal of the UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. FDA, CDC, NIH, and the Program Support Center (which covers the remaining components other than CMS and its contractors) began the design of the UFMS. Although this goal had originally been dropped after FDA had implemented UFMS, FDA has continued to be involved in the implementation of the UFMS system across the Department. A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009 the Department will migrate to Oracle Federal Financials version 11-5-10 and also implement iProcurement and PRISM as the global solutions for requisitioning and acquisitions.

Performance: UFMS has been fully implemented in FDA. Because UFMS is an integrated system and all OPDIVs must share it, FDA remains involved and participates in all future phased implementations of other OPDIVs in the Department. As such, in FY 2006, we participated in the Program Support Center's phased implementation of UFMS and did so again in FY 2007 for Indian Health Services (which went live on October 1, 2007). In FY 2008, FDA is stabilizing the UFMS environment and exploring/analyzing the effects of moving to a later version of ORACLE Federal Financials. In FY 2009, FDA Upgraded to UFMS Release 4.1 (Oracle 11.5.10.2) successfully and is currently deploying other initiatives that are currently in progress. They include Oracle Business Intelligence (OBI) Prototype for FDA, O&M 2009 initiatives (Supplier Management and Automation, eTravel, Audit Portal Migration, Automated User Provisioning, Grants Processing, Cash Management, Common Account Number (CAN) Generation, Smart Pay II, PO Mass Cancellation) just to mention a few. Also several Oracle Security and Performance Patches were and continue to be deployed to make UFMS compliant with Federal and business standards. Plans for FY 2010 include continue OBI development work, 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.

3. Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (292201)

Context: FDA's Office of Crisis Management (OCM), which includes the Office of Emergency Operations and Office of Security Operations, is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents," HSPD-8, "National Preparedness," and HSPD-9, "Defense of United States Agriculture and Food." In FY

2009, FDA will continue to enhance the Emergency Operations Network Incident Management System (EON IMS) and Geographic Information System (GIS) capabilities and continue to coordinate FDA's participation in exercises and work-groups, including National Level Exercises (NLEs).

Performance: In FY 2008, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.3 and will release a version in 2009 to establish a web-based portal for regulated industry; state and local health officials to submit reports of potentially harmful food as required by the Food & Drug Administration Amendment Act of 2007 (FDAAA). The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g.; melamine contaminated pet food, peanut butter contaminated with salmonella, and botulism in chili sauce. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2008 hurricane season, response activities related to outbreaks involving salmonella in imported produce, flooding in the mid-west, and wildfires and earthquakes in California. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners. OCM finalized the FDA Pandemic Influenza Emergency Response Plan during FY08 and conducted an FDA-wide Pandemic Influenza Exercise in October 2008. OCM will also update the FDA Emergency Response Plan, 3 incident-specific emergency response plans and develop an agency-wide National Incident Management System (NIMS) implementation plan in FY 2009.

OCM will enhance FDA's Incident Command System (ICS) structure and its ability to respond to food-related events in FY 2010 by improving response capabilities by incorporating subject matter expertise into strategic planning and day to day operations; improve Agency preparedness by conducting exercises to assess response capabilities to foodborne illness/outbreaks; and further integrate emergency policy and planning into Agency emergency operations.

INFRASTRUCTURE
GSA RENT, OTHER RENT AND WHITE OAK CONSOLIDATION

FDA's Infrastructure Program summarizes the budget program requirements that justify a $289,932,000 request for FY 2010. The Infrastructure Program includes the GSA Rental Payments, Other Rent and Rent-Related Activities, and the FDA White Oak Consolidation.

The Infrastructure Program funding table shows a three year span of program level resources, budget authority, and user fees displayed in the FY 2008 Actual level, FY 2009 Omnibus, and FY 2010 President's Budget Request.

FDA Program Resources Table

	FY 2008		FY 2009	FY 2010 President's	FY 2010 +/- FY
	Enacted	Actuals	Omnibus	Budget Request	2009 Omnibus
Program Level	**$258,468,000**	**$252,483,000**	**$267,183,000**	**$289,932,000**	**$22,749,000**
GSA Rent	$159,173,000	$145,111,000	$155,425,000	$173,111,000	$17,686,000
Other Rent	$60,759,000	$64,646,000	$70,477,000	$75,325,000	$4,848,000
White Oak	$38,536,000	$42,726,000	$41,281,000	$41,496,000	$215,000
Budget Authority	**$219,441,000**	**$219,425,000**	**$223,180,000**	**$237,180,000**	**$14,000,000**
GSA Rent	$130,612,000	$130,611,000	$134,351,000	$146,022,000	$11,671,000
Other Rent	$50,293,000	$50,278,000	$50,293,000	$52,622,000	$2,329,000
White Oak	$38,536,000	$38,536,000	$38,536,000	$38,536,000	$0
User Fees	**$39,027,000**	**$33,058,000**	**$44,003,000**	**$52,752,000**	**$8,749,000**
GSA Rent	**$28,561,000**	**$14,500,000**	**$21,074,000**	**$27,089,000**	**$6,015,000**
PDUFA	$23,498,000	$11,821,000	$16,000,000	$17,252,000	$1,252,000
MDUFMA	$3,622,000	$2,081,000	$3,930,000	$4,264,000	$334,000
ADUFA	$1,441,000	$598,000	$839,000	$885,000	$46,000
AGDUFA			$305,000	$305,000	$0
Proposed User Fees	**$0**	**$0**	**$0**	**$4,383,000**	**$4,383,000**
Generic Drugs				$2,262,000	$2,262,000
Reinspection				$2,121,000	$2,121,000
Other Rent	**$10,466,000**	**$14,368,000**	**$20,184,000**	**$22,703,000**	**$2,519,000**
PDUFA	$9,297,000	$13,409,000	$18,691,000	$20,154,000	$1,463,000
MDUFMA	$1,169,000	$850,000	$1,268,000	$1,376,000	$108,000
ADUFA	$0	$109,000	$153,000	$162,000	$9,000
AGDUFA			$72,000	$72,000	$0
Proposed User Fees	**$0**	**$0**	**$0**	**$939,000**	**$939,000**
Generic Drugs				$0	$0
Reinspection				$939,000	$939,000
White Oak	**$0**	**$4,190,000**	**$2,745,000**	**$2,960,000**	**$215,000**
PDUFA	$0	$4,190,000	$2,745,000	$2,960,000	$215,000

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 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])

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; Contract

Program Description and Accomplishments

The Infrastructure Program supports FDA's workforce at headquarters and nationwide by providing secure and cost-effective office and laboratory space for FDA employees to conduct mission critical work. Three accounts make up the Infrastructure Program: GSA Rental Payments, Other Rent and Rent-Related Activities and the FDA White Oak Consolidation. Each of these accounts is discussed below:

GSA Rental Account

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 guard services and security systems at these facilities.

FDA currently occupies over 7.2 million square feet of GSA space. Approximately two-thirds of the GSA rent charges for government-owned or GSA-leased space are for facilities in the Washington, D.C. area. The largest amounts include charges for the Parklawn complex, Module II in Beltsville, CFSAN's College Park complex, and the newly occupied buildings at the White Oak, Maryland campus. In addition, FDA-occupied space comprises approximately 240 leases including District Offices, Regional Offices, laboratories, and resident posts across the nation and in Puerto Rico.

In FY 2008, the GSA Rent program conducted several activities to ensure the FDA workforce has the space and security necessary to carry out FDA's mission of protecting public health in an efficient and effective manner. In FY 2008, FDA vacated seven GSA rented spaces. FDA's Office of Criminal Investigations (OCI) closed a field office after completing a long-term investigation, FDA's Office of Regulatory Affairs (ORA) consolidated their operations at one border station and terminated their on-site presence at two other border stations, and three office/lab buildings were returned to GSA as a result of functions and FTEs relocating to the consolidated White Oak campus.

The GSA Rent program worked with GSA to renegotiate leases and build out expansion space at three locations in order to accommodate increases in staffing, acquired new space for secured parking at one OCI field location, relocated eight offices because of expiring leases, and accomplished extensive renovations in two locations.

Other Rent and Rent-Related Account

The Other Rent and Rent-Related 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-owned, GSA owned or leased and FDA-managed, and FDA-leased properties located nationwide. Costs include commercial rent, utilities, operation and maintenance contracts, janitorial and grounds maintenance contracts, and security and guard services contracts. The account also includes costs for overtime utilities and other above-standard level services provided by GSA in GSA-managed facilities.

FDA is working on the implementation of numerous energy savings efforts that will decrease utility costs, increase the life span and efficiency of operating and maintaining facilities, and save energy overall. The implementation of these types of projects support and meet the requirements set forth in three Executive Orders: E.O. 13123, Greening the Government Thru Efficient Energy Management, E.O. 13327 Federal Real Property Asset Management, and E.O. 13423 Strengthening Federal Environmental, Energy, and Transportation Management. These projects also supports and meet 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 awarded the first Utility Energy Service Contract (UESC) at the FDA Complex in July 2007 in Beltsville, MD. The contract was based on the implementation of 21 specific energy and water conservation measures (ECMs) including replacing 3 chillers and 1 cooling tower at MOD 1, converting laboratory air handling units to new variable air volume controls and upgrading and enhancing the Digital Direct Controls at the MOD 1 & 2 laboratories and the MOD 1 vivarium. All these ECMs will achieve an estimated $1,416,640 annual savings in water, sewer, electricity and fuel costs representing a 35% utility cost reduction for this FDA Beltsville Facility Complex for many years to come. This UESC project is scheduled to be completed in September 2009.

FDA also awarded a UESC to Georgia Power, in September 2008, for the South East Regional Laboratory in Atlanta, Georgia. The ECMs performed under this contract included replacing Plumbing Devices, installing passive infrared occupancy wall switches, installing vending misers, installing an energy management and control system, retrofitting the boiler plant and the autoclave units, and replacing multi-zone air handling units. These ECMs are estimated to save $152, 202 in annual utility savings. Additional impacts include enhancing the indoor air quality by improving thermal comfort, ventilation and air distribution and indirectly resulting in an increase in productivity.

Finally FDA is considering several other Energy Saving Contracts for:

- The ORA District Laboratory in Irvine, CA from Southern California Edison Electric Power Company.
- The Winchester Engineering and Analytical Center in Winchester, Massachusetts; and
- The ORA San Juan, PR Complex.

White Oak Consolidation

White Oak will replace and centralize existing geographically disparate facilities with new, state-of-the art laboratories, office buildings and support facilities into one location. While the GSA appropriation will fund the design and construction of the new buildings at White Oak, FDA's appropriation and PDUFA user fees will fund building fit-out and move costs. FDA initiated relocation activities to White Oak in FY 2002. During FY 2008, FDA relocated 1,118 staff to the White Oak campus increasing the population to 3,174. In FY 2009, 1,401 employees will relocate to the White Oak campus, for a total on campus to 4,575. In FY 2010, FDA plans to relocate 1,159 staff from of the Office of the Commissioner and all of the Office Regulatory Affairs headquarters staff to the campus, bringing the population to 5,734. The current Master Plan for the consolidation at White Oak calls for the last phase of the consolidation in FY 2013. When complete, the campus will accommodate more than 7,700 FDA employees and contractors.

Construction of Office Building 51 and the Southwest Parking Garage was completed in FY 2008, and FDA moved into the new facilities in February 2008. The renovation of Historic Building 1 commenced in October 2007 and was completed in November 2008.Construction of Office Building 66 is underway and will be completed by May 2009. Construction of Office Buildings 31 and 32 began in December 2007 is scheduled for occupancy in March 2010. Construction of the Northeast Parking Garage started in June 2008 with an anticipated completion date of May 2009. In May 2008, design started for the Southeast Parking Garage. Buildings 52 and 72, the Life Sciences Laboratories II and III, and Office Building 71 design started in August 2008.

FIVE YEAR FUNDING TABLE – GSA RENT

The following table shows a five-year funding history for the Infrastructure Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2006 Actual	$133,368,000	$116,403,000	$16,965,000
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 Omnibus	$155,425,000	$134,351,000	$21,074,000
FY 2010 Estimate	$173,111,000	$146,022, 000	$27,089,000

FIVE YEAR FUNDING TABLE – OTHER RENT AND RENT-RELATED ACTIVITIES

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2006 Actual	$43,456,000	$35,400,000	$8,056,000
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 Omnibus	$70,477,000	$50,293,000	$20,184,000
FY 2010 Estimate	$75,325,000	$52,622,000	$22,703,000

FIVE YEAR FUNDING TABLE – WHITE OAK

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2006 Actual	$26,788,000	$21,755,000	$5,033,000
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 Omnibus	$41,281,000	$38,536,000	$2,745,000
FY 2010 Estimate	$41,496,000	$38,536,000	$2,960,000

Budget Request

The FY 2010 Request includes $289,932,000 in program level funding for the Infrastructure Program. The request represents an increase of $22,749,000 over the FY 2009 Omnibus program level funding.

GSA Rental Payments

The FY 2010 budget request for GSA Rental Payments is $173,111,000 This request includes $146,022,000 in budget authority and $27,089,000 in user fees. The GSA Rental Payments Program is requesting an increase of $17,686,000 including $11,671,000 in budget authority and $6,015,000 in current and proposed law user fees. This increase over the FY 2009 budget request is due primarily to retention of leased buildings at headquarters to house increased staff. Base funding for GSA Rental Payments covers the cost of rental payments to GSA for FDA's 7.2 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

The FY 2010 budget request for Other Rent and Rent Related is $75,325,000.. This request includes $52,622,000 in budget authority and $22,703,000 in user fees. The Other Rent and Rent-Related Program is requesting an increase of $4,848,000 including $2,329,000 in budget authority and $2,519,000 in current and proposed law user fees. The base funding allows FDA to operate, maintain and secure the facilities. The requested increase in funding will cover the escalating costs in commercial rent, security, and utility costs and prevent FDA from charging unavoidable costs to FDA programs, allowing them to fund mission-related activities in food protection and medical product development and safety.

White Oak Consolidation

The FY 2010 budget request for White Oak Consolidation is $41,496,000, an increase of $215,000 from the FY 2009 program level. The White Oak Consolidation request includes $38,536,000 in budget authority and $2,960,000 in user fees. The base funding will allow FDA to complete the relocation of the Office of the Commissioner (OC) and the Office of Regulatory Affairs (ORA) to Office Buildings 31 and 32; complete the decommissioning of the FDA Parklawn data center; provide IT, telecommunication and security infrastructure for Life Sciences Laboratories II and III, the Northwest and Southeast Garage, truck screening and distribution facilities, and the Child Care Center. This funding will provide the means to relocate 1,159 more staff to the campus in FY 2010, bringing the total staff on campus to 5,734. The PDUFA user fee funding allows the Infrastructure Program to provide for the relocation to White Oak, and funds facilities for employees and contractors who support the user fee process.

User Fee Increase

This request includes an increase of $8,749,000 in user fees from the Prescription Drug User Fee Act (PDUFA), Medical Devices User Fee and Modernization Act (MDUFMA), Animal Drug User Fee Act (ADUFA), the Animal Generic Drug User Fee Act (AGDUFA), and the proposed Generic Drug User Fee Act. The increases in user fees will cover the increased costs in GSA and commercial rent, security, and utility costs of those programs. The increase in PDUFA funds for the White Oak relocation allows the Infrastructure program to provide for relocation to the White Oak campus and support facilities for employees and contractors who support the user fee process.

BUILDINGS AND FACILITIES

FDA's Building and Facilities program narrative summarizes the budget program requirements that justify a $12,433,000 request for FY 2010.

The following table shows a three-year funding history for the Buildings and Facilities program.

FDA Program Resources Table

	FY 2008		FY 2009 Omnibus	FY 2010 President's Budget Request	FY 2010 +/- FY 2009 Omnibus
	Enacted	Actuals[1]			
Program Level	**$6,157,000**	**$7,534,000**	**$15,930,000**	**$12,433,000**	**-$3,497,000**
Budget Authority	**$2,433,000**	**$3,810,000**	**$12,433,000**	**$12,433,000**	**$0**
Natural Products Center	$3,724,000	$3,724,000	$3,497,000	**$0**	-$3,497,000

[1]Includes carry over funds from prior year appropriations and $3,724,000 for FY 2008 Omnibus Appropriations

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.*)

Allocation Method: Direct Federal; Contract

Program Description and Accomplishments

The Building and Facilities Program is a critical element of FDA's real property asset management program and provides direct support to accomplishing the Agency mission. It supports FDA's strategic goal to transform administrative systems and infrastructure to support FDA operations. Accordingly, funding is provided for new construction of mission critical laboratory, office and support space as well as for renovations and needed repairs and improvements to existing FDA-owned facilities across the U.S.

The Department of Health and Human Services (HHS) has developed a Real Property Asset Management Plan (RAMP), which outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets. The RAMP contains performance measures 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.

benchmarks that monitor key real property asset management criteria, including mission criticality, utilization, facility condition and operating costs.
The physical condition of FDA's owned assets, which includes a substantial amount of laboratory facilities, is of critical importance. A safe, suitable and reliable work environment is essential for FDA to protect the Nation's health, security, and economy. Improving and maintaining facilities often results in a positive effect on associated utilization and operating costs. An important component of FDA real property asset management is conducting facility condition assessments on a three-year cycle. Facility condition assessments evaluate such things as physical systems (*e.g.*, architectural, civil, mechanical, electrical), code compliance, life and other safety conditions, and finishes and aesthetics. The assessments result in a list of maintenance and repair deficiencies (i.e., Backlog of Maintenance and Repair [BMAR]) for the facility, a plant replacement value (i.e., current cost to replace the facility) and a Facility Condition Index (FCI) score.

The BMAR lists and estimates costs associated with addressing needed maintenance, repairs and replacement of equipment that is approaching, at, or past its useful life. This information is used to identify and prioritize short- and long-term projects using Building and Facilities Program funding. The FCI score is calculated using the BMAR and plant replacement value and HHS has established an FCI goal of 90 percent or greater for all owned facilities. Currently, approximately 63 percent of FDA's owned assets have an FCI score below the HHS established goal and require significant repairs and improvements.

FDA has utilized Building and Facilities Program funding provided in the previous two fiscal years to accomplish several mission and BMAR driven projects at each of its six owned sites to both improve the condition of these assets and to ensure the suitability of owned assets for conducting FDA's mission. The list below is representational and not comprehensive.

FDA's Gulf Coast Seafood Laboratory site located in Dauphin Island, AL is used by the Center for Food Safety and Applied Nutrition (CFSAN) to conduct research programs related to seafood safety, especially seafood harvested from the Gulf of Mexico. FDA has funded projects totaling approximately $340,000 to renovate/modernize the main laboratory, make minor repairs, and resurface the parking lot/roads.

The FDA Muirkirk Road Complex (MRC) located in Laurel, MD is used by CFSAN and the Center for Veterinary Medicine (CVM) to conduct research programs related to food and animal drug safety. In addition, laboratories at this site are used as part of the Laboratory and Food Emergency Response Networks. FDA has funded projects totaling approximately $1.8 million to complete the installation of an emergency generator for a laboratory building to ensure mission-critical research was protected; decommission laboratory exhaust systems in support of a Utility Energy Services Contract; replace aged and non-compliant fire alarm systems; install and/or update ground fault circuit interrupter protection and emergency and egress lighting; replace exit signs; retube boilers; overhaul cooling towers and chillers; design laboratory and office renovations; design a replacement laboratory nitrogen manifold system; replace variable frequency drives for laboratory air handling units and exhaust fans; replace reheat coils; and repave a bridge and repair associated sinkholes.

The Jefferson Laboratories Complex (JLC) located in Jefferson, AR houses the National Center for Toxicological Research (NCTR) and the Office of Regulatory Affairs' (ORA) Arkansas Regional Laboratory (ARL). NCTR conducts research that focuses on risk assessment, investigating toxicity, and studying the extrapolation of data from animal studies to humans, all of which inform FDA's regulatory policies. The ARL provides analytical laboratory support to ORA's regulatory mission in the Southwest Region. FDA has funded projects totaling approximately $12.7 million to complete the fit-out of four floors of a key administrative building; renovate existing space for critical primate research, neurotoxicology laboratories and magnetic resonance imaging (MRI) capabilities; design a critical infrastructure project to replace boilers at the site boiler plant; and complete various repair and improvement projects. Repair and improvement projects include repairing a processing area that supports animal research and replacing fire alarm systems, roofs, cooling towers, chillers, and direct expansion (DX) air handling units.

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 has funded projects totaling approximately $260,000 to replace the sanitary sewer system; to replace corroded rooftop central air conditioning units and direct expansion (DX) units; and to correct additional facility deficiencies.

The FDA's Pacific Regional Laboratory Southwest is located in Irvine, CA. The PRL-SW provides analytical laboratory support to ORA's regulatory mission in the Pacific Region. The facility also houses the Los Angeles District Office, which serves as ORA's inspection and compliance activity in the Los Angeles area. FDA has funded projects totaling approximately $100,000 to repair a chronic roof leak and perform a required sustainability study.

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 funded projects totaling approximately $470,000 to install mission critical furnaces and ovens and to renovate/modernize the main laboratory.

FDA has initiated a $200,000 feasibility study to begin the process of determining program needs and required facility modifications to expand its nanotechnology, cytoflow and imaging programs at the MRC, JLC and White Oak Federal Research Center. Finally, FDA spent $252,256 to complete facility condition and sustainability assessments for its owned assets.

The historical funding table shows a five-year history of program level funding, budget authority funding, and user fee funding.

Five Year Funding Table

The following table shows a five-year funding history for the Building and Facilities Program's program level, budget authority, and user fee resources.

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2006 Actual [1]	$8,510,000	$8,510,000	$0
FY 2007 Actual [2]	$10,382,000	$10,382,000	$0
FY 2008 Actual [3]	$7,534,000	$7,534,000	$0
FY 2009 Omnibus [4]	$15,930,000	$15,930,000	$0
FY 2010 Estimate	$12,433,000	$12,433,000	$0

[1] FY 2006 enacted level was $7,920,000. FY 2006 Actual includes carry over funds from prior year appropriations

[2] FY 2007 enacted level was $4,950,000. FY 2007 Actual includes carry over funds from prior year appropriations.

[3] FY 2008 enacted level was $6,157 including $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 FY 2008 actual includes carry over funds from prior year appropriations.

[4] Includes $3,497,000 for FY 2009 Omnibus Appropriations Act General Provision Sec. 725 that appropriates $3.497 to the National Center for Natural Products Research for construction and renovation.

Budget Request

The total FY 2010 request for the buildings and facilities account is $12,433,000. FDA will use its base resources in FY 2010 to fund various projects at its mission critical, owned sites that will enhance the FDA's ability to achieve its mission, provide a safe and productive work environment, and improve the condition of its owned assets.

FDA will prioritize the multitude of renovation, repair and improvement projects driven by mission requirements and its Backlog of Maintenance and Repair and utilize the FY 2010 funding to complete top priority projects. The following table provides a plan for use of the FY 2010 funds.

FY 2010 Buildings and Facilities Plan

Site and Brief Description of Projects	*Site Total*
Jefferson Laboratories Complex (NCTR & ARL) - Jefferson, AR – *Complete Bldg. 62 primate research area renovations; Replace Boiler #1; Design/renovate electrical distribution system at Substation #3; Design/install elevator in Bldg. 50; Develop Program of Requirements & concept design to renovate Bldgs. 14A & B; Replace chiller for Bldg. 26; Replace Bldg. 13 roof; Design/install water meters in multiple buildings; and Design ventilation system replacement projects for Bldgs. 5D & 53E*	$5,862,000
Muirkirk Road Complex (MOD I, MOD II, BRF – Laurel, MD – *Construct offices for the Office of Criminal Investigations and replace the boiler in BRF; Replace switchgear, motor controls, ventilation controls & air compressors in MOD I; and Renovate laboratories and replace the nitrogen system in MOD II*	$3,156,000
ORA Pacific Regional Laboratory SW – Irvine, CA – *Repaint exterior fire escapes, stairs, gates and panels; Repair wall cracks & install expansion control joints; and Replace lighting for main entrance walkway*	$410,000
Winchester Engineering and Analytical Center – Winchester, MA – *Upgrade ventilation, building monitoring & electrical systems; Clean duct system; and Replace roof and water heater*	$1,030,000
San Juan District Office – San Juan, PR – *Replace exterior doors & overhangs on multiple buildings; Replace hazmat/chemical storage building; Install uninterruptible power supply for main laboratory; and Modify/replace ramps & provide new handrails for ADA compliance*	$1,105,000
CFSAN Gulf Coast Seafood Laboratory – Dauphin Island, AL – *Insulate crawl space*	$70,000
Multiple FDA Sites – *Design Expansion of Nanotechnology, Cytoflow & Imaging programs*	$800,000
B&F PROJECT TOTAL	**$12,433,000**

FDA's use of Building and Facilities Program funding for FY 2010 will continue to make meeting mission requirements and sustaining and improving the condition of its owned real property assets a priority. Completion of these projects enhances the FDA's ability to achieve its critical mission of protecting and promoting the health of the American public.

Buildings and Facilities Program Activity Data[1]

Facility	Avg. FCI Score FY 2008	Avg. FCI Score FY 2009 (Enacted)	Avg. FCI Score FY 2010 (Request)
Gulf Coast Seafood Laboratory[2]	32	68	84
Jefferson Laboratory Complex[3]	80	81	84
Muirkirk Road Complex[4]	83	86	89
Pacific Regional Laboratory Southwest[5]	99	100	100
San Juan District Office and Laboratories[6]	73	84	89
Winchester Engineering and Analytic Center[7]	57	60	73

[1]The Backlog of Maintenance and Repairs (BMAR) at each site is significant. Funding is allocated to projects at each site in an effort to reduce the BMAR and improve the average Facility Condition Index (FCI) for the site. Without ongoing repair and improvement projects, the increase in BMAR each year would result in no change or a decrease in the FCI rather than an increase.

[2]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $487K to a total of approximately $500K.

[3]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $9.9M to a total of approximately $53.8M.

[4]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $3.5M) to a total of approximately $10.7M.

[5]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $48K to a total of approximately $93K.

[6]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $696K to a total of approximately $1.7M.

[7]Based on funding levels in FY2009 and FY2010, the BMAR for this site will decrease by approximately $2.16M to a total of approximately $3.65M.

Food and Drug Administration
Object Class Detail
Budget Authority

PERSONNEL COMPENSATION:	FY 2008 Actual	FY 2009 Ominbus	FY 2010 Request	FY 2010+/-FY2009
11.1 Full-time permanent	$570,381,973	$679,261,366	$722,241,832	$42,980,466
11.3 Other than full-time perm	72,835,912	90,557,493	96,287,545	5,730,052
11.5 Other personnel Comp	33,181,867	37,081,655	39,428,008	2,346,353
11.7 Military Personnel Compensation	38,505,126	52,911,412	55,712,950	2,801,538
11.8 Special Personal svcs pay	280,849	240,470	255,686	15,216
Subtotal Personnel Comp	**$715,185,727**	**$860,052,396**	**$913,926,021**	**$53,873,625**
12.1 Civilian Personnel Benefits	180,443,156	216,520,859	230,221,281	13,700,422
12.2 Military Personnel Benefits	21,792,785	27,948,336	29,428,136	1,479,800
13.0 Benefits - former personnel	48,651			
Subtotal Pay Costs	**$917,470,319**	**$1,104,521,591**	**$1,173,575,439**	**$69,053,848**
21.0 Travel & Transportation of persons	$26,242,445	$29,608,000	$34,937,440	$5,329,440
22.0 Transportation of things	4,049,893	6,157,834	6,527,304	$369,470
23.1 Rental payments to GSA	130,612,700	134,351,000	146,022,000	$11,671,000
23.2 Rent payments to others	50,278,012	50,293,077	52,622,438	$2,329,361
23.3 Communication, Util & Misc. Services	28,042,068	32,969,000	40,807,140	$7,838,140
24.0 Printing & Reproduction	2,083,886	3,151,864	3,214,901	$63,037
Contractual Costs:				
25.1 Advisory and Assistance Services	$86,496,149	94,353,573	$122,232,466	$27,878,893
25.2 Other Services	139,724,426	189,508,278	250,448,618	$60,940,340
25.3 Purchase of Goods & Svcs from Govt Acts.	108,583,381	121,641,000	155,668,844	$34,027,844
25.4 Operation & Maintenance of Facilities	53,095,241	55,769,455	70,173,011	$14,403,556
25.5 Research & Development Contracts	27,161,075	31,656,769	47,036,976	$15,380,207
25.7 Operation & Maintenance of Equipment	24,929,127	35,080,889	45,971,036	$10,890,147
25.8 Subsistence and support of persons	301			
Subtotal Contractual Costs	**$439,989,700**	**$528,009,964**	**$691,530,951**	**$163,520,987**
26.0 Supplies and Materials	30,535,110	35,917,981	39,868,959	3,950,978
31.0 Equipment	54,110,212	77,461,324	96,531,403	19,070,079
32.0 Lands & Structures	3,810,475	12,433,400	12,433,400	0
41.0 Grants, subsidies & Contributions	31,451,057	37,822,965	49,821,625	11,998,660
42.0 Ins claims & indemnities	1,950,335	2,082,000	2,082,000	0
43.0 Interest Account	17,788	114,000	114,000	0
62.0 Receivables collected				0
Subtotal Non-Pay Costs	**$803,173,681**	**$950,372,409**	**$1,176,513,561**	**$226,141,152**
TOTAL OBLIGATIONS	**$1,720,644,000**	**$2,054,894,000**	**$2,350,089,000**	**$295,195,000**

Food and Drug Administration
Object Class Detail
User Fees

PERSONNEL COMPENSATION:	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Request	FY 2010+/-FY2009
11.1 Full-time permanent	$182,735,174	$201,065,210	$275,011,000	$73,945,790
11.3 Other than full-time perm	24,300,600	25,009,000	38,000,000	12,991,000
11.5 Other personnel Comp	10,743,100	11,006,000	15,000,000	3,994,000
11.7 Military Personnel Compensation	13,895,500	14,033,000	21,915,000	7,882,000
11.8 Special Personal svcs pay	85,600	0	0	0
Subtotal Personnel Comp	**$231,759,974**	**$251,113,210**	**$349,926,000**	**$98,812,790**
12.1 Civilian Personnel Benefits	59,114,797	64,006,000	74,000,000	9,994,000
12.2 Military Personnel Benefits	7,265,500	8,013,000	11,000,000	2,987,000
13.0 Benefits - former personnel	16,428			
Subtotal Pay Costs	**$298,156,699**	**$323,132,210**	**$434,926,000**	**$111,793,790**
21.0 Travel & Transportation of persons	$7,407,315	$8,992,000	$10,911,290	$1,919,290
22.0 Transportation of things	1,102,165	3,000,000	5,000,000	2,000,000
23.1 Rental payments to GSA	14,500,100	17,074,000	25,089,000	8,015,000
23.2 Rent payments to others	884,184	20,184,000	22,703,000	2,519,000
23.3 Communication, Util & Misc. Services	11,016,643	11,101,000	17,227,196	6,126,196
24.0 Printing & Reproduction	407,083	700,000	1,087,320	387,320
Contractual Costs:				
25.1 Advisory and Assistance Services	$24,441,489	$25,001,000	29,129,032	4,128,032
25.2 Other Services	44,498,436	76,639,790	120,804,452	44,164,662
25.3 Purchase of Goods & Svcs from Govt Acts.	38,757,941	40,037,000	45,454,839	5,417,839
25.4 Operation & Maintenance of Facilities	21,313,166	24,055,000	29,022,581	4,967,581
25.5 Research & Development Contracts	31,306,165	32,039,000	40,209,677	8,170,677
25.7 Operation & Maintenance of Equipment	7,905,106	11,041,000	19,017,742	7,976,742
25.8 Subsistence and support of persons				
Subtotal Contractual Costs	**$168,222,303**	**$208,812,790**	**$283,638,323**	**$74,825,533**
26.0 Supplies and Materials	9,604,300	8,027,000	12,011,290	3,984,290
31.0 Equipment	11,574,393	11,034,000	14,822,581	3,788,581
32.0 Lands & Structures				
41.0 Grants, subsidies & Contributions	870,000			
42.0 Ins claims & indemnities	616,815	864,000	864,000	0
43.0 Interest Account		0		0
62.0 Receivables collected				
Subtotal Non-Pay Costs	**$226,205,301**	**$289,788,790**	**$393,354,000**	**$103,565,210**
TOTAL OBLIGATIONS	**$524,362,000**	**$612,921,000**	**$828,280,000**	**$215,359,000**

Food and Drug Administration
Object Class Detail
Program Level

PERSONNEL COMPENSATION:	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Request	FY 2010+/-FY2009
11.1 Full-time permanent	$753,117,147	$880,326,576	$997,252,832	$116,926,256
11.3 Other than full-time perm	97,136,512	115,566,493	134,287,545	18,721,052
11.5 Other personnel Comp	43,924,967	48,087,655	54,428,008	6,340,353
11.7 Military Personnel Compensation	52,400,626	66,944,412	77,627,950	10,683,538
11.8 Special Personal svcs pay	366,449	240,470	255,686	15,216
Subtotal Personnel Comp	**$946,945,701**	**$1,111,165,606**	**$1,263,852,021**	**$152,686,415**
12.1 Civilian Personnel Benefits	239,557,953	280,526,859	304,221,281	23,694,422
12.2 Military Personnel Benefits	29,058,285	35,961,336	40,428,136	4,466,800
13.0 Benefits - former personnel	65,079	0		
Subtotal Pay Costs	**$1,215,627,018**	**$1,427,653,801**	**$1,608,501,439**	**$180,847,638**
21.0 Travel & Transportation of persons	$33,649,760	$38,600,000	$45,848,730	$7,248,730
22.0 Transportation of things	5,152,058	9,157,834	11,527,304	2,369,470
23.1 Rental payments to GSA	145,112,800	151,425,000	171,111,000	19,686,000
23.2 Rent payments to others	51,162,196	70,477,077	75,325,438	4,848,361
23.3 Communication, Util & Misc. Services	39,058,711	44,070,000	58,034,336	13,964,336
24.0 Printing & Reproduction	2,490,969	3,851,864	4,302,221	450,357
Contractual Costs:				
25.1 Advisory and Assistance Services	110,937,638	119,354,573	151,361,498	32,006,925
25.2 Other Services	184,222,862	266,148,068	371,253,070	105,105,002
25.3 Purchase of Goods & Svcs from Govt Acts.	147,341,322	161,678,000	201,123,683	39,445,683
25.4 Operation & Maintenance of Facilities	74,408,407	79,824,455	99,195,592	19,371,137
25.5 Research & Development Contracts	58,467,240	63,695,769	87,246,653	23,550,884
25.7 Operation & Maintenance of Equipment	32,834,233	46,121,889	64,988,778	18,866,889
25.8 Subsistence and support of persons	301	0		0
Subtotal Contractual Costs	**$608,212,003**	**$736,822,754**	**$975,169,274**	**$238,346,520**
26.0 Supplies and Materials	40,139,410	43,944,981	51,880,249	7,935,268
31.0 Equipment	65,684,605	88,495,324	111,353,984	22,858,660
32.0 Lands & Structures	3,810,475	12,433,400	12,433,400	0
41.0 Grants, subsidies & Contributions	32,321,057	37,822,965	49,821,625	11,998,660
42.0 Ins claims & indemnities	2,567,150	2,946,000	2,946,000	0
43.0 Interest Account	17,788	114,000	114,000	0
62.0 Receivables collected		0		0
Subtotal Non-Pay Costs	**$1,029,378,982**	**$1,240,161,199**	**$1,569,867,561**	**$329,706,362**
TOTAL OBLIGATIONS	**$2,245,006,000**	**$2,667,815,000**	**$3,178,369,000**	**$510,554,000**

Food and Drug Administration
Object Class Detail
Salaries and Expenses - Budget Authority

PERSONNEL COMPENSATION:	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Request	FY 2010+/-FY2009
11.1 Full-time permanent	$577,381,973	$679,261,366	$722,241,832	$42,980,466
11.3 Other than full-time perm	79,835,912	90,557,493	96,287,545	5,730,052
11.5 Other personnel Comp	35,181,867	37,081,655	39,428,008	2,346,353
11.7 Military Personnel Compensation	45,505,126	52,911,412	55,712,950	2,801,538
11.8 Special Personal svcs pay	280,849	240,470	255,686	15,216
Subtotal Personnel Comp	**$738,185,727**	**860,052,396**	**$913,926,021**	**$53,873,625**
12.1 Civilian Personnel Benefits	187,443,156	216,520,859	230,221,281	13,700,422
12.2 Military Personnel Benefits	23,792,785	27,948,336	29,428,136	1,479,800
13.0 Benefits - former personnel				
Subtotal Pay Costs	**$949,470,319**	**$1,104,521,591**	**$1,173,575,439**	**$155,051,272**
21.0 Travel & Transportation of persons	$30,474,345	$29,608,000	$34,937,440	$5,329,440
22.0 Transportation of things	4,049,893	6,157,834	6,527,304	369,470
23.2 Rent payments to others	130,612,700	134,351,000	146,022,000	11,671,000
23.3 Communication, Util & Misc. Services	3,065,912	3,827,877	3,866,539	38,662
24.0 Printing & Reproduction	39,042,068	38,969,000	53,807,140	14,838,140
Contractual Costs:				
25.1 Advisory and Assistance Services	71,496,149	$94,353,573	122,232,466	27,878,893
25.2 Other Services	142,251,121	$189,509,278	245,448,618	55,939,340
25.3 Purchase of Goods & Svcs from Govt Acts.	108,583,381	$121,641,000	166,668,844	45,027,844
25.4 Operation & Maintenance of Facilities	58,095,241	$55,769,455	79,173,011	23,403,556
25.7 Operation & Maintenance of Equipment	27,161,075	$41,656,769	47,036,976	5,380,207
Subtotal Contractual Costs	**407,586,967**	**502,930,075**	**660,559,915**	**157,629,840**
26.0 Supplies and Materials	30,535,110	35,917,981	39,868,959	3,950,978
Subtotal Non-Pay Costs	**$645,366,995**	**$751,761,767**	**$945,589,297**	**$193,827,529.53**
TOTAL OBLIGATIONS	**$1,594,837,314**	**$1,856,283,358**	**$2,119,164,736**	**$348,878,801.53**

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

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Estimate
General Fund Discretionary Appropriation:			
Appropriation (Enacted)	1,882,622	2,054,894	2,350,089
Across-the-board reductions (Enacted)	12,128	0	
Subtotal, Adjusted Appropriation	**1,870,494**	**2,054,894**	**2,350,089**
Discretionary Appropriation: Color Certification			
Appropriation	7,000	7,700	7,700
Subtotal, appropriation	**7,000**	**7,700**	**7,700**
Total, Discretionary Appropriation	**1,870,494**	**2,054,894**	**2,350,089**
Offsetting collections (spending authority) from:			
Federal Funds			
Trust Funds	-		
Non-Federal Sources	908,000	922,421	1,161,000
Portion Precluded from obligation	(307,000)	(307,000)	(333,000)
Subtotal, offsetting collections	**601,000**	**615,421**	**828,000**
Unobligated balance, start of year	134,000	326,330	329,280
Recoveries of prior year obligations	1,094	-	-
Total Amounts Available for Obligation	2,606,588	2,996,645	3,507,369
Less Unobligated balance, end of year	(325,577)	(328,830)	(329,000)
Less Unobligated balance, lapsing	(5)		
Total obligations[1]	**2,281,006**	**2,667,815**	**3,178,369**

[1]Total Obligations excludes CRADAs and Reimbursables

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]	2,622,267,000[38]	2,603,879,000[39]	2,622,267,000[40]
2010	3,136,218,000[41]			

* Appropriation contains salaries and expenses (S&E), PDUFA, MDUFMA and ADUFA only.

[1] Includes $1,109,950,000 (including $94,537,000 of GSA Rent) S&E, $145,434,000 for PDUFA ($5,643,000 is GSA Rent), $14,817,000 for MQSA fee collections, $1,030,000 for Export Certification, $3,877,000 for Certification fund, $1,061,000 for FOIA, $12,700,000 for Seafood Transfer User Fees, and $17,000,000 for proposed new user fees.

[2] Includes $1,072,950,000 (including $94,537,000 of GSA Rent) in S&E, $145,434,000 for PDUFA ($5,643,000 is for GSA Rent). This does not include $14,817,000 for MQSA fee collections.

[3] Includes $1,035,538,000 (including $94,537,000 of GSA Rent) in S&E, and $145,434,000 for PDUFA ($5,643,000 is for GSA Rent). Excludes $14,817,000 for MQSA fee collections.

[4] Includes rescission of $2,977,000, S&E of $1,037,661,000 (including $94,311,000 of GSA Rent), and $145,434,000 for PDUFA ($5,643,000 is GSA Rent). Excludes $14,817,000 for MQSA fee collections, $1,030,000 for Export Certification, $3,877,000 for Certification fund, $1,061,000 for FOIA, $12,700,000 for Seafood Transfer User Fees, $17,000,000 for new user fees, or $13,400,000 for Bioterrorism.

[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.
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[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] Includes $2,622,267,000 in S&E, and $15,260,000 in ADUFA fees, $134,351,000 in GSA Rental Payments, $510,665,000 in PDUFA fees, and $52,547,000 in MDUFMA fees. Excludes MQSA fee collections, Export Certification, and Color Certification.

[39] Includes $2,603,879,000 in S&E, and $497,108,000 for PDUFA fees, $52,547,000 for MDUFMA fees, $15,260,000 for ADUFA fees, $151,381,000 in GSA Rental Payments. Excludes MQSA fee collections, Export Certification, and Color Certification.

[40] 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), $583,303 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 (including $146,022,000 of GSA Rent) in S&E, 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 ($2,262,000 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.

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	6,157,000 [11]
2009	2,433,000	12,433,000	12,433,000	15,930,000 [12]
2010	12,433,000			

[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.

[11] Reflects FY 2008 Omnibus Appropriations Act, which includes Sec. 734, a general provision appropriating $3.75 million (minus 0.7% rescission) to the National Center for Natural Product Research for construction and renovation.

[12] Reflects FY2009 Omnibus Appropriations Act, which includes Sec. 725, a general provision appropriating $3.497 million to the National Center for Natural Product Research for construction and renovation.

Food and Drug Administration
Detail of Full-Time Equivalent (FTE) Employment
Program Level

Project[1]	FY 2008 Actual	FY 2009 Omnibus[2]	FY 2010 Estimate
Center for Food Safety and Applied Nutrition	753	854	947
Center for Drug Evaluation and Research	2,397	2,791	2,996
Center for Biologics Evaluation and Research	858	916	960
Center for Veterinary Medicine	378	424	456
Center for Devices and Radiological Health	1,130	1,204	1,275
National Center for Toxological Research	192	198	210
Office of Regulatory Affairs	3,315	3,775	4,365
Headquarters and Office of the Commissioner	733	737	867
Export Certification	17	18	18
Color Certification	39	36	36
TOTAL	**9,812**	**10,953**	**12,130**

Note:

[1] FY 2008 Actuals do not include 72 Reimbursable FTE, 21 PEPFAR and 5 CRADA FTE, FY 2009 and FY 2010 do not Include 69 Reimbursable FTE, 21 PEPFAR and 5 CRADA FTE.

[2] The FY 2009 FTE level in these Congressional Justifications reflects a correction of -36 FTE's made after the MAX budget database closed for production of the President's Budget for FY 2010.

Five Year History of GS/GM Average Grade

Year	Grade
FY 2006	11.9
FY 2007	12.3
FY 2008	12.3
FY 2009	12.3
FY 2010	12.3

FOOD AND DRUG ADMINISTRATION
DETAIL FOR FTE BY GRADE

	FY 2008 Actual	FY 2009 Omnibus[1]	FY 2010 Estimate
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	33	49	49
Total ES			
GS-15	931	959	1,002
GS-14	1,640	1,732	1,872
GS-13	2,898	2,943	3,232
GS-12	1,653	1,686	1,845
GS-11	514	549	674
GS-10	32	33	49
GS-9	379	399	541
GS-8	144	151	190
GS-7	348	366	484
GS-6	51	54	57
GS-5	104	127	170
GS-4	12	118	125
GS-3	3	81	90
GS-2	-	72	79
GS-1	-	9	15
Subtotal, GS	8,709	9,279	10,425
AL		1	1
ST/SL		1	1
RS		31	31
CC - 08/07/06	202	232	232
CC - Other	522	565	596
Subtotal, CC	724	797	828
AD (includes Title 42)	409	579	579
Wage Grade	34	44	44
Consultants		266	266
Total FTE (End of Year)	9,910	11,048	12,225
Average ES Level	-		-
Average ES Salary	164,400	169,300	174,200
Average GS grade	12	12	12
Average GS salary	127,160	134,469	133,602

[1] The FY 2009 FTE level in these Congressional Justifications reflects a correction of -36 FTE's made after the MAX budget database closed for production of the President's Budget for FY 2010.

FY 2010 HHS Enterprise Information Technology Fund: E-Gov Initiatives

The FDA will contribute $5,562,652 of its FY 2010 budget to support Department enterprise information technology initiatives as well as E-Government initiatives. Operating Division contributions are combined to create an Enterprise Information Technology (EIT) Fund that finances both the specific HHS information technology initiatives identified through the HHS Information Technology Capital Planning and Investment Control process and E-Government initiatives. These 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, $710,874.82 is allocated to support E-Government initiatives for FY 2010. This amount supports the E-Government initiatives as follows:

FY 2010 HHS Contributions to E-Gov Initiatives*	FDA
Line of Business - Federal Health Architecture (FHA)	$625,067.26
Line of Business - Human Resources	$20,477.18
Line of Business - Grants Management	$770.12
Line of Business - Financial	$23,181.41
Line of Business - Budget Formulation and Execution	$15,415.65
Line of Business - IT Infrastructure	$25,963.20
E-Gov Initiatives Total	**$710,874.82**

*The total for all HHS FY 2010 inter-agency E-Government and Line of Business contributions for the initiatives identified above, and any new development items, is not currently projected by the Federal CIO Council to increase above the FY 2009 aggregate level. 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-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.

Lines of Business-Human Resources Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital. HHS has been selected as a Center of Excellence and will be leveraging its HR investments to provide services to other Federal agencies.

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. An HHS agency, 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 and has applied to be a GMLOB consortia lead. 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-IT Infrastructure: This initiative provides the potential to leverage spending on commodity IT infrastructure to gain savings; to promote and use common, interoperable architectures that enable data sharing and data standardization; secure data interchanges; and, to grow a Federal workforce with interchangeable skills and tool sets.

Geocraphic Distribution of Facilities

Building Name	Center	City	City	State Code	State	OP DIV Subdivision	Ownership
Dauphin Island - Seafood Laboratory	CFSAN	0865	DAUPHIN ISLAND	01	AL	HEADQUARTERS-FIELD	FDA Owned
Dauphin Island - Generator Buildings	CFSAN	0865	DAUPHIN ISLAND	01	AL	HEADQUARTERS-FIELD	FDA Owned
Dauphin Island - Outer Buildings	CFSAN	0865	DAUPHIN ISLAND	01	AL	HEADQUARTERS-FIELD	FDA Owned
Resident Post - Birmingham, AL	ORA	0350	BIRMINGHAM	01	AL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Mobile, AL	ORA	2100	MOBILE	01	AL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Montgomery, AL	ORA	2130	MONTGOMERY	01	AL	SOUTHEAST-ATLANTA	GSA Leased
Daycare - Tundra Tykes	ORA	0130	ANCHORAGE	02	AK	PACIFIC-OAKLAND	GSA Leased
Resident Post - Anchorage, AK	ORA	0130	ANCHORAGE	02	AK	PACIFIC-OAKLAND	GSA Owned
Resident Office - OCI Phoenix	OCI	0370	PHOENIX	04	AZ	HEADQUARTERS-FIELD	GSA Leased
Border Station - Nogales, AZ	ORA	0330	NOGALES	04	AZ	SOUTHWEST-DALLAS	GSA Leased
Border Station - Truck Compound - Nogales, AZ	ORA	0330	NOGALES	04	AZ	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Phoenix, AZ	ORA	0490	TEMPE	04	AZ	SOUTHWEST-DALLAS	GSA Leased
Border Station - San Luis, AZ	ORA	0417	SAN LUIS	04	AZ	SOUTHWEST-DALLAS	GSA Owned
Border Station - San Luis, AZ	ORA	0417	SAN LUIS	04	AZ	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Tucson, AZ	ORA	0530	TUCSON	04	AZ	SOUTHWEST-DALLAS	GSA Owned
NCTR - Building 5D - Diet Prep - Lab	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 6 - Breeding Colony	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 7 - Boiler Plant	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 9-Main Electrical Substation	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 10 - Library	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 11-Water Treatment Plant	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 12 - Cafeteria and Conference Room	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 13-Admin Graphics	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 14A -lab and Animal Holding	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 14B - Labs and Animal Holding	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 14C - Lab	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 15 - Admin Office	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 16 - Paint Shop	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 17 - Multi-use	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 20 - Cooling Tower	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 21 - Security Building	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
Regional Laboratory- Arkansas - Building 26	ORA	2045	JEFFERSON	05	AR	SOUTHWEST-DALLAS	FDA Owned
NCTR - Building 28 - Golf Cart Charging Station	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 31 - Communications And Copy Center	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 32 - Storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 37 - Hazardous Storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 44 - Waste Water Treatment	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 45 - Maintenance	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 46 - Incinerator	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 50 - Main Admission	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 51 - Labs	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 52 - Warehouse	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 53A Labs and Animals	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 53B - Labs and Animals	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 53C -Labs and Animals	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Haz Mat Portable At 53C	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 53D -Labs and Animals	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 53E - Labs	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 54 - Occup Health EMCS	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 58 - Main Corridors - storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 58B - Connecting Corridors	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 5A-Lab - Animal Rooms	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 5B - Labs and Admin	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Haz Mat Portable At 5B	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 5C - Admin and Computer Center - Storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 60 - Microbiology Labs	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 62 Labs, BSL and Primates	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 70 - Common - Conference Room	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 71 - Residence - Dormitories	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 72 - Residence - Dormitories	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 73 - Residence - Dormitories	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 74 - Residence - Dormitories	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 85A - warehouse and laundry	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 85B - storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building 85C - storage	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Guard Portable Shed Delivery	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Guard Portable Shed Roadway	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building T-45 - Modular Offices - Facility Maint Contractor	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
NCTR - Building T-5 - Office Trailer	NCTR	2045	JEFFERSON	05	AR	HEADQUARTERS-FIELD	FDA Owned
Resident Post - Little Rock, AR	ORA	2320	LITTLE ROCK	05	AR	SOUTHWEST-DALLAS	GSA Owned
District Office with Lab - San Francisco	ORA	0010	ALAMEDA	06	CA	PACIFIC-OAKLAND	GSA Leased
Field Office - OCI Los Angeles	OCI	3250	SAN CLEMENTE	06	CA	HEADQUARTERS-FIELD	FDA Leased
Irvine Regional Office and Laboratory	ORA	1713	IRVINE	06	CA	PACIFIC-OAKLAND	FDA Owned
Irvine Regional Laboratory - Hazmat	ORA	1713	IRVINE	06	CA	PACIFIC-OAKLAND	FDA Owned
Irvine Regional Laboratory - Security Gate House	ORA	1713	IRVINE	06	CA	PACIFIC-OAKLAND	FDA Owned
Regional Field Office - Pacific - Oakland	ORA	2480	OAKLAND	06	CA	PACIFIC-OAKLAND	GSA Owned
Resident Office - OCI San Francisco	OCI	2480	OAKLAND	06	CA	HEADQUARTERS-FIELD	GSA Leased
Border Station - Calexico, CA	ORA	0520	CALEXICO	06	CA	PACIFIC-OAKLAND	GSA Owned
Resident Post - Carson, CA	ORA	0602	CARSON	06	CA	PACIFIC-OAKLAND	CUSTOMS
Border Station - Calexico, CA	ORA	0520	CALEXICO	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Los Angeles, CA	ORA	1980	LOS ANGELES	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Nisco Pacific Warehouse - Compton, CA	ORA	0810	COMPTON	06	CA	PACIFIC (OAKLAND)	GSA LEASED
Resident Post - Fresno, CA	ORA	1370	FRESNO	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - LAX - El Segundo	ORA	1980	EL SEGUNDO	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Ontario, CA	ORA	2550	ONTARIO	06	CA	PACIFIC-OAKLAND	GSA Leased
Border Station - Otay Mesa, CA	ORA	3260	SAN DIEGO	06	CA	PACIFIC-OAKLAND	GSA Owned
Border Station - Otay Mesa, CA	ORA	2610	OTAY	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Sacramento, CA	ORA	3150	SACRAMENTO	06	CA	PACIFIC-OAKLAND	GSA Owned
Resident Post - San Diego, CA	ORA	3260	SAN DIEGO	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - San Francisco Airport, CA	ORA	3730	SAN FRANCISCO	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - San Jose, CA	ORA	3340	SAN JOSE	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - San Pedro, CA	ORA	1970	LONG BEACH	06	CA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Stockton, CA	ORA	3770	STOCKTON	06	CA	PACIFIC-OAKLAND	GSA Owned
Border Station - Tecate, CA	ORA	3835	TECATE	06	CA	PACIFIC-OAKLAND	GSA Owned

Building Name	Center	City	City	State Code	State	OP DIV Subdivision	Ownership
District Office with Lab - Denver	ORA	1435	LAKEWOOD	08	CO	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Bridgeport, CT	ORA	0080	BRIDGEPORT	09	CT	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Hartford, CT	ORA	0280	HARTFORD	09	CT	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Wilmington, DE	ORA	0490	WILMINGTON	10	DE	CENTRAL-PHILADELPHIA	GSA Leased
Mary E Switzer Building SW	OC	0010	WASHINGTON	11	DC	HEADQUARTERS	GSA Owned
District Office - Florida - Maitland	ORA	1895	MAITLAND	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Field Office - OCI Miami	OCI	2541	PLANTATION	12	FL	HEADQUARTERS-FIELD	GSA Leased
Parking - Sunrise, FL OCI	OCI	2541	PLANTATION	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Boca Raton, FL	ORA	0290	BOCA RATON	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Fort Myers, FL	ORA	1070	FORT MYERS	12	FL	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Jacksonville, FL	ORA	1510	JACKSONVILLE	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Miami, FL- Import	ORA	2010	MIAMI	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Miami, FL- Domestic	ORA	2010	MIAMI	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Tallahassee, FL	ORA	2940	TALLAHASSEE	12	FL	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Tampa, FL	ORA	2950	TAMPA	12	FL	SOUTHEAST-ATLANTA	GSA Leased
District Office - Regional Office - Atlanta	ORA	0280	ATLANTA	13	GA	SOUTHEAST-ATLANTA	GSA Leased
Parking - OCI	OCI	0280	ATLANTA	13	GA	HEADQUARTERS-FIELD	GSA Owned
Regional Laboratory - Southeast	ORA	0280	ATLANTA	13	GA	SOUTHEAST-ATLANTA	GSA Leased
Resident Office - OCI Atlanta	OCI	0280	ATLANTA	13	GA	HEADQUARTERS-FIELD	GSA Owned
Resident Post - Savannah, Ga	ORA	4910	SAVANNAH	13	GA	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Tifton, GA	ORA	5490	TIFTON	13	GA	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Honolulu, HI	ORA	2400	HONOLULU	15	HI	PACIFIC-OAKLAND	GSA Owned
Resident Post - Boise, ID	ORA	0160	BOISE	16	ID	PACIFIC-OAKLAND	GSA Leased
Border Station - Eastport, ID	ORA	0445	EASTPORT	16	ID	PACIFIC-OAKLAND	GSA Owned
District Office - Chicago	ORA	1670	CHICAGO	17	IL	CENTRAL-CHICAGO	GSA Leased
Field Office -Regional - Central - Chicago	ORA	1670	CHICAGO	17	IL	CENTRAL-CHICAGO	GSA Leased
Field Office - OCI Chicago	OCI	4867	LISLE	17	IL	HEADQUARTERS-FIELD	GSA Leased
Moffett Center	CFSAN	0610	BEDFORD PARK	17	IL	HEADQUARTERS-FIELD	GSA Leased
Parking - Union Station	ORA	1670	CHICAGO	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Bensenville, IL	ORA	0740	BENSENVILLE	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Gurnee, IL	ORA	3670	GURNEE	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Hinsdale, IL	ORA	3980	HINSDALE	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Mount Vernon, IL	ORA	5900	MT VERNON	17	IL	CENTRAL-CHICAGO	GSA Owned
Resident Post - Peroia, IL	ORA	6850	PEORIA	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Springfield, IL	ORA	8220	SPRINGFIELD	17	IL	CENTRAL-CHICAGO	GSA Leased
Resident Post - Evansville, IN	ORA	1480	EVANSVILLE	18	IN	CENTRAL-CHICAGO	GSA Leased
Resident Post - Indianapolis, IN	ORA	2210	INDIANAPOLIS	18	IN	CENTRAL-CHICAGO	GSA Leased
Resident Post - South Bend, IN	ORA	4580	SOUTH BEND	18	IN	CENTRAL-CHICAGO	GSA Leased
Daycare - Shared Use	ORA	2260	DES MOINES	19	IA	SOUTHWEST-DALLAS	GSA Leased
Parking - Ampco System Parking	ORA	2260	DES MOINES	19	IA	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Davenport, IA	ORA	2080	DAVENPORT	19	IA	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Des Moines, IA	ORA	2260	DES MOINES	19	IA	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Sioux City, IA	ORA	7850	SIOUX CITY	19	IA	SOUTHWEST-DALLAS	GSA Owned
District Office- Annex - Lab - Kansas	ORA	3080	LENEXA	20	KS	SOUTHWEST-DALLAS	GSA Leased
District Office- Kansas City	ORA	3080	LENEXA	20	KS	SOUTHWEST-DALLAS	GSA Leased
Field Office - OCI Kansas City	OCI	3705	MISSION	20	KS	HEADQUARTERS-FIELD	GSA Leased
Resident Post - Wichita, KS	ORA	5880	WICHITA	20	KS	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Louisville, KY	ORA	2090	LOUISVILLE	21	KY	CENTRAL-PHILADELPHIA	GSA Leased
Resident Office - OCI New Orleans	OCI	0510	COVINGTON	22	LA	HEADQUARTERS-FIELD	GSA Leased
Resident Post - Citiplace Centre	ORA	0150	BATON ROUGE	22	LA	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Lafayette, LA	ORA	1230	LAFAYETTE	22	LA	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Mandeville Square Shopping Center	ORA	1400	MANDEVILLE	22	LA	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Metairie Center	ORA	1545	METAIRIE	22	LA	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Shreveport, LA	ORA	2130	SHREVEPORT	22	LA	SOUTHEAST-ATLANTA	GSA Leased
Border Station - Calais, ME	ORA	1250	CALAIS	23	ME	NORTHEAST-NEWYORK	GSA Leased
Border Station - Houlton, ME	ORA	3750	HOULTON	23	ME	NORTHEAST-NEWYORK	GSA Leased
Border Station - Houlton, ME	ORA	3750	HOULTON	23	ME	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Augusta, Me	ORA	0160	AUGUSTA	23	ME	NORTHEAST-NEWYORK	GSA Leased
12345 Parklawn Drive	OC	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Ammendale Building -Glassware Washing and Document Rooms	CDER/CFSAN	0100	BELTSVILLE	24	MD	HEADQUARTERS	GSA Leased
Beltsville Research Facility - Laboratory	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Beltsville Research Facility - Support Bldg	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Beltsville Research Facility - Carpentry Shop	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Beltsville Research Facility - Maintenance Building	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Beltsville Research Facility - Hazmat Trailers	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Beltsville Research Facility - Block Building	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
OCI Office Of Internal Affairs	OCI	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Corporate Building	CDRH	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Harvey W Wiley Building	CFSAN	0370	COLLEGE PARK	24	MD	HEADQUARTERS	GSA Owned
University Station	CFSAN	1330	RIVERDALE	24	MD	HEADQUARTERS	GSA Leased
Crabb Building	OC/ORA	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Crabb CVM Building	CVM	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
District Office - Baltimore	ORA	0050	BALTIMORE	24	MD	CENTRAL-PHILADELPHIA	GSA Leased
Fishers Lane 5630	CDER/OC	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Montrose Metro 2	ORA/CDER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Fda Laboratory Building 1 - Mod1	CFSAN	0900	LAUREL	24	MD	HEADQUARTERS	FDA Owned
Fda Laboratory Building 2 - Mod2	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Metro Park North 1	CDER/CDRH	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Metro Park North 2	OC/OCI/CDER/CVM	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Metro Park North 4	CVM/CDER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Metro Park North 5	CVM	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Muirkirk - B1-Animal Caretakers	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - B2-Research Fac Dogs	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - B3-Research Fac Lamb	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - B4-Research Fac-Swin	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - C1-Animal Caretakers	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - 8501 G Muirkirk Rd	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - C3-Research Fac Cows	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - C4-Research Fac-Sheep	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - C5-Research Fac-Cattle	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - C6 Research Fac Cattle	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - D-1 8501 L Muirkirk Rd	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - D2-Feed Mixing	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - E1-Research Fac-Poultry	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - F1-Quarantine	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned

Building Name	Center	City	City	State Code	State	OP DIV Subdivision	Ownership
Muirkirk - H-Aquaculture	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - L-Hay Storage	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - M-Animal Loafing	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - N-Pump Equipment	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - Pasture Pads	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
8501 T Muirkirk Rd	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
Muirkirk - Waste Storage Area	CVM	0900	LAUREL	24	MD	HEADQUARTERS	GSA Owned
NIH Bldg 14D	CBER	0310	BETHESDA	24	MD	HEADQUARTERS	NIH OWNED
NIH Bldg 29	CBER	0310	BETHESDA	24	MD	HEADQUARTERS	NIH OWNED
NIH Bldg 29A	CBER/CDER	0310	BETHESDA	24	MD	HEADQUARTERS	NIH OWNED
NIH Bldg 29B	CBER/CDER	0310	BETHESDA	24	MD	HEADQUARTERS	NIH OWNED
Nicholson Lane Research Center - GSA Lease	CBER	0860	KENSINGTON	24	MD	HEADQUARTERS	GSA Leased
Nicholson Lane Research Center	CBER	0860	KENSINGTON	24	MD	HEADQUARTERS	FDA Leased
Oakgrove Building 2094	CDRH	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Oakgrove Building 2098	CDRH	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Piccard Building 1350	CDRH/ORA	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Parklawn Building	OC/ORA/CDER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Rockwall II Building	CBER/CDER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Rockwall Building	CBER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
Resident Post - Dundalk, MD - Import	ORA	0050	BALTIMORE	24	MD	CENTRAL-PHILADELPHIA	GSA Leased
OCI Task Force Maryland - Special Prosecution Staff	OCI	0100	BELTSVILLE	24	MD	HEADQUARTERS	GSA Leased
Technology Center	CDRH/OC	0630	GAITHERSBURG	24	MD	HEADQUARTERS	GSA Leased
FDA Warehouse - Mail Screening Facility and Document Rooms	OC/CBER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
FDA Warehouse - Wilkins	OC	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
White Oak OC Building 1	OC	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
White Oak Central Shared Used Building 2	CDER/CDRH/OC	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
White Oak CDER Office Building 2	CDER	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
White Oak Engineering Physics Lab Building 62	CDRH/OC	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
Woodmont Office Center	CBER	1360	ROCKVILLE	24	MD	HEADQUARTERS	GSA Leased
White Oak CDER Office Building 1	CDER/OC	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
White Oak Life Sciences Building	CDER/CDRH	1450	SILVER SPRING	24	MD	HEADQUARTERS	GSA Owned
Resident Post - Boston, MA	ORA	0120	BOSTON	25	MA	NORTHEAST-NEWYORK	GSA Leased
District Office - New England	ORA	1275	STONEHAM	25	MA	NORTHEAST-NEWYORK	GSA Leased
Resident Office - OCI Boston	OCI	1000	PEABODY	25	MA	HEADQUARTERS-FIELD	GSA Leased
Resident Post - Worcester, MA	ORA	1520	WORCESTER	25	MA	NORTHEAST-NEWYORK	GSA Leased
WEAC Engineering And Analytical Center	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC- Storage Warehouse 7	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC- Old Mouse House	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Storage Warehouse 1	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC- Fire Extinguisher Shed	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Hazmat Trailer 1	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Hazmat Trailer 2	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Hazmat Building	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Freezer 1	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
WEAC - Freezer 2	ORA	1503	WINCHESTER	25	MA	NORTHEAST-NEWYORK	FDA Owned
Border Station - Port Huron, MI	ORA	4060	PORT HURON	26	MI	CENTRAL-CHICAGO	GSA Leased
Border Station - Sault Ste Marie, MI	ORA	4480	SAULT STE MARIE	26	MI	CENTRAL-CHICAGO	GSA Owned
District Office with Lab - Detroit	ORA	1260	DETROIT	26	MI	CENTRAL-CHICAGO	GSA Leased
District Office - Detroit	ORA	1260	DETROIT	26	MI	CENTRAL-CHICAGO	GSA Leased
Border Station - Detroit, MI	ORA	1260	DETROIT	26	MI	CENTRAL-CHICAGO	GSA Owned
Resident Post - Grand Rapids, MI	ORA	2010	GRAND RAPIDS	26	MI	CENTRAL-CHICAGO	GSA Leased
Resident Post - Kalamazoo, MI	ORA	2520	KALAMAZOO	26	MI	CENTRAL-CHICAGO	GSA Owned
District Office - Minneapolis	ORA	4760	MINNEAPOLIS	27	MN	CENTRAL-CHICAGO	GSA Leased
Resident Post - International Falls, MN	ORA	3480	INTERNATIONAL FALLS	27	MN	CENTRAL-CHICAGO	GSA Leased
Parking Garage - JRA Facility No 3	ORA	1220	JACKSON	28	MS	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Jackson, MS	ORA	1220	JACKSON	28	MS	SOUTHEAST-ATLANTA	GSA Owned
Division of Drug Analysis	CDER	7080	ST LOUIS	29	MO	HEADQUARTERS-FIELD	GSA Leased
Resident Post - St Louis, MO	ORA	7080	ST LOUIS	29	MO	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Springfield, MO	ORA	7460	SPRINGFIELD	29	MO	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Helena MT	ORA	0590	HELENA	30	MT	PACIFIC-OAKLAND	GSA Leased
Border Station - Sweetgrass, Mt	ORA	1125	SWEETGRASS	30	MT	PACIFIC-OAKLAND	GSA Owned
Resident Post - Omaha, NE	ORA	3620	OMAHA	31	NE	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Las Vegas, NV	ORA	0120	LAS VEGAS	32	NV	PACIFIC-OAKLAND	GSA Owned
Resident Post - Reno, NV	ORA	0170	RENO	32	NV	PACIFIC-OAKLAND	GSA Owned
Resident Post - Concord, NH	ORA	0070	CONCORD	33	NH	NORTHEAST-NEWYORK	GSA Owned
District Office - New Jersey	ORA	2498	PARSIPPANY	34	NJ	CENTRAL-PHILADELPHIA	GSA Leased
Field Office - OCI New York	OCI	1520	JERSEY CITY	34	NJ	HEADQUARTERS-FIELD	FDA Leased
Resident Post - Elizabeth, NJ	ORA	0860	ELIZABETH	34	NJ	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - North Brunswick, NJ	ORA	2140	NORTH BRUNSWICK	34	NJ	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Voorhees, NJ	ORA	3465	VOORHEES	34	NJ	CENTRAL-PHILADELPHIA	GSA Leased
Border Station - Columbus, NM	ORA	0200	COLUMBUS	35	NM	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Albuerque, NM	ORA	0030	ALBUQUERQUE	35	NM	SOUTHWEST-DALLAS	GSA Leased
Border Station - Santa Teresa, NM	ORA	0735	SANTA TERESA	35	NM	SOUTHWEST-DALLAS	GSA Owned
Border Station - Lewiston Bridge	ORA	3220	LEWISTON	36	NY	NORTHEAST-NEWYORK	GSA Leased
Border Station - Peace Bridge	ORA	0750	BUFFALO	36	NY	NORTHEAST-NEWYORK	GSA Leased
District Office, Regional Office and Lab - New York	ORA	4170	JAMAICA	36	NY	NORTHEAST-NEWYORK	GSA Leased
Import Office - Buffalo	ORA	0750	BUFFALO	36	NY	NORTHEAST-NEWYORK	GSA Leased
Parking - Buffalo Niagara Center	ORA	0750	BUFFALO	36	NY	NORTHEAST-NEWYORK	GSA Leased
Border Station - Alexandria Bay, NY	ORA	0090	ALEXANDRIA BAY	36	NY	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Albany, NY	ORA	0050	ALBANY	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - Binghamton, NY	ORA	0540	BINGHAMTON	36	NY	NORTHEAST-NEWYORK	GSA Owned
Border Station - Champlain, NY	ORA	1080	CHAMPLAIN	36	NY	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Cargo Building - Champlain NY	ORA	1080	CHAMPLAIN	36	NY	NORTHEAST-NEWYORK	GSA Owned
Resident Post - Long Island, NY	ORA	1050	CENTRAL ISLIP	36	NY	NORTHEAST-NEWYORK	GSA Owned
Border Station - Massena, NY	ORA	5275	ROOSEVELTOWN	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - New Windsor, NY	ORA	4130	NEW WINDSOR	36	NY	NORTHEAST-NEWYORK	GSA Leased
Border Station - Ogdensburg, NY	ORA	4420	OGDENSBURG	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - Rochester, NY	ORA	5230	ROCHESTER	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - Syracuse, NY	ORA	6010	SYRACUSE	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - White Plains, NY	ORA	6670	WHITE PLAINS	36	NY	NORTHEAST-NEWYORK	GSA Leased
Resident Post - Wilmington, NC	ORA	5060	WILMINGTON	37	NC	SOUTHEAST-ATLANTA	GSA Leased
Parking - Terry Sanford Federal Building	ORA	3750	RALEIGH	37	NC	SOUTHEAST-ATLANTA	GSA Owned
Parking Deck - Moore Square	ORA	3750	RALEIGH	37	NC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Arden, NC	ORA	0131	ARDEN	37	NC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Charlotte, NC	ORA	0870	CHARLOTTE	37	NC	SOUTHEAST-ATLANTA	GSA Leased

Building Name	Center	City	City	State Code	State	OP DIV Subdivision	Ownership
Resident Post - Greenville, NC	ORA	1950	GREENVILLE	37	NC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Greensboro, NC	ORA	1940	GREENSBORO	37	NC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Raleigh, NC	ORA	3750	RALEIGH	37	NC	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Fargo, ND	ORA	1020	FARGO	38	ND	CENTRAL-CHICAGO	GSA Owned
Border Station - Pembina, ND	ORA	2500	PEMBINA	38	ND	CENTRAL-CHICAGO	GSA Leased
District Office - Forensic Chemistry - Cincinnati	ORA	1610	CINCINNATI	39	OH	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Brunswick, OH	ORA	1085	BRUNSWICK	39	OH	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Columbus, OH	ORA	1800	COLUMBUS	39	OH	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Toledo, OH	ORA	8120	TOLEDO	39	OH	CENTRAL-PHILADELPHIA	GSA Leased
Parking Garage - OKC Federal	ORA	3550	OKLAHOMA CITY	40	OK	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Oklahoma City, OK	ORA	3550	OKLAHOMA CITY	40	OK	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Tulsa, OK	ORA	4780	TULSA	40	OK	SOUTHWEST-DALLAS	GSA Leased
Resident Post - Portland Airport, OR	ORA	1650	PORTLAND	41	OR	PACIFIC-OAKLAND	GSA Leased
Resident Post - Beaverton, OR	ORA	0180	BEAVERTON	41	OR	PACIFIC-OAKLAND	GSA Leased
District Office, Regional Office and Lab - Philadelphia	ORA	6540	PHILADELPHIA	42	PA	CENTRAL-PHILADELPHIA	GSA Owned
Resident Post - Harrisburg, PA	ORA	3500	HARRISBURG	42	PA	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - OCI Philadelphia Field Office	OCI	6540	PHILADELPHIA	42	PA	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Pittsburgh, PA	ORA	6600	PITTSBURGH	42	PA	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Scranton, PA	ORA	7460	SCRANTON	42	PA	CENTRAL-PHILADELPHIA	GSA Owned
Quonset Hut - Building 336	N/A	0053	DAVISVILLE	44	RI	HEADQUARTERS	FDA Owned
Resident Post - OCI - Providence, RI	OCI	0156	NORTH PROVIDENCE	44	RI	NORTHEAST-NEWYORK	GSA Leased
Resident Post - Providence, RI	ORA	0057	EAST PROVIDENCE	44	RI	NORTHEAST-NEWYORK	GSA Leased
Parking Garage - MJ Perry Jr	ORA	0520	COLUMBIA	45	SC	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Charleston, SC	ORA	0410	CHARLESTON	45	SC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Columbia, SC	ORA	0520	COLUMBIA	45	SC	SOUTHEAST-ATLANTA	GSA Owned
Resident Post - Greenville, SC	ORA	1040	GREENVILLE	45	SC	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Sioux Falls, SD	ORA	2450	SIOUX FALLS	46	SD	CENTRAL-CHICAGO	GSA Leased
Resident Post - Memphis, TN	ORA	1620	MEMPHIS	47	TN	SOUTHEAST-ATLANTA	GSA Leased
District Office - Nashville	ORA	1760	NASHVILLE	47	TN	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Chattanooga, TN	ORA	0400	CHATTANOOGA	47	TN	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Knoxville, TN	ORA	1300	KNOXVILLE	47	TN	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Memphis, TN	ORA	1620	MEMPHIS	47	TN	SOUTHEAST-ATLANTA	GSA Leased
District Office and SW Imports - Dallas	ORA	1730	DALLAS	48	TX	SOUTHWEST-DALLAS	GSA Leased
Regional Office - Dallas, TX	ORA	1730	DALLAS	48	TX	SOUTHWEST-DALLAS	GSA Leased
Resident Office - OCI Austin	OCI	0330	AUSTIN	48	TX	HEADQUARTERS-FIELD	GSA Leased
Resident Post - Austin, TX	ORA	0330	AUSTIN	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - Bota, TX - Bridge of the America's	ORA	2190	EL PASO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Resident Post - DFW Airport, TX - Grapevine	ORA	1730	DALLAS	48	TX	SOUTHWEST-DALLAS	GSA Leased
Border Station - Eagle Pass, TX	ORA	2030	EAGLE PASS	48	TX	SOUTHWEST-DALLAS	GSA Leased
Resident Post - El Paso, TX	ORA	2190	EL PASO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Resident Post - El Paso, TX	ORA	2190	EL PASO	48	TX	SOUTHWEST-DALLAS	GSA Leased
Border Station - El Paso, TX	ORA	2190	EL PASO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Fort Worth, TX	ORA	2450	FORT WORTH	48	TX	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Houston, TX	ORA	3280	HOUSTON	48	TX	SOUTHWEST-DALLAS	GSA Leased
Border Station - USBS Columbia Import Dock, Laredo, TX	ORA	3899	LAREDO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - USBS J&L Bldg. 2 Admin.	ORA	3899	LAREDO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - Laredo World Trade Bridge, TX	ORA	3899	LAREDO	48	TX	SOUTHWEST-DALLAS	GSA Leased
Border Station - Los Tomates, TX	ORA	0940	BROWNSVILLE	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - Pharr, TX	ORA	5330	PHARR	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - Pharr, TX	ORA	5330	PHARR	48	TX	SOUTHWEST-DALLAS	GSA Owned
Border Station - Rio Grande City, TX	ORA	5780	RIO GRANDE CITY	48	TX	SOUTHWEST-DALLAS	GSA Leased
Resident Post - San Antonio, TX	ORA	6090	SAN ANTONIO	48	TX	SOUTHWEST-DALLAS	GSA Leased
Border Station - Ysletta, TX	ORA	2190	EL PASO	48	TX	SOUTHWEST-DALLAS	GSA Owned
Resident Post - Salt Lake City, UT	ORA	1700	SALT LAKE CITY	49	UT	SOUTHWEST-DALLAS	GSA Leased
Border Station - Highgate Springs, VT	ORA	0245	HIGHGATE SPRINGS	50	VT	NORTHEAST (NEW YORK)	GSA Owned
Prior Notice Center	ORA	2034	RESTON	51	VA	HEADQUARTERS	CUSTOMS
Resident Post - Norfolk, VA-Import	ORA	1760	NORFOLK	51	VA	CENTRAL-PHILADELPHIA	FDA Leased
Resident Post - Norfolk, VA-Import	ORA	1760	NORFOLK	51	VA	CENTRAL-PHILADELPHIA	GSA Owned
Resident Post - Falls Church, VA	ORA	0930	FALLS CHURCH	51	VA	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Richmond, VA	ORA	2060	RICHMOND	51	VA	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Roanoke VA	ORA	2100	ROANOKE	51	VA	CENTRAL-PHILADELPHIA	GSA Leased
Daycare - Park Place Building - Joint Use	ORA	1960	SEATTLE	53	WA	PACIFIC-OAKLAND	GSA Leased
District Office with Regional Lab - Seattle	ORA	0170	BOTHELL	53	WA	PACIFIC-OAKLAND	GSA Owned
Border Station - Blaine, WA	ORA	0150	BLAINE	53	WA	PACIFIC-OAKLAND	GSA Owned
Resident Post - Oroville, WA	ORA	1610	OROVILLE	53	WA	PACIFIC-OAKLAND	GSA Owned
Resident Post - Seattle, WA	ORA	1960	SEATTLE	53	WA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Spokane Valley, WA	ORA	2110	SPOKANE VALLEY	53	WA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Tacoma, WA	ORA	2230	TACOMA	53	WA	PACIFIC-OAKLAND	GSA Leased
Resident Post - Morgantown, WV	ORA	1840	MORGANTOWN	54	WV	CENTRAL-PHILADELPHIA	GSA Leased
Resident Post - Green Bay, WI	ORA	2000	GREEN BAY	55	WI	CENTRAL-CHICAGO	GSA Leased
Resident Post - Madison, WI	ORA	2780	MADISON	55	WI	CENTRAL-CHICAGO	GSA Leased
Resident Post - Wauwatosa, WI	ORA	5130	WAUWATOSA	55	WI	CENTRAL-CHICAGO	GSA Leased
Resident Office - OCI San Juan	OCI	0930	SAN JUAN	RQ	PR	HEADQUARTERS-FIELD	GSA Leased
Resident Post - Aguada, PR	ORA	0020	AGUADA	RQ	PR	SOUTHEAST-ATLANTA	GSA Leased
Resident Post - Ponce, PR	ORA	0760	PONCE	RQ	PR	SOUTHEAST-ATLANTA	GSA Leased
San Juan - FDA Laboratory Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - New Administration Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Administration Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Conference Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Maintenance Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Generator Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Boat House Building	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
San Juan - Guard Booth	ORA	0930	SAN JUAN	RQ	PR	SOUTHEAST-ATLANTA	FDA Owned
Resident Post - St. Thomas, VI	ORA	0900	ST. THOMAS	VQ	VI	SOUTHEAST (ATLANTA)	GSA Leased

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2008 Actual	PREMARKET												PREMARKET TOTAL	
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION				PREMARKET INSPECTIONS					
					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	16,288	30	8,804	17	8,978	48	3,840	10	-	-	-	-	37,910	105
Field Activities	-	-	-	-	-	-	-	-	-	-	-	-	-	-
FOODS TOTAL	**16,288**	**30**	**8,804**	**17**	**8,978**	**48**	**3,840**	**10**	**-**	**-**	**-**	**-**	**37,910**	**105**
HUMAN DRUGS														
Center for Drug Evaluation & Research	384,154	1,565	20,683	55	25,086	143	7,780	48	7,147	55	3,957	29	448,807	1,895
Field Activities	621	4	0	0	0	0	0	0	14,276	88	4,462	28	19,359	120
PDUFA (non-add): Center	*245,582*	*990*	*2,924*	*24*	*8,040*	*45*	*3,771*	*22*	*4,401*	*34*	*2,102*	*15*	*266,820*	*1,130*
Field	-	-	-	-	-	-	-	-	*3,996*	*21*	*1,739*	*11*	*5,735*	*32*
HUMAN DRUGS TOTAL	**384,775**	**1,569**	**20,683**	**55**	**25,086**	**143**	**7,780**	**48**	**21,423**	**143**	**8,419**	**57**	**468,166**	**2,015**
BIOLOGICS														
Center for Biologics Evaluation & Research	139,109	544	18,005	127	17,396	69	442	2	2,252	9	-	-	177,204	751
Field Activities	0	0	0	0	0	0	0	0	4,056	18	169	1	4,225	19
PDUFA (non-add): Center	*60,793*	*261*	-	-	*8,229*	*35*	-	-	*514*	*2*	-	-	*69,536*	*298*
Field	-	-	-	-	-	-	-	-	*1,524*	*8*	-	-	*1,524*	*8*
MDUFMA (non-add): Center	*5,256*	*24*	-	-	*489*	*2*	*24*	-	*113*	*1*	-	-	*5,882*	*27*
Field	-	-	-	-	-	-	-	-	*258*	*2*	-	-	*258*	*2*
BIOLOGICS TOTAL	**139,109**	**544**	**18,005**	**127**	**17,396**	**69**	**442**	**2**	**6,308**	**27**	**169**	**1**	**181,429**	**770**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	40,644	209	1,863	14	561	4	-	-	-	-	-	-	*43,068*	*227*
Field Activities	0	0	0	0	0	0	0	0	1,517	9	765	4	*2,282*	*13*
ADUFA (non-add): Center	*12,260*	*59*	-	-	-	-	-	-	-	-	-	-	*12,260*	*59*
ANIMAL DRUGS & FEEDS TOTAL	**40,644**	**209**	**1,863**	**14**	**561**	**4**	**-**	**-**	**1,517**	**9**	**765**	**4**	**45,350**	**240**
DEVICES AND RADIOLOGICAL HEALTH														
Center for Devices & Radiological Health	101,065	618	10,897	51	7,472	55	1,753	13	-	-	-	-	121,187	737
Field Activities	-	-	-	-	-	-	-	-	7,134	44	344	2	7,478	46
MQSA (non-add): Center													-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA (non-add): Center	15,786	120	1,019	*6*	*1,167*	*11*	*274*	*3*	-		-		*18,246*	*140*
Field	-	-	-	-	-	-	-	-	972	6	-	-	*972*	*6*
DEVICES TOTAL	**101,065**	**618**	**10,897**	**51**	**7,472**	**55**	**1,753**	**13**	**7,134**	**44**	**344**	**2**	**128,665**	**783**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**29,602**	**133**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**29,602**	**133**
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**46,603**	**251**	**3,815**	**21**	**4,067**	**27**	**944**	**6**	**2,487**	**19**	**663**	**5**	**58,579**	**329**
USER FEES (non-add): PDUFA	*16,826*	*130*	*161*	*2*	*893*	*8*	*207*	*2*	*573*	*7*	*211*	*3*	*18,871*	*153*
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA	*2051*	*15*	*99*	*1*	*161*	*1*	*29*	-	*131*	*1*	-	-	*2,472*	*18*
ADUFA	*563*	*4*	-	-	-	-	-	-	-	-	-	-	*563*	*4*
HEADQUARTERS / OC TOTAL	**46,603**	**251**	**3,815**	**21**	**4,067**	**27**	**944**	**6**	**2,487**	**19**	**663**	**5**	**58,579**	**329**
SUB-TOTAL:	**728,484**	**3,220**	**93,669**	**418**	**63,560**	**346**	**14,759**	**79**	**38,870**	**242**	**10,359**	**69**	**949,701**	**4,374**
Total Center	727,863	3,217	93,669	418	63,560	346	14,759	79	11,886	83	4,620	34	916,357	4,177
Total Field	621	4	-	-	-	-	-	-	26,984	159	5,739	35	33,344	198
(PDUFA, MQSA, MDUFMA, ADUFA	359,117	1,603	4,203	33	18,979	102	4,305	27	12,482	82	4,052	29	403,138	1,877
User Fees - non add)														
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
Other Rent and Rent Related MDUFMA (non-add)														
Other Rent and Rent Related PDUFA (non-add)														
Other Rent and Rent Related ADUFA (non-add)														
GSA Rent														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
Other Current Law User Fees														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2008 Actual	POSTMARKET														POSTMARKET TOTAL		TOTAL ALL FDA	
	OUTREACH COORDINATION		POSTMARKET APPLIED		POSTMARKET LABORATORY ANALYSES				POSTMARKET INSPECTIONS									
	COMPLIANCE		RESEARCH		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	79,639	408	26,216	126	9,990	40	6,280	43	2,601	10	3,115	20	1,438	1	129,279	648	167,189	753
Field Activities	86,277	467	1,100	7	41,075	232	57,080	324	72,235	376	2,867	16	79,974	438	340,608	1,861	340,608	1,861
FOODS TOTAL	**165,916**	**875**	**27,316**	**133**	**51,065**	**272**	**63,360**	**367**	**74,836**	**386**	**5,982**	**36**	**81,412**	**439**	**469,887**	**2,509**	**507,797**	**2,614**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	120,133	374	7,601	46	1,765	12	1,324	9	6,252	49	810	5	859	6	138,744	501	587,551	2,396
Field Activities	27,273	178	0	0	9,165	60	3,123	20	26,967	173	3,123	20	4,364	29	74,016	480	93,375	600
PDUFA (non-add): Center	*52,437*	*122*	*2,025*	-	-	-	-	-	-	-	-	-	-	-	*54,462*	*122*	*321,282*	*1,252*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*5,735*	*32*
HUMAN DRUGS TOTAL	**147,406**	**552**	**7,601**	**46**	**10,930**	**72**	**4,447**	**29**	**33,219**	**222**	**3,933**	**25**	**5,223**	**35**	**212,760**	**981**	**680,926**	**2,996**
BIOLOGICS																		
Center for Biologics Evaluation & Research	22,346	95	182	1	-	-	-	-	2,546	11	-	-	-	-	25,074	107	202,278	858
Field Activities	6,307	44	0	0	0	0	0	0	18,665	135	1,353	6	681	5	27,005	190	31,230	209
PDUFA (non-add): Center	*1,354*	*6*	-	-	-	-	-	-	-	-	-	-	-	-	1,354	6	*70,890*	*304*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*1,524*	*8*
MDUFMA (non-add): Center	*123*	*1*	-	-	-	-	-	-	-	-	-	-	-	-	123	1	*6,005*	*28*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*258*	*2*
BIOLOGICS TOTAL	**28,653**	**139**	**182**	**1**	**-**	**-**	**-**	**-**	**21,211**	**146**	**1,353**	**6**	**681**	**5**	**52,079**	**297**	**233,508**	**1,066**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	22,671	109	6,411	42	-	-	-	-	-	-	-	-	-	-	*29,082*	*151*	72,150	378
Field Activities	11,715	66	0	0	4,478	26	1,124	6	13,832	78	266	1	3,778	21	*35,193*	*198*	37,475	211
ADUFA (non-add): Center	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	12,260	*59*
ANIMAL DRUGS & FEEDS TOTAL	**34,386**	**175**	**6,411**	**42**	**4,478**	**26**	**1,124**	**6**	**13,832**	**78**	**266**	**1**	**3,778**	**21**	**64,275**	**349**	**109,625**	**589**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	71,233	338	1,314	7	11,057	48									83,604	393	204,791	1,130
Field Activities	16,812	135	-	-	2,280	18	2,267	14	33,208	151	3,260	19	5,188	52	63,015	388	70,493	434
MQSA (non-add): Center	4,047	21													4,047	21	4,047	21
Field	5,360	5	-	-	-	-	-	-	3,882	3	-	-	-	-	9,242	8	9,242	8
MDUFMA (non-add): Center	4,529	21	44	-	380	3									4,953	24	23,199	164
Field	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	-	972	6
DEVICES TOTAL	**88,045**	**473**	**1,314**	**7**	**13,337**	**66**	**2,267**	**14**	**33,208**	**151**	**3,260**	**19**	**5,188**	**52**	**146,619**	**781**	**275,284**	**1,564**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**14,841**	**59**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**14,841**	**59**	**44,443**	**192**
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**31,739**	**187**	**3,042**	**9**	**5,455**	**37**	**4,866**	**35**	**12,049**	**83**	**1,011**	**7**	**6,580**	**47**	**64,742**	**405**	**123,320**	**733**
USER FEES (non-add): PDUFA	*2,954*	*13*	*111*	-	-	-	-	-	-	-	-	-	-	-	*3,065*	*13*	*21,936*	*166*
MQSA (HQ / OC)	*176*	*2*	-	-	-	-	-	-	*72*	-	-	-	-	-	*248*	*2*	*248*	*2*
MDUFMA	*454*	*2*	*4*	-	*37*	-	-	-	-	-	-	-	-	-	*495*	*2*	*2,967*	*21*
ADUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*563*	*4*
HEADQUARTERS / OC TOTAL	**31,739**	**187**	**3,042**	**9**	**5,455**	**37**	**4,866**	**35**	**12,049**	**83**	**1,011**	**7**	**6,580**	**47**	**64,742**	**405**	**123,320**	**733**
SUB-TOTAL:	**496,145**	**2,401**	**60,707**	**297**	**85,265**	**473**	**76,064**	**452**	**188,354**	**1,066**	**15,805**	**94**	**102,862**	**598**	**1,025,203**	**5,380**	**1,974,903**	**9,754**
Total Center	347,761	1,511	59,607	290	28,267	137	12,470	87	23,448	153	4,936	32	8,877	54	485,366	2,264	1,401,720	6,440
Total Field	148,384	890	1,100	7	56,999	336	63,594	365	164,906	913	10,869	61	93,985	545	539,837	3,117	573,181	3,314
(PDUFA, MQSA, MDUFMA, ADUFA	71,434	193	2,184	-	417	3	-	-	3,954	3	-	-	-	-	77,989	199	481,130	2,077
User Fees - non add)																		
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocation)																	**107,372**	**0**
Other Rent and Rent Related MDUFMA (non-add)																	*850*	*0*
Other Rent and Rent Related PDUFA (non-add)																	*17,599*	*0*
Other Rent and Rent Related ADUFA (non-add)																	*109*	*0*
GSA Rent																	**145,111**	*0*
GSA Rent PDUFA (non-add)																	*11,821*	*0*
GSA Rent MDUFMA (non-add)																	*2,081*	*0*
GSA Rent ADUFA (non-add)																	*598*	*0*
Other Current Law User Fees																	10,086	57
Buildings and Facilities																	**7,534**	0
TOTAL S&E PROGRAM:																	**2,245,006**	**9,811**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2009 Omnibus	PREMARKET												PREMARKET TOTAL	
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION				PREMARKET INSPECTIONS					
					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	17,244	35	9,104	21	12,681	70	4,200	28	-	-	-	-	43,229	154
Field Activities	0	0	0	0	0	0	0	0	0	0	0	0	-	-
FOODS TOTAL	**17,244**	**35**	**9,104**	**21**	**12,681**	**70**	**4,200**	**28**	**-**	**-**	**-**	**-**	**43,229**	**154**
HUMAN DRUGS														
Center for Drug Evaluation & Research	417,632	1,814	21,323	57	25,981	149	8,119	49	7,795	57	4,808	34	485,658	2,160
Field Activities	780	4	0	0	0	0	0	0	14,911	86	8,854	54	24,545	144
PDUFA (non-add): Center	*267,854*	*1,156*	*3,220*	*25*	*8,401*	*45*	*3,968*	*22*	*4,804*	*35*	*2,615*	*18*	*290,862*	*1,301*
Field	-	-	-	-	-	-	-	-	*4,819*	*26*	*2,301*	*14*	*7,120*	*40*
HUMAN DRUGS TOTAL	**418,412**	**1,818**	**21,323**	**57**	**25,981**	**149**	**8,119**	**49**	**22,706**	**143**	**13,662**	**88**	**510,203**	**2,304**
BIOLOGICS														
Center for Biologics Evaluation & Research	151,776	590	18,637	127	20,164	74	523	2	2,639	9	-	-	193,739	802
Field Activities	0	0	0	0	0	0	0	0	4,170	22	195	1	4,365	23
PDUFA (non-add): Center	*62,779*	*251*	-	-	*8,498*	*34*	-	-	*531*	*2*	-	-	*71,808*	*287*
Field	-	-	-	-	-	-	-	-	*3,358*	*10*	-	-	*3,358*	*10*
MDUFMA (non-add): Center	*9,599*	*26*	-	-	*893*	*3*	*44*	-	*207*	*1*	-	-	*10,743*	*30*
Field	-	-	-	-	-	-	-	-	*507*	*2*	-	-	*507*	*2*
BIOLOGICS TOTAL	**151,776**	**590**	**18,637**	**127**	**20,164**	**74**	**523**	**2**	**6,809**	**31**	**195**	**1**	**198,104**	**825**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	51,083	236	2,254	14	676	4	-	-	-	-	-	-	*54,013*	*254*
Field Activities	0	0	0	0	0	0	0	0	1,634	9	780	4	*2,414*	*13*
ADUFA (non-add): Center	*13,362*	*66*	-	-	-	-	-	-	-	-	-	-	*13,362*	*66*
Field	-	-	-	-	-	-	-	-	*250*	*2*	-	-	*250*	*2*
AGDUFA (non-add): Center	4,118	20	-	-	-	-	-	-	-	-	-	-	*4,118*	*20*
Field	-	-	-	-	-	-	-	-	*143*	*1*	-	-	*143*	*1*
ANIMAL DRUGS & FEEDS TOTAL	**51,083**	**236**	**2,254**	**14**	**676**	**4**	**-**	**-**	**1,634**	**9**	**780**	**4**	**56,427**	**267**
DEVICES AND RADIOLOGICAL HEALTH														
Center for Devices & Radiological Health	115,976	636	17,308	66	8,457	57	1,984	12	-	-	-	-	143,725	771
Field Activities	-	-	-	-	-	-	-	-	7,780	40	470	2	8,250	42
MQSA (non-add): Center													-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA (non-add): Center	19,708	147	1,265	8	1,449	13	340	3	-	-			*22,762*	*171*
Field	-	-	-	-	-	-	-	-	1,049	6	-	-	*1,049*	*6*
DEVICES TOTAL	**115,976**	**636**	**17,308**	**66**	**8,457**	**57**	**1,984**	**12**	**7,780**	**40**	**470**	**2**	**151,975**	**813**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**34,649**	**129**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**34,649**	**129**
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**56,943**	**245**	**3,963**	**31**	**5,129**	**26**	**1,119**	**7**	**2,938**	**17**	**1,140**	**7**	**71,232**	**332**
USER FEES (non-add): PDUFA	*24,551*	*103*	*239*	*2*	*1,255*	*6*	*295*	*2*	*1,003*	*5*	*365*	*2*	*27,707*	*120*
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA	*4,183*	*16*	*181*	*1*	*334*	*1*	*55*	-	*252*	*1*	-	-	*5,005*	*19*
ADUFA	*656*	*4*	-	-	-	-	-	-	-	-	-	-	*656*	*4*
AGDUFA	*187*	*1*	-	-	-	-	-	-	*6*	-	-	-	*193*	*1*
HEADQUARTERS / OC TOTAL	**56,943**	**245**	**3,963**	**31**	**5,129**	**26**	**1,119**	**7**	**2,938**	**17**	**1,140**	**7**	**71,232**	**332**
SUB-TOTAL:	**811,434**	**3,560**	**107,238**	**445**	**73,088**	**380**	**15,945**	**98**	**41,867**	**240**	**16,247**	**102**	**1,065,819**	**4,825**
Total Center	810,654	3,556	107,238	445	73,088	380	15,945	98	13,372	83	5,948	41	1,026,245	4,602
Total Field	780	4	-	-	-	-	-	-	28,495	158	10,299	61	39,574	223
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA User Fees - non add)	*406,997*	*1,790*	*4,905*	*36*	*20,830*	*102*	*4,702*	*27*	*16,929*	*91*	*5,281*	*34*	*459,643*	*2,080*
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
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 AGDUFA (non-add)														
GSA Rent														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
GSA Rent AGDUFA (non-add)														
Other Current Law User Fees														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2009 Omnibus	POSTMARKET														POSTMARKET TOTAL		TOTAL ALL FDA	
	OUTREACH COORDINATION		POSTMARKET APPLIED		POSTMARKET LABORATORY ANALYSES				POSTMARKET INSPECTIONS									
	COMPLIANCE		RESEARCH		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	90,298	437	46,216	131	12,490	45	8,780	47	3,760	15	4,123	21	1,590	4	167,257	700	210,486	854
Field Activities	101,342	451	1,100	6	61,446	292	70,600	364	92,197	478	18,440	82	93,111	493	438,236	2,165	438,236	2,165
FOODS TOTAL	**191,640**	**888**	**47,316**	**137**	**73,936**	**337**	**79,380**	**411**	**95,957**	**493**	**22,563**	**103**	**94,701**	**497**	**605,493**	**2,865**	**648,722**	**3,019**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	153,827	487	5,773	45	1,830	12	1,374	9	8,609	64	981	6	1,169	8	173,563	631	659,221	2,791
Field Activities	31,680	186	0	0	14,453	75	4,154	24	28,323	176	9,080	59	5,981	35	93,671	555	118,216	699
PDUFA (non-add): Center	*65,973*	*204*	-	-	-	-	-	-	-	-	-	-	-	-	*65,973*	*204*	*356,835*	*1,505*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*7,120*	*40*
HUMAN DRUGS TOTAL	**185,507**	**673**	**5,773**	**45**	**16,283**	**87**	**5,528**	**33**	**36,932**	**240**	**10,061**	**65**	**7,150**	**43**	**267,234**	**1,186**	**777,437**	**3,490**
BIOLOGICS																		
Center for Biologics Evaluation & Research	35,457	101	188	1	-	-	-	-	2,924	12	-	-	-	-	38,569	114	232,308	916
Field Activities	7,514	44	0	0	0	0	0	0	24,943	145	1,540	9	819	9	34,817	207	39,182	230
PDUFA (non-add): Center	*1,398*	*6*	-	-	-	-	-	-	-	-	-	-	-	-	1,398	6	*73,206*	*293*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*3,358*	*10*
MDUFMA (non-add): Center	*225*	*1*	-	-	-	-	-	-	-	-	-	-	-	-	225	1	*10,968*	*31*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*507*	*2*
BIOLOGICS TOTAL	**42,971**	**145**	**188**	**1**	**-**	**-**	**-**	**-**	**27,867**	**157**	**1,540**	**9**	**819**	**9**	**73,386**	**321**	**271,490**	**1,146**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	29,515	127	6,987	43	-	-	-	-	-	-	-	-	-	-	*36,502*	*170*	*90,515*	*424*
Field Activities	12,541	69	0	0	5,770	31	1,238	6	16,568	88	1,062	5	4,236	25	41,415	224	43,829	238
ADUFA (non-add): Center															-	-	13,362	*66*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	250	*2*
AGDUFA (non-add): Center															-	-	4,118	*20*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	143	*1*
ANIMAL DRUGS & FEEDS TOTAL	**42,056**	**196**	**6,987**	**43**	**5,770**	**31**	**1,238**	**6**	**16,568**	**88**	**1,062**	**5**	**4,236**	**25**	**77,917**	**394**	**134,344**	**662**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	84,629	366	1,684	12	13,937	55	-	-	-	-	-	-	-	-	100,250	433	243,975	1,204
Field Activities	23,446	127	0	0	3,520	18	2,712	14	35,381	155	6,119	31	6,224	55	77,402	400	85,652	443
MQSA (non-add): Center	*6,003*	*26*	-	-	-	-	-	-	-	-	-	-	-	-	*6,003*	*26*	*6,003*	*26*
Field	*7,223*	*5*	*0*	*0*	*0*	*0*	*0*	*0*	*5,854*	*3*	*0*	*0*	*0*	*0*	*13,077*	*8*	*13,077*	*8*
MDUFMA (non-add): Center	*5,622*	*26*	*55*	*1*	*472*	*3*	-	-	-	-	-	-	-	-	*6,149*	*30*	*28,911*	*201*
Field	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	-	-	*1,049*	*6*
DEVICES TOTAL	**108,075**	**493**	**1,684**	**12**	**17,457**	**73**	**2,712**	**14**	**35,381**	**155**	**6,119**	**31**	**6,224**	**55**	**177,652**	**833**	**329,627**	**1,647**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**17,862**	**69**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**17,862**	**69**	**52,511**	**198**
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**43,038**	**177**	**3,022**	**9**	**8,562**	**39**	**6,706**	**34**	**16,053**	**84**	**3,120**	**16**	**8,538**	**46**	**89,039**	**405**	**160,271**	**737**
USER FEES (non-add): PDUFA	*5,003*	*15*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*5,003*	*15*	*32,710*	*135*
MQSA (HQ / OC)	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*835*	*2*	*8*	-	*67*	-	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*910*	*2*	*5,914*	*22*
ADUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*656*	*4*
AGDUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*193*	*1*
HEADQUARTERS / OC TOTAL	**43,038**	**177**	**3,022**	**9**	**8,562**	**39**	**6,706**	**34**	**16,053**	**84**	**3,120**	**16**	**8,538**	**46**	**89,039**	**405**	**160,271**	**737**
SUB-TOTAL:	**613,287**	**2,571**	**82,832**	**316**	**122,008**	**567**	**95,564**	**498**	**228,759**	**1,216**	**44,465**	**229**	**121,668**	**675**	**1,308,583**	**6,073**	**2,374,402**	**10,899**
Total Center	436,764	1,695	81,732	310	36,819	151	16,860	90	31,346	175	8,224	43	11,297	58	623,042	2,522	1,649,286	7,124
Total Field	176,523	876	1,100	6	85,189	416	78,704	408	197,413	1,041	36,241	187	110,371	617	685,541	3,551	725,115	3,774
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA User Fees - non add)	*92,447*	*287*	*63*	*1*	*539*	*3*	-	-	*5,927*	*3*	-	-	-	-	*98,976*	*294*	*558,618*	*2,375*
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocatio																	**111,758**	**0**
Other Rent and Rent Related MDUFMA (non-add)																	*1,268*	*0*
Other Rent and Rent Related PDUFA (non-add)																	*21,436*	*0*
Other Rent and Rent Related ADUFA (non-add)																	*153*	*0*
Other Rent and Rent Related AGDUFA (non-add)																	*72*	*0*
GSA Rent																	**155,425**	*0*
GSA Rent PDUFA (non-add)																	*16,000*	*0*
GSA Rent MDUFMA (non-add)																	*3,930*	*0*
GSA Rent ADUFA (non-add)																	*839*	*0*
GSA Rent AGDUFA (non-add)																	*305*	*0*
Other Current Law User Fees																	10,300	54
Buildings and Facilities																	**15,930**	0
TOTAL S&E PROGRAM:																	**2,667,815**	**10,953**

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2010 Estimate	PREMARKET													
	PREMARKET REVIEW		PREMARKET APPLIED RESEARCH		PREMARKET OUTREACH/COORDINATION				PREMARKET INSPECTIONS				PREMARKET 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	17,844	40	9,478	30	16,000	90	4,990	35	-	-	-	-	48,312	195
Field Activities	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed Reinspection user fee (non-add): Center													-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed Food Inspection and Facility Registration user fee (non-add): Center													-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
FOODS TOTAL	**17,844**	**40**	**9,478**	**30**	**16,000**	**90**	**4,990**	**35**	**-**	**-**	**-**	**-**	**48,312**	**195**
HUMAN DRUGS														
Center for Drug Evaluation & Research	486,863	1,926	22,281	61	26,700	149	8,388	49	8,163	57	5,433	37	557,828	2,279
Field Activities	818	4	0	0	0	0	0	0	16528	103	9748	57	27,094	164
PDUFA (non-add): Center	*300,951*	*1,203*	*3,407*	*25*	*8,761*	*45*	*4,144*	*22*	*5,084*	*35*	*3,037*	*20*	*325,384*	*1,350*
Field	-	-	-	-	-	-	-	-	*5,622*	*32*	*2,684*	*17*	*8,306*	*49*
Proposed GDUFA (non-add): Center	*26,504*	*56*	-	-	-	-	-	-	-	-	-	-	*26,504*	*56*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proposed Reinspection user fee (non-add): Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUMAN DRUGS TOTAL	**487,681**	**1,930**	**22,281**	**61**	**26,700**	**149**	**8,388**	**49**	**24,691**	**160**	**15,181**	**94**	**584,922**	**2,443**
BIOLOGICS														
Center for Biologics Evaluation & Research	172,392	623	20,186	127	22,741	78	591	2	2,977	10	-	-	218,887	840
Field Activities	0	0	0	0	0	0	0	0	4,377	22	204	1	4,581	23
PDUFA (non-add): Center	*71,818*	*269*	-	-	*9,722*	*36*	-	-	*608*	*2*	-	-	*82,148*	*307*
Field	-	-	-	-	-	-	-	-	*3,489*	*10*	-	-	*3,489*	*10*
MDUFMA (non-add): Center	*9,686*	*26*	-	-	*902*	*3*	*44*	-	*209*	*1*	-	-	*10,841*	*30*
Field	-	-	-	-	-	-	-	-	*507*	*3*	-	-	*507*	*3*
Proposed Reinspection user fee (non-add): Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BIOLOGICS TOTAL	**172,392**	**623**	**20,186**	**127**	**22,741**	**78**	**591**	**2**	**7,354**	**32**	**204**	**1**	**223,468**	**863**
ANIMAL DRUGS & FEEDS														
Center for Veterinary Medicine	54,308	238	3,043	16	690	4	0	0	0	0	0	0	*58,041*	*258*
Field Activities	0	0	0	0	0	0	0	0	1,729	9	822	4	*2,552*	*13*
ADUFA (non-add): Center	*15,290*	*66*	-	-	-	-	-	-	-	-	-	-	*15,290*	*66*
Field	-	-	-	-	-	-	-	-	*250*	*2*	-	-	*250*	*2*
AGDUFA (non-add): Center	4,382	20	0	0	0	0	0	0	0	0	0	0	*4,382*	*20*
Field	-	-	-	-	-	-	-	-	*143.00*	*1.00*	-	-	*143*	*1*
Proposed Reinspection user fee (non-add): Center														
Field	-	-	-	-	-	-	-	-	-	-	-	-		
Proposed Food Inspection and Facility Registration user fee (non-add): Center														
Field	-	-	-	-	-	-	-	-	-	-	-	-		
ANIMAL DRUGS & FEEDS TOTAL	**54,308**	**238**	**3,043**	**16**	**690**	**4**	**-**	**-**	**1,729**	**9**	**822**	**4**	**60,593**	**271**
DEVICES AND RADIOLOGICAL HEALTH														
Center for Devices & Radiological Health	123,558	657	18,341	66	8,818	58	2,068	13	-	-	-	-	152,785	794
Field Activities	0	0	0	0	0	0	0	0	7943	40	543	2	8,486	42
MQSA (non-add): Center													-	-
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA (non-add): Center	*22,384*	*160*	*1,437*	*9*	*1,646*	*14*	*386*	*3*	-	-	-	-	*25,853*	*186*
Field	-	-	-	-	-	-	-	-	*1,049*	*7*	-	-	*1,049*	*7*
Proposed Reinspection user fee (non-add): Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DEVICES TOTAL	**123,558**	**657**	**18,341**	**66**	**8,818**	**58**	**2,068**	**13**	**7,943**	**40**	**543**	**2**	**161,271**	**836**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**36,582**	**135**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**36,582**	**135**
HEADQUARTERS / OFFICE OF THE COMMISSIONER														
Headquarters / Office of the Commissioner	**68,573**	**276**	**5,164**	**31**	**6,006**	**30**	**1,285**	**8**	**3,343**	**19**	**1,342**	**8**	**85,713**	**372**
USER FEES (non-add): PDUFA	*26,163*	*108*	*239*	*2*	*1,297*	*6*	*291*	*2*	*1,039*	*6*	*402*	*3*	*29,431*	*126*
MQSA (HQ / OC)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
MDUFMA	*4172*	*16*	*187*	*1*	*331*	*1*	*56*	-	*230*	*1*	*0*	-	*4,976*	*19*
ADUFA	*693*	*4*	-	-	-	-	-	-	-	-	-	-	*693*	*4*
GDUFA	*968*	*0*	-	*0*	-	*0*	-	*0*	-	*0*	-	*0*	*968*	-
AGDUFA	*198*	*1*	-	*0*	-	*0*	-	*0*	*6*	*0*	-	*0*	*204*	*1*
Proposed Reinspection user fee	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	-	-
Proposed Food Inspection and Facility Registration user fee	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
HEADQUARTERS / OC TOTAL	**68,573**	**276**	**5,164**	**31**	**6,006**	**30**	**1,285**	**8**	**3,343**	**19**	**1,342**	**8**	**85,713**	**372**
SUB-TOTAL:	**924,356**	**3,764**	**115,075**	**466**	**80,955**	**409**	**17,322**	**107**	**45,061**	**260**	**18,093**	**109**	**1,200,861**	**5,115**
Total Center	923,538	3,760	115,075	466	80,955	409	17,322	107	14,483	86	6,775	45	1,158,148	4,873
Total Field	818	4	-	-	-	-	-	-	30,578	174	11,318	64	42,713	242
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, proposed user fees			5,270	37	*22,659*	*105*	*4,921*	*27*	*12,215*	*65*			*45,065*	*234*
User Fees - non add)														
Plus:														
Other Rent and Rent-Related (incl. White Oak Relocation)														
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 GDUFA (non-add)														
Other Rent and Rent Related AGDUFA (non-add)														
Other Rent and Rent Related Proposed Reinspection														
GSA Rent														
GSA Rent PDUFA (non-add)														
GSA Rent MDUFMA (non-add)														
GSA Rent ADUFA (non-add)														
GSA Rent GDUFA (non-add)														
GSA Rent AGDUFA (non-add)														
GSA Rent Proposed Reinspection														
Other Current Law User Fees														
Buildings and Facilities														
TOTAL S&E PROGRAM:														

FDA FUNDING BY FUNCTIONAL ACTIVITY
TOTAL = S&E PROGRAM LEVEL
(Dollars in thousands)

FY 2010 Estimate	POSTMARKET														POSTMARKET TOTAL		TOTAL ALL FDA	
	OUTREACH COORDINATION		POSTMARKET APPLIED		POSTMARKET LABORATORY ANALYSES				POSTMARKET INSPECTIONS									
	COMPLIANCE		RESEARCH		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	102,142	456	54,222	140	13,240	50	13,719	55	4,510	17	5,473	27	3,363	7	196,669	752	244,981	947
Field Activities	127,159	519	1,100	5	100,387	346	81,385	364	141,350	690	27,971	121	121,284	525	600,635	2,569	600,635	2,569
Proposed Reinspection user fee (non-add): Center	1,054	7							0	0	0	0	0	0	1,054	7	1,054	7
Field	0	0	0	0	0	0	0	0	4,413	34	4,726	33	0	0	9,139	67	9,139	67
Proposed Food Inspection and Facility Registration user fee (non-add): Center					1,000	1	1,000	1	3,500	10	1,000	4	1,000	3	7,500	19	7,500	19
Field	0	0	0	0	16,200	44	0	0	26,400	85	2,400	6	0	0	45,000	135	45,000	135
FOODS TOTAL	**229,301**	**975**	**55,322**	**145**	**113,627**	**396**	**95,104**	**419**	**145,860**	**707**	**33,444**	**148**	**124,647**	**532**	**797,304**	**3,321**	**845,616**	**3,516**
HUMAN DRUGS																		
Center for Drug Evaluation & Research	182,551	557	5,975	44	1,878	12	1,410	9	10,116	73	1,561	10	1,757	12	205,248	717	763,076	2,996
Field Activities	34,441	186	-	-	16,863	80	4,381	24	38,504	199	14,852	72	8,801	38	117,843	599	144,937	763
PDUFA (non-add): Center	*81,183*	*245*	-	-	-	-	-	-	*278*	*2*	*139*	*1*	-	-	*81,600*	*248*	*406,984*	*1,598*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		*8,306*	*49*
Proposed GDUFA (non-add): Center	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		*26,504*	*56*
Field	-	-	-	-	-	-	-	-	*2,022*	*8*	*4,023*	*4*	-	-	*6,045*	*12*	*6,045*	*12*
Proposed Reinspection user fee (non-add): Field	-	-	-	-	-	-	-	-	*1,169*	*9*	*1,191*	*9*	-	-	*2,360*	*18*	*2,360*	*18*
HUMAN DRUGS TOTAL	**216,992**	**743**	**5,975**	**44**	**18,741**	**92**	**5,791**	**33**	**48,620**	**272**	**16,413**	**82**	**10,558**	**50**	**323,091**	**1,316**	**908,013**	**3,759**
BIOLOGICS																		
Center for Biologics Evaluation & Research	38,621	106	204	1	-	-	-	-	3,285	12	-	-	-	-	42,110	119	260,997	959
Field Activities	7,928	44	0	0	0	0	0	0	28,498	154	2,318	10	1,408	7	40,153	215	44,734	238
PDUFA (non-add): Center	*1,599*	*6*	-	-	-	-	-	-	-	-	-	-	-	-	1,599	6	*83,747*	*313*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*3,489*	*10*
MDUFMA (non-add): Center	*227*	*1*	-	-	-	-	-	-	-	-	-	-	-	-	227	1	*11,068*	*31*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*507*	*3*
Proposed Reinspection user fee (non-add): Field	-	-	-	-	-	-	-	-	*321*	*2*	*161*	*1*	-	-	482	3	*482*	*3*
BIOLOGICS TOTAL	**46,549**	**150**	**204**	**1**	**-**	**-**	**-**	**-**	**31,783**	**166**	**2,318**	**10**	**1,408**	**7**	**82,263**	**334**	**305,731**	**1,197**
ANIMAL DRUGS & FEEDS																		
Center for Veterinary Medicine	38,962	154	8,195	44	0	0	0	0	0	0	0	0	0	0	47,157	198	*105,198*	*456*
Field Activities	17,042	69	0	0	10,598	43	1,302	6	22,685	126	4,417	30	7,228	23	63,272	298	65,824	311
ADUFA (non-add): Center															-	-	15,290	*66*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	250	*2*
AGDUFA (non-add): Center															-	-	4,382	*20*
Field	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	143	*1*
Proposed Reinspection user fee (non-add): Center	*74*	-	-	-	-	-	-	-	-	-	-	-	-	-	74	-	74	*0*
Field	-	-	-	-	-	-	-	-	*1,267*	*10*	*1,141*	*9*	-	-	2,408	19	2,408	*19*
Proposed Food Inspection and Facility Registration user fee (non-add): Center	*3,000*	*9*	-	-	-	-	-	-	-	-	-	-	-	-	3,000	9	3,000	*9*
Field	-	-	-	-	*4,500*	*12*	-	-	*3,500*	*12*	*2,000*	*6*	-	-	10,000	30	10,000	*30*
ANIMAL DRUGS & FEEDS TOTAL	**56,004**	**223**	**8,195**	**44**	**10,598**	**43**	**1,302**	**6**	**22,685**	**126**	**4,417**	**30**	**7,228**	**23**	**110,429**	**496**	**171,022**	**767**
DEVICES AND RADIOLOGICAL HEALTH																		
Center for Devices & Radiological Health	104,243	413	1,805	12	14,980	56	0	0	0	0	0	0	0	0	121,028	481	273,813	1,275
Field Activities	24,699	127	0	0	4,634	18	2,821	14	41,506	192	8,380	39	7,075	52	89,115	443	97,601	485
MQSA (non-add): Center	*6,003*	*26*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*6,003*	*26*	*6,003*	*26*
Field	*7,223*	*5*	*0*	*0*	*0*	*0*	*0*	*0*	*5,854*	*3*	*0*	*0*	*0*	*0*	*13,077*	*8*	*13,077*	*8*
MDUFMA (non-add): Center	*6,385*	*30*	*62*	*1*	*536*	*3*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*6,983*	*34*	*32,836*	*220*
Field	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	-	-	*1,049*	*7*
Proposed Reinspection user fee (non-add): Field	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*2,048*	*16*	*1,024*	*8*	*0*	*0*	*3,072*	*24*	*3,072*	*24*
DEVICES TOTAL	**128,942**	**540**	**1,805**	**12**	**19,614**	**74**	**2,821**	**14**	**41,506**	**192**	**8,380**	**39**	**7,075**	**52**	**210,143**	**924**	**371,414**	**1,760**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH			**22,163**	**75**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**22,163**	**75**	**58,745**	**210**
HEADQUARTERS / OFFICE OF THE COMMISSIONER																		
Headquarters / Office of the Commissioner	**54,310**	**208**	**3,023**	**10**	**13,027**	**48**	**8,415**	**37**	**23,274**	**116**	**5,206**	**24**	**12,093**	**53**	**119,348**	**496**	**205,061**	**867**
USER FEES (non-add): PDUFA	*5,810*	*18*	*0*	*0*	*0*	*0*	*0*	*0*	*20*	*0*	*10*	*0*	*0*	*0*	*5,840*	*18*	*35,270*	*144*
MQSA (HQ / OC)	*165*	*2*	-	-	-	-	-	-	*73*	-	-	-	-	-	*238*	*2*	*238*	*2*
MDUFMA	*860*	*3*	*8*	-	*70*	-	*0*	-	*0*	-	*0*	-	*0*	-	*938*	*3*	*5,914*	*22*
ADUFA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*693*	*4*
GDUFA	-	*0*	-	*0*	-	*0*	-	*0*	*74*	*0*	*147*	*0*	-	*0*	*221*	-	*1,189*	*0*
AGDUFA	-	*0*	-	*0*	-	*0*	-	*0*	-	*0*	-	*0*	-	*0*	-	-	*204*	*1*
Proposed Reinspection user fee	*249*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*4258*	*9*	*3835*	*8*	-	-	*8,342*	*17*	*8,341*	*18*
Proposed Food Inspection and Facility Registration user fee	*2,192*	*7*	-	-	*3,288*	*9*	-	-	*2,558*	*9*	*1,462*	*4*	-	-	*9,500*	*29*	*9,500*	*29*
HEADQUARTERS / OC TOTAL	**54,310**	**208**	**3,023**	**10**	**13,027**	**48**	**8,415**	**37**	**23,274**	**116**	**5,206**	**24**	**12,093**	**53**	**119,348**	**496**	**205,061**	**867**
SUB-TOTAL:	**732,098**	**2,838**	**96,687**	**331**	**175,608**	**653**	**113,433**	**509**	**313,728**	**1,578**	**70,178**	**334**	**163,009**	**717**	**1,664,742**	**6,961**	**2,865,603**	**12,077**
Total Center	520,829	1,894	95,587	326	43,125	166	23,544	101	41,185	218	12,240	61	17,213	72	753,723	2,838	1,911,870	7,710
Total Field	211,269	944	1,100	5	132,482	487	89,889	408	272,543	1,360	57,938	273	145,796	645	911,018	4,123	953,731	4,366
(PDUFA, MQSA, MDUFMA, ADUFA, GDUFA, AGDUFA, proposed user fees User Fees - non add)	*109,455*	*336*	*70*	*1*	*606*	*3*	-	-	*8,247*	*13*	*4,172*	*5*	-	-	*122,550*	*358*	*765,118*	*2,973*
Plus:																		
Other Rent and Rent-Related (incl. White Oak Relocation)																	**116,821**	0
Other Rent and Rent Related MDUFMA (non-add)																	*1,376*	*0*
Other Rent and Rent Related PDUFA (non-add)																	*23,114*	*0*
Other Rent and Rent Related ADUFA (non-add)																	*162*	*0*
Other Rent and Rent Related GDUFA (non-add)																	-	*0*
Other Rent and Rent Related AGDUFA (non-add)																	*72*	*0*
Other Rent and Rent Related Proposed Reinspection																	*939*	*0*
GSA Rent																	**173,111**	**0**
GSA Rent PDUFA (non-add)																	*17,252*	*0*
GSA Rent MDUFMA (non-add)																	*4,264*	*0*
GSA Rent ADUFA (non-add)																	*885*	*0*
GSA Rent GDUFA (non-add)																	*2,262*	*0*
GSA Rent AGDUFA (non-add)																	*305*	*0*
GSA Rent Proposed Reinspection																	*2,121*	*0*
Other Current Law User Fees																	10,400	54
Buildings and Facilities																	**12,433**	0
TOTAL S&E PROGRAM:																	**3,178,368**	**12,130**

FDA Research Activities

Purpose

In response to a FY 2006 appropriations conference report, FDA is providing a budget justification for its research activities that describes the activities funded at the base level and the activities funded by proposed increases.

A funding table will display FDA's total research funding followed by a descriptive justification by each FDA Center, ORA, and OC.

FDA Research Activities Funding
(Dollars in $000)

FDA Programs	**FY 2008**	**FY 2009**	**FY 2010**
Foods	$36,120	$56,420	$64,800
Field (non-add)	$1,100	$1,100	$1,100
Human Drugs	$28,284	$27,096	$28,256
Biologics	$18,187	$18,825	$20,390
Animal Drugs and Feeds	$8,274	$9,241	$11,238
Devices and Radiological Health	$12,211	$18,992	$20,146
National Center for Toxicological Health	$44,443	$52,511	$58,745
OC and HQ Operations	$6,857	$6,985	$8,187
TOTAL	**$154,376**	**$190,070**	**$211,762**

** Source is the FDA Functional Activity Tables.

Foods Program Program's Research Activities

The FDA Foods Program (Center) FY 2010 funding for research activities are estimated to be $64,800. Of this amount, $56,420 represents base funding to support the research activities described below. $8,380,000 represents the funding increase supporting new or expanded existing research described below.

Base Funding Supporting Research – Center Activities

The Center for Food Safety and Applied Nutrition (CFSAN) conducts food, cosmetic, and color additive safety research to protect the public's food and cosmetic supply from harmful illnesses, environmental contaminants, or other threats caused by natural or man-made events.

CFSAN's research program consists of three integrated programs designed to meet the food safety, food defense, applied nutrition, and cosmetic safety regulatory needs of the agency. These programs include a strong intramural research capability, a small extramural research program, and a "Centers of Excellence" (COE) program that currently consists of three academic/government/industry consortia. The intramural program consists of research efforts in chemistry, microbiology, molecular biology, food

science, toxicology, immunology, social sciences, education, and risk assessment. Methods for sampling, detecting and confirming hazards in a variety of food types so that we can unequivocally establish evidentiary support to our regulatory actions. Some examples of this research include:

- Prevalence and behavior of microbiological and chemical hazards in foods in order to provide the data needed to assess risks, determine the effectiveness of potential control strategies, establish food safety standards, and provide practical food safety guidance to industry, particularly small business.
- Identification of virulence factors, epidemiological markers, and other determinants that influence the ability of pathogenic microorganisms to use foods as a vehicle for disease transmission thereby providing enhanced epidemiological investigation, earlier interventions, and more accurate product tracebacks.
- Development of techniques and data needed to conduct quantitative risk assessments of foodborne threats to public health
- Development of analytical methods that are suitable for application to the myriad of different foods, food ingredients, dietary supplements, and cosmetics and that will support regulatory actions
- Provision of reference standards for an array of chemical contaminants, biologically derived toxins, micronutrients, dietary supplements, cosmetic ingredients that can be used by regulatory agencies for the evaluation of domestic and imported products
- Consumer and Industry studies that allow consumer messages related to food and cosmetic safety that maximize the Agency's message while minimizing unwarranted fears or unintended consequences that would negatively impact industry

Program Increases Supporting Research – Center Activities

Funds will be used to support research in the following critical areas:

- Allergens – development and evaluation of reference standards, rapid test kits, methods of confirmation and new methods for evaluating allergencity of processed foods.

- Biotechnology – techniques and methods for evaluating/detecting foods modified by approved or accidental manipulation of genes to support risk assessment development and the establishment of a surveillance program.

- Genomics and Proteomics technologies – adaptation of the fundamental technologies underlying these ‘genomics’ research engines that would allow us to meet specific regulatory needs such as epidemiology, rapid methods for multiplex screening of both chemical and microbial contaminants, and confirmatory testing.

- Rapid test kit development – kits that can be used in the fields with little or no expertise. A number of programs would benefit from these methods including food pathogens and marine toxins.

- Confirmatory methods – methods to support results from rapid, field deployable test kit.

- Virology- method development as well as fundamental science. For example, culturing techniques for viruses which can not currently be cultured.

- Bioinformatics – computer science and technology which allows the analysis of cross-platform data (acquired from several different methods). New software algorithms for data analysis. Improved storage, transfer and sharing of data.

- In vitro testing – new methods for assessing significant and unreasonable risk in dietary supplements, toxicology, new food additives, cosmetics and nanotechnology.

- Cosmetic safety—new analytical technology to support cosmetic ingredient safety, including nanoparticles. The assessment of nanoparticle safety through toxicological analysis when applied to skin is critical.

- Centers of Excellence – funding to be provided in support of CFSAN's Centers of Excellence (COE), including FDA's newest COE at the Western Region FDA Center of Excellence at the University of California at Davis.

- Laboratory enhancement—capital equipment; standard equipment; capacity for handling of select agents; improvements and expansion of safety; maintenance and oversight of research tracking and reporting database; laboratory build-outs and renovations; and quality assurance program.

Base Funding Supporting Research – Food Field Activities

The Office of Regulatory Affairs (ORA) funding of research activities for FY 2010 are estimated to be $1,100,000. This $1,100,000 represents the base funding that supports ORA's research activities described below. ORA's research, development, and evaluation activities are conducted in order to provide convincing and prevailing scientific and analytical base for regulatory decisions that protect and promote public health. It is this research that informs policy and regulation to improve the safety, efficacy, and quality of FDA-regulated products.

ORA participates in food defense research activities including methods development and validation for the detection of potential bioterrorism agents such as *Bacillus anthracis* and *Clostridium botulinum* neurotoxin, and potential chemical contaminants such as cynadie, ricin, T2 toxin, and radionuclides. Engaging in these and other food defense

research activities improves FDA's ability to respond to threats to the American food supply and supports activities of the Food Emergency Response Network (FERN).

Human Drug Program Research Activities

The Human Drug Program Research Activities for FY 2010 are estimated to be $28,256,000. Of this amount, $27,096 represents base funding and $1,160,000 represents the funding increase supporting new or expanded existing research activities in the Human Drugs Program as part of its mission to ensuring the American public has adequate access to safe, effective, and high quality drug and therapeutic biologic products.

A significant portion of the funding accounted for as research activities within the Human Drugs Program covers the Orphan Drug Program. The Office of Orphan Products Development (OOPD) promotes development of products that demonstrate promise for diagnosis and/or treatment of rare diseases or conditions by administering a grant program that provides funding for clinical research in rare diseases.

As part of its efforts to develop medical counter measures in the case of terrorist attacks, CDER studies broadly acting stimulators of the immune system in animal models to assess protective effects against various infectious agents potentially used in bioterrorist attacks. CDER models studies in animals to ensure that products are safe to study in humans. This research analyzes specific immune deficiencies in animal models of bioterrorism-related radiation injury to clarify clinical problems potentially treatable with therapeutic proteins. CDER develops new assays for anthrax toxin that more closely model toxin activity in humans than current mouse cell assays, and provide biomarkers for assessing anthrax toxin effects in vivo.

CDER also performs research to develop regulatory standards and risk assessment criteria to reach sound, science-based public health decisions when evaluating the safety and effectiveness of drug products. This research allows CDER to clarify mechanisms of cell death induced by cancer drugs in order to enable better bioassays to serve as markers for safety and efficacy of novel cancer drugs. This research also allows CDER to identify biomarkers of cancer development and progression to facilitate diagnosis and monitoring of treatment efficacy.

Biologics Program Research Activities

The Biologics program research activities for FY 2010 are estimated to be $20,390,000. This funding supports the scientific endeavors aimed at ensuring the safety, efficacy, and availability of biological products that advance the public's health. In order to pursue these goals, FDA maintains a scientific staff that collectively has a unique regulatory, product development, and cross-product perspective. The staff also has significant expertise in the complex field of biological product manufacturing that enables them to

address any of the myriad problems that might occur throughout the manufacturing process.

The research activities at CBER create new knowledge that provides scientific expertise, new laboratory and testing tools, data that support science-based regulatory decision-making and policy development and that facilitates development of novel biologics.

The base funding of $18,825,000 supports the research activities described below:

- Maintaining a staff, which includes physician scientists, that has expertise in the multidisciplinary, disease-oriented science required for biological product evaluation

- Maintaining the ability to respond to emerging issues relevant to the Center's regulatory responsibilities

- Convening cooperative groups of sponsors, academia, and other government agencies to resolve specific scientific problems affecting the safety or efficacy of products regulated by CBER

- Identifying significant potential challenges in product development so they can be addressed and resolved before they cause problems

- Developing, evaluating, and refining existing methods, reagents and standards

- Evaluating, developing, and integrating into the regulatory process novel scientific technologies and preclinical models

- Developing and analyzing novel techniques and technologies for evaluating biologics that reduce, refine, or replace use of animal models

- Improving the design of clinical trial design and the evaluation of data gathered during such studies

- Enhancing scientific approaches to risk assessment, risk management, and risk communication

- Enhancing and extending active, population-based safety surveillance by developing improved analytical tools and accessing large databases--a strategy that will build on CBER pilot projects done in collaboration with the Centers for Medicare and Medicaid Services, the Vaccine Safety Datalink, the Centers for Disease Control and Prevention, and other partners.

In addition, CBER will undertake the following activities with increased resources in FY 2010:

- A scientific workshop will be conducted for identification, assessment, monitoring of and response to top priority pathogen threats to blood and tissue supply, in order to enable FDA to proactively forecast and recommend best possible solutions to top priority pathogen threats to blood and tissues supply.

- Data will be gathered and analyzed from studies aimed to compare and evaluate high throughput, novel technologies for detection of pathogens in biologics and cell substrates used to manufacture vaccines and other biologics.

Animal Drugs and Feeds Program Research Activities

The FY 2010 estimate is $11.238,000 for the Animal Drugs and Feeds (ADF) research activities. The ADF research program conducts applied and basic research in support of current and evolving FDA regulatory issues. The research answers regulatory questions and provides data for policy formulation related to the ADF's core functions. Regulatory research supporting premarket and medical product safety validates the safety and efficacy of animal derived food and animal health products to ensure approved products are safe to eat for humans and animals. Development of analytical methods and evaluation of screening tests for detection of drug residues in imported and domestic food products supports the ADF compliance program. ADF research also involves development of methods to detect material prohibited by the BSE feed regulation that could compromise animal feed safety. The ADF program serves as leader for the National Antimicrobial Resistance Monitoring System (NARMS) program, which monitors trends in the antimicrobial drugs used in food-producing animals to identify the development of resistance among bacterial foodborne pathogens.
The ADF research program also conducts regulatory research in support of Pandemic Influenza Preparedness (enforcement against extra label use of antiviral drugs in poultry) and bioterrorism (screening methods to detect the presence of pesticides and industrial contaminants that could be introduced into the United States animal feed supplies by bioterrorists).

Under the Modernizing Medical Product Safety and Development Initiative, the ADF FY 2010 research increase totals $1,997,000 . The ADF program will strengthen its capacity to support emerging areas of science and manufacturing that are essential to regulation of FDA products by using genomics, proteomics, and metabolomics technologies as a source of biomarkers to individualize or personalize medical and veterinary treatment.

Medical Devices and Radiological Health Research Activities

The Medical Devices and Radiological Health Program Research Activities for FY 2010 are estimated to be $20,146,000. This $20,146,000 represents the funding that supports research activities in four crucial areas: critical path, premarket research, patient safety, and import safety. Laboratory research supports pre- and post-market approval and activities by development of scientific understanding, standards methods of testing, and

domestic and international standards development and recognition. In FY 2010, CDRH plans to conduct research in these broad areas:

- biological risk assessment, infection control, and toxicity to understand bioeffects of medical devices
- chemistry and materials science to develop analytical procedures, mathematical models and data related to the safety and performance of implanted devices
- imaging and applied mathematics to provide scientific expertise in radiation-emitting products, medical imaging systems, and devices using computer-assisted diagnostics
- optical physics, sensors, fiber optics, electrophysics, electromagnetics, electrical stimulation, and electrophysiology for improved safety and performance
- ultrasound and blood flow research to develop measurement methods and instrument calibration procedures
- magnetic resonance imaging device safety to characterize implanted devices and device materials
- application of electronics, software engineering, and systems engineering to assess medical device safety and performance

Program Increases Supporting Research – Center Activities

The Devices Program's request for additional budget authority in FY 2010 includes support for CDRH research activities. These activities support device review and safety through ongoing development of scientific understanding, standards methods of testing, technology assessment, domestic and international standards development and recognition, and guidance development. In FY 2010 CDRH plans to strengthen and support research in these areas:

- Nanotechnology research will provide answers on new product safety and will support guidance development for safe and effective devices. Research focuses on assessment of critical properties and biological effects of nanoengineered particles in cells and the compatibility of nanoengineered materials in the body.
- Genomics research, with specific emphasis on molecular diagnostics and personalized medicine, will ensure sufficient expertise to regulate diagnostic technology used to develop drugs and dosing based on an individual's genetic make-up (personalized medicine).
- Development and validation of new clinical trial methods to evaluate imaging devices involving human readers will result in more powerful clinical studies of imaging device efficacy at less cost.
- Development of increased capabilities to assess the design and engineering of electronic medical devices and software will advance the safety, effectiveness, and premarket review of medical products.

National Center for Toxicological Research (NCTR) Activities

NCTR's mission is to conduct research that enables FDA product centers to make sound science-based regulatory decisions. Therefore, the Center's estimated FY 2010 funding of $58,745,000 will be used entirely for research. Of this amount, $52,511,000 represents base funding support for research activities. The remaining balance available to NCTR for FY 2010 includes increases of $1,625,000 for research supporting the Food Safety Initiative, $3,919,000 for research supporting the Medical Products Initiative, and $690,000 for pay increases.

Base Funding Supporting Research Activities

Using base funding, NCTR conducts research in three program areas: Personalized Nutrition and Medicine, Food Protection, and Enhancing Product Safety. Under Personalized Nutrition and Medicine, NCTR aims to define and characterize both individual responses to regulated products and biomarkers for an individual's susceptibility to toxicants, disease risk, and health status. In support of Food Protection, NCTR will provide techniques to *prevent* contamination of the food supply or the environment and to ensure timely *intervention* strategies by developing rapid, field-ready standards for the early detection of microbial or chemical threats to the food supply. Under Enhancing Product Safety, NCTR scientists use toxicological methods to identify risks associated with the use of food, food additives, food and feed contaminants, and medical products and devices. FDA scientists can then use this toxicity data to develop reliable and reproducible techniques for conducting safety assessments of FDA-regulated products. A sampling of research conducted at NCTR includes projects to:

- define and characterize individual responses to regulated products
- develop interventions to reduce disparities among subpopulations by optimizing nutrient intakes and treatment of disease by individualizing prevention and medical strategies using community-based participatory research
- evaluate the safety of antimicrobial agents on human health and provide data that can be used for development of industry guidelines
- develop and apply sensitive molecular tools to rapidly detect and characterize microbiological and chemical agents that compromise food safety
- predict adverse events by integrating data from new technologies with traditional toxicological data using statistical approaches and advanced computer technologies
- identify gender-specific biomarkers to improve risk/benefit decisions for treatments
- direct the second phase of the research consortium, Microarray Quality Control (MAQC) to address the quality standards and data analysis challenges of using microarray technology in the clinical setting.

Food Safety Increase and Medical Products Increase Supporting Research Activities

The FY 2010 program increase of $1,625,000 to support the Food Safety Initiative enables NCTR to continue its ongoing Food Protection research activities. The additional funds will allow scientists to conduct studies to better understand the interactions between bacteria and milk. This increased understanding may help to reduce or eliminate organisms that lead to spoilage. NCTR will also continue development of an integrated genomic knowledge base for *Salmonella* including identification of knowledge gaps and development of projects to address those gaps. This research allows FDA to increase identification and understanding of food vulnerabilities that pose risks for the American public. To expand the understanding and use of detection and mitigation measures, NCTR will conduct validation of mobile, field-rugged rapid-detection systems in collaboration with the Office of Regulatory Affairs' Arkansas Regional Laboratory.

The FY 2010 program increase of $3,919,000 to support the Medical Products Initiative will allow NCTR to continue research to define the correlations between an individual's nutrition, health, and genetic profile. The increase will also support NCTR's nanotechnology studies and development of noninvasive imaging techniques for evaluation of neurological effects of pediatric anesthetics. These two areas of research will help FDA to better understand the consequences of exposure to these FDA-regulated products and can be used to provide guidelines for their safe and effective use. NCTR will also work toward developing a prototype that integrates an agency-wide bioinformatics data warehouse (Janus databases) with analytical tools to manage and analyze omic data (genomic, proteomic, and metabolomic) voluntarily submitted by industry. This research facilitates earlier detection of potential adverse events and fosters personalized nutrition and medicine.

Headquarters and Office of the Commissioner Activities

The Headquarters and Office of the Commissioner Research Activities for FY 2010 are estimated to be $8,187,000. Of this amount, $6,985,000 represents base funding and $1,202,000 represents funding increases supporting new or expanded existing research.

The Office of Orphan Products Development (OOPD) Program has two grants programs that support pre-market research. The first supports new and continuing extramural pre-market 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.

The purpose of the second grant program, the Pediatric Consortia Grant Program, is to stimulate the development (research), production, and distribution of pediatric medical

devices with grants to non-profit consortia. These demonstration grants are not limited to addressing diseases or conditions that are considered to be rare.

In general, OOPD grant funding is for two to four years. The list below of RD&E activities is representational and not comprehensive:

- reviewing of solicited grant applications by OOPD staff to ensure program requirements are met
- coordinating and convening peer review panels to provide technical review of grant proposals to ensure the best scientific proposals are funded
- selecting grant applications for funding
- conducting site visits to grantees to ensure extramural funded studies, which involve human subjects, are consistent with grant agreement terms and minimize FDA's exposure to risk of violations in human subjects protection requirements
- monitoring the grant-funded products to satisfy regulatory and program requirements
- modernizing the transmission of applications and other review information through full electronic submissions
- improving the OOPD database system to allow for more efficient and effective retrieval of information and other internal management practices.
- seeking out opportunities to present the OOPD scientific programs and facilitate discussion in scientific and regulatory issues and research needs.

A significant portion of the funding accounted for as research activities within the Human Drugs Program covers the Orphan Drug Program. The Office of Orphan Products Development (OOPD) promotes development of products that demonstrate promise for diagnosis and/or treatment of rare diseases or conditions by administering a grant program that provides funding for pre-market clinical research in rare diseases.

The Office of Women's Health (OWH) Research and Development Program addresses gaps in current knowledge, uses novel approaches for conducting and funding research, and sets new standards of excellence for women's health research. The program funds research projects at FDA and occasionally at academic facilities. The program is also responsible for meeting Congressional mandates to track the participation of women in clinical studies. The list below of RD&E activities is representational and not comprehensive:

- aligning OWH research priorities with FDA's Critical Path Initiative and identifying key opportunities especially in information technology and data management to advance our understanding of sex/gender based science
- using a peer review process to select the highest quality research projects of regulatory significance to FDA
- implementing a process to identify the highest priority women's health research needs in FDA in order to advance a science program that integrates these priorities with FDA's Critical Path Initiative

- partnering with other HHS organizations to identify gaps in women's health and sex/gender differences research and leveraging current funding to address those gaps
- seeking internal and external opportunities to present OWH's scientific portfolio and facilitate discussion in cross cutting women's health scientific issues including identifying research needs.

A portion of the funding accounted for as research activities within Devices and Radiological Health is for Pediatric Consortia Grants administered by the Office of Orphan Products Development. 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. The goal of FDA's Pediatric Consortia Grant Program is to stimulate the development (research), production, and distribution of pediatric medical devices with grants to non-profit consortia. The demonstration grants are not limited to addressing diseases or conditions that are considered to be rare.

Food and Drug Administration
HIV/AIDS
(Dollars in Thousands)

Program	FY 2006 Actual [1]	FY 2007 Actual [2]	FY 2008 Actual [3]	FY 2009 Omnibus	FY 2010 Estimate
HIV/AIDS					
Human Drugs	*$35,173*	*$30,789*	*$38,128*	*$39,539*	*$40,809*
Biologics	*$30,905*	*$35,009*	*$33,088*	*$36,188*	*$40,791*
Medical Devices	*$2,224*	*$2,303*	*$2,536*	*$3,021*	*$3,054*
Toxicological	*$0*	*$0*	*$95*	*$41*	*$0*
Other Acticities	*$3,045*	*$3,467*	*$3,469*	*$3,663*	*$3,895*
Field Activity	*$17,411*	*$18,993*	*$17,542*	*$18,531*	*$19,624*
Total HIV/AIDS	**$ 88,758**	**$ 90,563**	**$ 94,858**	**$ 100,983**	**$ 108,173**

[1] *Includes 1.0% recission.*

[2] *Includes 1.0% recission.*

[3] *Includes 0.7% recission.*

FOOD AND DRUG ADMINISTRATION
User Fee History
(Dollars in Thousands)

USER FEES: Appropriations

	FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2008 Actual		FY 2009 Omnibus		FY 2010 Estimate	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
Definite Appropriations:												
PDUFA												
- ***Human Drugs***	*1,049*	*$185,555*	*1,110*	*$205,279*	*1,103*	*$223,476*	*1,252*	*$321,282*	*1,505*	*$356,835*	*1,598*	*$406,984*
- ***Biologics***	*243*	*$41,175*	*213*	*$52,014*	*242*	*$48,540*	*304*	*$70,890*	*293*	*$73,206*	*313*	*$83,747*
- ***Office of Regulatory Affairs***	*39*	*$6,138*	*44*	*$7,389*	*50*	*$6,266*	*40*	*$7,259*	*50*	*$10,478*	*59*	*$11,795*
- ***Headquarters and Office of the Commissioner***	*124*	*$14,020*	*114*	*$14,829*	*121*	*$16,042*	*166*	*$21,936*	*135*	*$32,710*	*144*	*$35,270*
- ***GSA Rent***		*$11,212*		*$14,100*		*$9,001*		*$11,821*		*$16,000*		*$17,252*
- ***Other Rent and Rent Related Activities***		*$8,334*		*$7,000*		*$7,000*		*$13,409*		*$18,691*		*$20,154*
- ***FDA Consolidation at White Oak***		*$3,000*		*$5,033*		*$10,105*		*$4,190*		*$2,745*		*$2,960*
Subtotal, PDUFA	**1,455**	**$269,434**	**1,481**	**$305,644**	**1,516**	**$320,430**	**1,762**	**$450,787**	**1,983**	**$510,665**	**2,114**	**$578,162**
MDUFMA												
- ***Medical Devices and Radiological Health***	*108*	*$15,492*	*130*	*$19,838*	*151*	*$22,329*	*164*	*$23,289*	*201*	*$28,911*	*220*	*$32,836*
- ***Biologics***	*22*	*$5,260*	*26*	*$5,452*	*28*	*$5,731*	*28*	*$6,005*	*31*	*$10,968*	*31*	*$11,068*
- ***Office of Regulatory Affairs***	*8*	*$966*	*8*	*$1,123*	*8*	*$1,182*	*8*	*$1,230*	*8*	*$1,556*	*11*	*$1,556*
- ***Headquarters and Office of the Commissioner***	*15*	*$2,644*	*20*	*$2,654*	*21*	*$2,808*	*21*	*$2,967*	*22*	*$5,914*	*22*	*$5,914*
- ***GSA Rent***		*$2,237*		*$2,237*		*$2,349*		*$2,081*		*$3,930*		*$4,264*
- ***Other Rent and Rent Related Activities***		*$562*		*$765*		*$803*		*$850*		*$1,268*		*$1,376*
Subtotal, MDUFMA	**153**	**$27,161**	**184**	**$32,069**	**208**	**$35,202**	**221**	**$36,422**	**262**	**$52,547**	**284**	**$57,014**
ADUFA												
- ***Animal Drugs and Feeds***	*39*	*$7,538*	*54*	*$8,264*	*51*	*$10,969*	*59*	*$12,260*	*66*	*$13,362*	*66*	*$15,290*
- ***Office of Regulatory Affairs***									*2*	*$250*	*2*	*$250*
- ***Headquarters and Office of the Commissioner***	*3*	*$384*	*4*	*$493*	*4*	*$522*	*4*	*$563*	*4*	*$656*	*4*	*$693*
- ***GSA Rent***		*$567*		*$628*		*$675*		*$598*		*$839*		*$885*
- ***Other Rent and Rent Related Activities***		*$0*		*$291*		*$103*		*$109*		*$153*		*$162*
Subtotal, ADUFA	**42**	**$8,489**	**58**	**$9,676**	**55**	**$12,269**	**63**	**$13,530**	**72**	**$15,260**	**72**	**$17,280**
AGDUFA												
- ***Animal Drugs and Feeds***									*20*	*$4,118*	*20*	*$4,382*
- ***Office of Regulatory Affairs***									*1*	*$143*	*1*	*$143*
- ***Headquarters and Office of the Commissioner***									*1*	*$193*	*1*	*$204*
- ***GSA Rent***										*$305*		*$305*
- ***Other Rent and Rent Related Activities***										*$72*		*$72*
Subtotal, AGDUFA									**22**	**$4,831**	**22**	**$5,106**
Proposed Definite Appropriations:												
Generic Prescription Drug User Fee (GDUFA):												
- ***Human Drugs***											*56*	*$26,504*
- ***Office of Regulatory Affairs***											*12*	*$6,045*
- ***Headquarters and Office of the Commissioner***											*0*	*$1,189*
- ***GSA Rent***												*$2,262*
- ***Other Rent and Rent Related Activities***												*$0*
Subtotal, Generic Prescription Drug											***68***	***$36,000***
Food Export Certification User Fee:												
- ***Foods***											*7*	*$1,063*
- ***Animal Drugs and Feeds***											*0*	*$74*
- ***Office of Regulatory Affairs***											*19*	*$3,015*
Subtotal, Food Export Certification User Fee											***26***	***$4,152***
Reinspection User Fee:												
- ***Office of Regulatory Affairs***											***112***	***14,446***
Foods Program Estimate											*48*	*$6,124*
Human Drugs Program Estimate											*18*	*$2,360*
Biologics Program Estimate											*3*	*$482*
Animal Drugs and Feeds Program Estimate											*19*	*$2,408*
Devices and Radiological Health Program Estimate											*24*	*$3,072*
- ***Headquarters and Office of the Commissioner***											*17*	*$8,341*
- ***GSA Rent***												*$2,121*
- ***Other Rent and Rent Related Activities***												*$939*
Subtotal, Reinspection User Fee											***129***	***25,847***
Food Inspection and Facility User Fee												
- ***Foods***											*19*	*$7,500*
- ***Animal Drugs and Feeds***											*9*	*$3,000*
- ***Office of Regulatory Affairs***											*165*	*$55,000*
- ***Headquarters and Office of the Commissioner***											*33*	*$9,500*
Subtotal, Food Inspection and Facility User Fee											***226***	***75,000***
Indefininate Appropriations:												
MQSA												
- ***Devices and Radiological Health***	*26*	*$4,373*	*26*	*$4,784*	*21*	*$4,141*	*21*	*$4,047*	*26*	*$6,003*	*26*	*$6,003*
- ***Office of Regulatory Affairs***	*8*	*$8,586*	*8*	*$8,980*	*8*	*$9,457*	*8*	*$9,242*	*8*	*$13,077*	*8*	*$13,077*
- ***Headquarters and Office of the Commissioner***	*2*	*$226*	*2*	*$234*	*2*	*$240*	*2*	*$248*	*2*	*$238*	*2*	*$238*
Subtotal, MQSA	**36**	**$13,185**	**36**	**$13,998**	**31**	**$13,838**	**31**	**$13,537**	**36**	**$19,318**	**36**	**$19,318**
Export Certification	**8**	**$1,425**	**13**	**$2,033**	18	$2,732	**17**	**$2,707**	**18**	**$2,600**	**18**	**$2,700**
Certification Fund	**35**	**$5,506**	**33**	**$5,694**	36	$6,954	**39**	**$7,379**	**36**	**$7,700**	**36**	**$7,700**
Total, User Fees	**1,729**	**$325,200**	**1,805**	**$369,114**	**1,864**	**$391,425**	**2,133**	**$524,362**	**2,429**	**612,921**	**3,031**	**828,279**

USER FEES: Obligations

	FY 2003 Actual		FY 2004 Actual		FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2008 Actual	
	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$	FTE	$
PDUFA:												
- ***Human Drugs***	*742*	*$125,103*	*972*	*$162,653*	*1,049*	*$185,555*	*1,110*	*$205,279*	*1,103*	*$223,476*	*1,252*	*$321,282*
- ***Biologics***	*269*	*$44,959*	*217*	*$40,170*	*243*	*$41,175*	*213*	*$52,014*	*242*	*$48,540*	*304*	*$70,890*
- ***Office of Regulatory Affairs***	*41*	*$5,629*	*41*	*$5,808*	*39*	*$6,138*	*44*	*$7,389*	*50*	*$6,266*	*40*	*$7,259*
- ***Headquarters and Office of the Commissioner***	*149*	*$15,745*	*122*	*$13,535*	*124*	*$14,020*	*114*	*$14,829*	*121*	*$16,042*	*166*	*$21,936*
- ***GSA Rent***		*$8,719*		*$6,146*		*$11,212*		*$14,100*		*$9,001*		*$11,821*
- ***Other Rent and Rent Related Activities***		*$0*		*$3,770*		*$8,334*		*$7,000*		*$7,000*		*$13,409*
- ***White Oak***		*$0*		*$0*		*$3,000*		*$5,033*		*$10,105*		*$4,190*
Subtotal, PDUFA	**1,201**	**$200,155**	**1,352**	**$232,082**	**1,455**	**$269,434**	**1,481**	**$305,644**	**1,516**	**$320,430**	**1,762**	**$450,787**
MDUFMA												
- ***Medical Devices and Radiological Health***	*14*	*$10,661*	*100*	*$17,253*	*108*	*$15,492*	*130*	*$19,838*	*151*	*$22,329*	*164*	*$23,289*
- ***Biologics***	*5*	*$2,157*	*21*	*$3,437*	*22*	*$5,260*	*26*	*$5,452*	*28*	*$5,731*	*28*	*$6,005*
- ***Office of Regulatory Affairs***	*4*	*$449*	*6*	*$676*	*8*	*$966*	*8*	*$1,123*	*8*	*$1,182*	*8*	*$1,230*
- ***Headquarters and Office of the Commissioner***	*10*	*$1,071*	*10*	*$1,142*	*15*	*$2,644*	*20*	*$2,654*	*21*	*$2,808*	*21*	*$2,967*
- ***GSA Rent***		*$400*		*$1,080*		*$2,237*		*$2,237*		*$2,349*		*$2,081*
- ***Other Rent and Rent Related Activities***		*$100*		*$287*		*$562*		*$765*		*$803*		*$850*
Subtotal, MDUFMA	**33**	**$14,838**	**137**	**$23,875**	**153**	**$27,161**	**184**	**$32,069**	**208**	**$35,202**	**221**	**$36,422**
ADUFA												
- ***Animal Drugs and Feeds***			*3*	*$983*	*39*	*$7,538*	*54*	*$8,264*	*51*	*$10,969*	*59*	*$12,260*
- ***Headquarters and Office of the Commissioner***			*0*	*$0*	*3*	*$384*	*4*	*$493*	*4*	*$522*	*4*	*$563*
- ***GSA Rent***				*$100*		*$567*		*$628*		*$675*		*$598*
- ***Other Rent and Rent Related Activities***						*$0*		*$291*		*$103*		*$109*
Subtotal, ADUFA				**$1,083**	**42**	**$8,489**	**58**	**$9,676**	**55**	**$12,269**	**63**	**$13,530**
MQSA	38	$13,074	36	$12,716	36	$13,185	36	$13,998	31	$13,838	31	$13,537
Export Certification	13	$1,663	11	$1,806	8	$1,425	13	$2,033	18	$2,732	17	$2,707
Certification Fund	32	$7,855	35	$6,128	35	$5,506	33	$5,694	36	$6,954	39	$7,379
Subtotal	**83**	$22,592	**82**	$20,650	**79**	$20,116	**82**	$21,725	**85**	$23,524	**87**	$23,623
Total, FDA	**1,317**	**$237,585**	**1,571**	**$277,690**	**1,729**	**$325,200**	**1,805**	**$369,114**	**1,864**	**$391,425**	**2,133**	**$524,362**

USER FEES: Collections

	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Estimate
	$	$	$	$	$	$
PDUFA Collections	$307,959	$340,093	$375,597	$485,165	$510,665	$578,162
MDUFMA Collections	$31,103	$35,011	$29,825	$48,956	$52,547	$57,014
ADUFA Collections	$8,302	$11,018	$13,472	$11,420	$15,260	$17,280
AGDUFA Collections	$0	$0	$0	$0	$4,831	$5,106
Generic Prescription Drug Collections	$0	$0	$0	$0	$0	$36,000
Generic Animal Drug Collections	$0	$0	$0	$0	$0	$0
Food Export Certification User Fee	$0	$0	$0	$0	$0	$4,152
Reinspection User Fee	$0	$0	$0	$0	$0	$25,847
Food Insoection and Facility Registration User Fee	$0	$0	$0	$0	$0	$75,000
MQSA Collections	$13,922	$13,485	$13,600	$16,347	$19,318	$19,318
Export Certification	$2,205	$2,164	$2,780	$2,885	$2,600	$2,700
Certification Fund	$5,926	$6,633	$6,640	$7,606	$7,700	$7,700
Total, User Fees Collections	**$369,417**	**$408,405**	**$441,914**	**$572,379**	**$612,921**	**$828,279**

Food and Drug Administration

FY 2008- FY 2010 Cross-cutting Information

(Program Level in Millions)

	FY 2008 Actual	FY 2009 Omnibus	FY 2010 Estimate
Antimicrobial Resistance	**26.400**	**27.454**	**27.965**
Budget Authority (non-add)	*24.024*	*24.933*	*25.255*
Bioterrorism	**233.674**	**286.646**	**292.379**
Food Defense (non-add)	*170.696*	*213.225*	*217.489*
Medical Countermeasures (non-add)	*56.192*	*66.587*	*67.919*
Physical Security (non-add)	*6.786*	*6.834*	*6.971*
Budget Authority (non-add)	*233.473*	*286.439*	*292.169*
Blood Safety	**93.410**	**111.402**	**123.586**
Budget Authority (non-add)	*65.008*	*78.003*	*86.075*
BSE (Prion Disease)	**26.717**	**31.640**	**33.426**
Budget Authority (non-add)	*25.090*	*29.835*	*31.429*
Drug Marketing, Advertising, and Communication Activities	**10.666**	**17.388**	**17.863**
Budget Authority (non-add)	*8.401*	*15.038*	*15.401*
Drug Safety	**555.370**	**652.747**	**752.356**
Pre-market (non-add)	*386.572*	*433.724*	*497.878*
Post-market (non-add)	*168.798*	*219.023*	*254.478*
Budget Authority (non-add)	*290.090*	*355.756*	*397.003*
Food Labeling	**16.083**	**14.040**	**21.132**
Budget Authority (non-add)	*16.083*	*14.040*	*21.132*
Food Protection	**694.806**	**785.033**	**1044.291**
Food Defense (non-add)	*170.696*	*213.225*	*213.225*
Food Safety (non-add)	*524.110*	*571.808*	*831.066*
Budget Authority (non-add)	*694.806*	*785.033*	*949.872*
User Fees (non-add)	*0.000*	*0.000*	*94.419*
Human Generic Drugs Program	**87.724**	**87.987**	**129.863**
Office of Generic Drugs (non-add)	*41.372*	*41.543*	*70.729*
Field Drug Program (for Generic Drugs (non-add)	*5.875*	*5.324*	*11.669*
Budget Authority (non-add)	*87.724*	*87.987*	*91.269*
Immunization	**17.514**	**21.499**	**24.109**
Budget Authority (non-add)	*10.711*	*13.336*	*14.964*
Medical Device Surveillance	**21.193**	**21.064**	**20.541**
Budget Authority (non-add)	*17.850*	*19.059*	*18.483*
Pandemic Influenza	**35.495**	**37.241**	**39.193**
Budget Authority (non-add)	*33.861*	*35.402*	*37.229*
Over-the-Counter Drugs	**14.492**	**14.912**	**15.078**
Budget Authority (non-add)	*7.111*	*7.428*	*7.453*
Women's Health	**39.367**	**46.600**	**47.750**
Budget Authority (non-add)	*16.786*	*17.506*	*18.054*
Office of Women's Health (non-add)	*5.273*	*6.000*	*6.040*
Breast Cancer (MQSA) (non-add)	*19.254*	*24.465*	*24.614*
Tissues	**10.830**	**14.550**	**17.629**
Budget Authority (non-add)	*10.258*	*13.543*	*16.582*
Pre-Market Human Drug Review	**633.230**	**681.924**	**779.377**
Budget Authority (non-add)	*290.992*	*308.511*	*333.660*
White Oak	**42.726**	**41.281**	**41.496**

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 on-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 2008, FY 2009, and FY 2010.

FDA Central Budget

(Dollars in Thousands)

	FY 2008 Actuals									
	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
FOODS										
Center for Food Safety & Applied Nutrition	3,604		616		5,992		1,865		12,077	-
Field Activities	7,587		136		14,572		3,669		25,964	-
FOODS TOTAL	**11,191**	**-**	**752**	**-**	**20,564**	**-**	**5,534**	**-**	**38,041**	**-**
HUMAN DRUGS										
Center for Drug Evaluation & Research	7,931	11,258	3,296	1,800	20,246	19,267	4,480	6,301	35,953	38,626
Field Activities	2,187	446	39	53	4,200	516	1,057	162	7,483	1,177
HUMAN DRUGS TOTAL	**10,118**	**11,704**	**3,335**	**1,853**	**24,446**	**19,783**	**5,537**	**6,463**	**43,436**	**39,803**
BIOLOGICS										
Center for Biologics Evaluation & Research	4,041	3,908	5,952	4,422	6,175	8,692	2,111	1,028	18,279	18,050
Field Activities	709	243	14	29	1,360	282	342	89	2,425	643
BIOLOGICS TOTAL	**4,750**	**4,151**	**5,966**	**4,451**	**7,535**	**8,974**	**2,453**	**1,117**	**20,704**	**18,693**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,879	914	220	49	3,777	1,230	572	282	6,448	2,475
Field Activities	915		16	-	1,760	0	443		3,134	-
ANIMAL DRUGS & FEEDS TOTAL	**2,794**	**914**	**236**	**49**	**5,537**	**1,230**	**1,015**	**282**	**9,582**	**2,475**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	6,780	1,938	607	106	8,386	3,543	2,778	520	18,551	6,107
Field Activities	1,487	63	27	7	2,856	73	719	23	5,089	166
DEVICES TOTAL	**8,267**	**2,001**	**634**	**113**	**11,242**	**3,616**	**3,497**	**543**	**23,640**	**6,273**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**442**		**6**		**1,523**		**325**		**2,296**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**2,789**	**518**	**577**	**152**	**7,293**	**485**	**1,861**	212	**12,520**	**1,367**
TOTAL BA and UF:	**40,351**	**19,288**	**11,506**	**6,618**	**78,140**	**34,088**	**20,222**	**8,617**	**150,219**	**68,611**

FDA Central Budget

(Dollars in Thousands)

	FY 2009 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	5,532		655		3,095		1,624		10,906	-
Field Activities	9,085		955		6,285		3,947		20,272	-
FOODS TOTAL	**14,617**	**-**	**1,610**	**-**	**9,380**	**-**	**5,571**	**-**	**31,178**	**-**
HUMAN DRUGS										
Center for Drug Evaluation & Research	8,509	9,008	2,753	1,440	9,662	21,515	6,068	5,043	26,992	40,912
Field Activities	2,619	357	275	42	1,811	576	1,138	131	5,843	1,211
HUMAN DRUGS TOTAL	**11,128**	**9,365**	**3,028**	**1,482**	**11,473**	**22,091**	**7,206**	**5,174**	**32,835**	**42,123**
BIOLOGICS										
Center for Biologics Evaluation & Research	3,007	3,127	8,062	3,539	3,263	9,704	910	822	15,242	18,954
Field Activities	849	195	89	23	587	314	370	70	1,895	660
BIOLOGICS TOTAL	**3,856**	**3,322**	**8,151**	**3,562**	**3,850**	**10,018**	**1,280**	**892**	**17,137**	**19,614**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,958	731	538	39	1,483	1,374	651	226	4,630	2,619
Field Activities	1,096		116		759		474		2,445	-
ANIMAL DRUGS & FEEDS TOTAL	**3,054**	**731**	**654**	**39**	**2,242**	**1,374**	**1,125**	**226**	**7,075**	**2,619**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	6,303	1,551	393	85	4,447	3,956	2,062	417	13,205	6,727
Field Activities	1,780	51	187	6	1,232	82	774	18	3,973	172
DEVICES TOTAL	**8,083**	**1,602**	**580**	**91**	**5,679**	**4,038**	**2,836**	**435**	**17,178**	**6,899**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**985**		**291**		**650**		**385**		**2,311**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**2,285**	**415**	**460**	**122**	**2,738**	**542**	**1,177**	169	**6,660**	**1,346**
TOTAL BA and UF:	**44,008**	**15,435**	**14,774**	**5,296**	**36,012**	**38,063**	**19,580**	**6,896**	**114,374**	**72,601**

FDA Central Budget

(Dollars in Thousands)

	FY 2009 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	5,532		655		3,095		1,624		10,906	-
Field Activities	9,085		955		6,285		3,947		20,272	-
FOODS TOTAL	**14,617**	**-**	**1,610**	**-**	**9,380**	**-**	**5,571**	**-**	**31,178**	**-**
HUMAN DRUGS										
Center for Drug Evaluation & Research	8,509	11,664	2,753	1,976	9,662	25,606	6,068	6,544	26,992	45,790
Field Activities	2,619	462	275	58	1,811	686	1,138	178	5,843	1,384
HUMAN DRUGS TOTAL	**11,128**	**12,126**	**3,028**	**2,034**	**11,473**	**26,292**	**7,206**	**6,722**	**32,835**	**47,174**
BIOLOGICS										
Center for Biologics Evaluation & Research	3,007	4,048	8,062	4,856	3,263	11,550	910	1,137	15,242	21,591
Field Activities	849	252	89	31	587	374	370	97	1,895	754
BIOLOGICS TOTAL	**3,856**	**4,300**	**8,151**	**4,887**	**3,850**	**11,924**	**1,280**	**1,234**	**17,137**	**22,345**
ANIMAL DRUGS & FEEDS										
Center for Veterinary Medicine	1,958	947	538	54	1,483	1,634	651	308	4,630	2,943
Field Activities	1,096		116		759		474		2,445	-
ANIMAL DRUGS & FEEDS TOTAL	**3,054**	**947**	**654**	**54**	**2,242**	**1,634**	**1,125**	**308**	**7,075**	**2,943**
DEVICES AND RADIOLOGICAL HEALTH										
Center for Devices & Radiological Health	6,303	2,008	393	117	4,447	4,708	2,062	568	13,205	7,401
Field Activities	1,780	66	187	8	1,232	97	774	26	3,973	197
DEVICES TOTAL	**8,083**	**2,074**	**580**	**125**	**5,679**	**4,805**	**2,836**	**594**	**17,178**	**7,598**
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	**985**		**291**		**650**		**385**		**2,311**	**-**
HEADQUARTERS / OFFICE OF THE COMMISSIONER	**2,285**	**537**	**460**	**167**	**2,738**	**645**	**1,177**	226	**6,660**	**1,575**
TOTAL BA and UF:	**44,008**	**19,984**	**14,774**	**7,267**	**36,012**	**45,300**	**19,580**	**9,084**	**114,374**	**81,635**

User Fee data based PDUFA 5 year Plan dated 4-27-09

FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services Charges and Assessments
Fiscal Year 2008

Assessments:

Quality of Worklife Initiative **$0**
The Quality of Work Life was created to help HHS employees deal with the multitude of changes impacting the worksite.

Safety Management Information System **$0**
TAP for a department-wide, computerized accident and injury reporting and analysis system required by the Department of Labor.

Safety, Health and Environmental Management **$0**
Agreement enables the Department to continue conducting program evaluations and environmental compliance assessments of occupational safety and health as required

Energy Program Review **$0**
Energy Efficiency and Water Conservation at Federal Facilities mandate a myriad of requirements from energy and water conservation in HHS facilities. HHS must ensure that all such requirements are met.

Health and Wellness Center **$1,381**
Funds from the Health and Wellness Center are used to provide a portion of the on-going operational costs of a healthy facility.

IT Access for Disable Persons **$32,017**
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.

Media Outreach **$0**
TAP provides funding to support Secretarial public affairs initiatives, including production and distribution of public services announcement and video news reports.

President's Council on Bioethics **$246,063**
TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology.

National Rural Development Partnership **$0**
TAP is managed by USDA's Rural Development Administration. Under the partnership, States develop State Rural Develop Councils which supports rural development through cooperation among Federal, State and Local governments

Federal Laboratory Consortium **$16,562**
TAP to fund FLC research and development. US Department of Commerce's National Institute of Standards and Technology (NIST) is the recipient of these funds on behalf of FLC.

Radio Spectrum Management **$0**
Support for spectrum management services provided by the National Telecommunications and Information Administration (NTIA).
NTIA manages the Federal Governments use of the radio spectrum.

ALJ examinations **$957**
OMP is delegating examining authority for all competitive service positions except for Administrative Law Judges, and is requiring employing agencies to reimburse OMP for the cost of the ALJ program.

Fees for Service:

PROGRAM SUPPORT CENTER/FOH/OS **$34,147,057**

Provides various services to the FDA. The following is a breakdown of costs.

Human Resources, Personnel and Payroll: $7,494,780

Administrative Operations Service: $10,600,000
Includes costs for security, building operations, shredding, storage, graphics, property disposal, transhare and mail

Financial Management Services: $1,266,106

Office of the Director (OD): $82,621

Employee related programs and Childcare.

Office of Secretary (OS): $5,172,960
Includes costs for Audit Resolution, Contracts and Grants and Tracking Accounting in Government Grants and a portion of Commissioned Corp. In FY 2006 there were new costs for HHS Net and Web Communications.

FOH: $1,554,866
FDA agency health units and services

Unified Financial Management Systems (UFMS) $5,534,261
The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.

HCAS O&M $2,441,463
HCAS O&M services provide support for daily operations of the HCAS application.

NIH Management Fund **$15,513,000**
Agreement to support the Center for Biologics, Evaluation and Research activities on the NIH Campus. Includes Building Operations, Telecom, Utilities and various common services.

NIH Patents **$1,359,268**
Agreement with NIH for support developing patent applications for FDA.

JOINTLY FUNDED PROJECTS:

Enterprise Information Management **$6,444,906**
FDA's contribution to the HHS Enterprise Infrastructure Fund. The funds are used for Enterprise Information Tech programs/projects outlined in the Enterprise Info Tech Strategic Plan or which benefit the corporate enterprise, such as enterprise buys/licenses.

Human Resource Center – Rockville $**16,079,200**

International Health Bilateral Agreement **$1,018,646**
Agreement to provide funding in support of the Bilateral Multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs

OPM Job Information Federal Assessment **$73,748**
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.

Tri-Council Activities **$51,861**
AP to support government wide financial, information technology, procurement and other management activities.

Office of Pacific Health and Human Services **$15,694**
Agreement to support funding for health activities in support of the Office of Pacific Health and Human Services.

Motor Vehicle Information & Management **$8,000**
Agreement to support the MVIMS which generates reports on federal agency vehicle fleet expenditures.

NIH eRA Grants Management System **$198,877**
Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System

Financial Shared Services Study **$0**
Agreement to work on achieving projected milestones and offering recommendations to the senior leadership on the change management initiatives required to implement decisions.

Office of Public Health/Blood Safety **$387,500**
Agreement to provide funding for the advisory committee on Blood Safety.

Presidential Advisory Council on HIV/AIDS **$34,000**
Agreement to provide funding to the NIH Office of AIDS research

Core Support from National Academy of Science **$86,010**
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

Federal Executive Board, Dallas **$0**
President's Management Council asked Federal agencies to fund the FEBs, and HHS agreed to support the Dallas-Fort Worth (DFW) FEB. This covers costs of the Executive Director position.

National Science Advisory Board for Biosecurity **$0**
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.

Surgeon's Call to Action to Improve Health Literacy **$0**
The Office of Disease Prevention and Health Promotion (ODPHP) will host sessions with experts on how to implement improvements to health literacy and develop the Call to Action document.

Homeland Security Presidential Directive 12 **$315,065**
Support the Policy for a Common Identification Standard for Federal Employees and Contractors.

Regional Health Administrators **$577,407**
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.

Capital Security Cost sharing **$5,066**
Department of State charge for a "Head Tax", (Capital Security Cost Sharing).

DHHS CFO Audit of Financial Statements (OIG) **$352,293**
IAG establishes funding to provide audit services in support of the fiscal year 2009 financial statement audit of the Department of Health and Human Services.

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2008 Actual, and FY 2009 and 2010 Estimates

Activity	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate
DHHS ASSESSMENTS [1]	**296,980**	**275,361**	**283,622**
FEE FOR SERVICE	**58,995,049**	**62,257,763**	**66,754,819**
Program Support Center/FOH/OS	*34,147,057*	37,561,763	41,317,939
Unified Financial Management System	*5,534,261*	*5,616,000*	*5,784,480*
HHS Consolidated Acquisition Solution (HCAS O & M)	*2,441,463*	1,665,000	1,714,950
NIH Management Fund	*15,513,000*	16,290,000	16,778,700
NIH Patents	*1,359,268*	1,125,000	1,158,750
JOINTLY FUNDED PROJECTS	**25,648,273**	**25,976,375**	**28,565,075**
Enterprise Information Management	*6,444,906*	*5,690,128*	*6,508,000*
Human Resources Consolidation Costs	*16,079,200*	*17,040,000*	*18,744,000*
International Health - Bilateral Agreement	*1,018,646*	*1,018,646*	*1,018,646*
Other Jointly Funded Projects [2]	*2,105,521*	*2,227,601*	*2,294,429*
Total	**84,940,302**	**88,509,498**	**95,603,515**

[1] FY 2009 estimates from the FY 2009 JFA document dated 9-11-09
[2] Includes Jointly Funded Projects under $1,000,000. In FY 09 Includes funding for Media Monitoring

Sources of Funding to FDA by Other Federal Agencies

Federal Agencies	FY 2009 Estimate	FY 2010 Estimate	Reason for Funds
Department of Health and Human Services			
Office of the Director - National Institutes of Health	$633,700	$647,641	Research for NIH Intramural AIDS Program
Office of the Director - National Institutes of Health	$333,200	$340,530	FARE Awards
Office of the Director - National Institutes of Health	$150,000	$153,300	Determination of Aflatoxin Orchation A & Fumonisins in Botanical Dietary Supplements Raw Materials
Office of the Director - National Institutes of Health	$50,000	$51,100	Study Botanical Dietary Supplements in Raw Materials and Finished Products
Office of the Director - National Institutes of Health	$50,000	$51,100	Determine Arsenic Cadmium, Lead and Mercury in Botanical Dietary Supplements
Office of the Director - National Institutes of Health	$50,000	$51,100	Test Botanical Dietary Supplements
Office of the Director - National Institutes of Health	$500	$511	Development and Validation of AIAC Official Methods of analysis
Clinical Center - NIH	$10,000	$10,220	Flow Cytometry Facility
Clinical Center - NIH	$90,000	$91,980	Bench to Bedside Program
Clinical Center - NIH	$65,000	$66,430	Imageguided Interventional Therapeutics
National Cancer Institute - NIH	$30,000	$30,660	Provide support to the Papillomavirus Systems
National Cancer Institute - NIH	$65,000	$66,430	Provide core facility for testing of Oligonucleotides
National Cancer Institute - NIH	$40,000	$40,880	Provide core facility for Biotechnology Services
National Cancer Institute - NIH	$19,000	$19,418	Provide core facility (Zajac)
National Heart , Lung and Blood Institute - NIH	$138,000	$141,036	Support the HIV Nano Assay Project
National Heart , Lung and Blood Institute - NIH	$75,000	$76,650	HIV Diversity and Blood Safety
National Heart , Lung and Blood Institute - NIH	$26,500	$27,083	Core Facility Biotechnology Services
National Institute of Biomedical Imaging and Bioengineering -NIH	$468,000	$478,296	Assessment of Medical Imaging Systems
National Institute of Child Health and Human Development - NIH	$10,000	$10,220	Provide Flow Cytometry Facility
National Institute of Child Health and Human Development - NIH	$4,000	$4,088	Synthesis of Peptides- Biotechnology Services
National Institute of Denta l and Craniofacial Research - NIH	$60,700	$62,035	Provide Core Facility Biotechnology services
National Institute of Diabetes and Digestive and Kidney Disorders - NIH	$143,283	$146,435	Core Facility Biotechnology
National Institute of Disability and Rehabilitation Research - NIH	$250,000	$255,500	Provide Joint Laboratories for Medical Device Applications
National Institute of Environmental Health Sciences - NIH	$12,523,951	$12,799,478	Conduct toxicological assessments
National Institute of Allergy and Infectious Diseases - NIH	$880,164	$899,528	Conduct Biodefense Research Projects
National Institute of Allergy and Infectious Diseases - NIH	$600,000	$613,200	Assess the safety of cell substrates and vaccine components
National Institute of Allergy and Infectious Diseases - NIH	$25,000	$25,550	Support the Pandemic Influenza Workshop on Immune Correlates
National Institute of Allergy and Infectious Diseases - NIH	$15,000	$15,330	Provide core facility for Biotechnology Services
National Institute of Allergy and Infectious Diseases - NIH	$1,267,400	$1,295,283	Provide Scientific Approach to Facilitate Development of Vaccines and Related Products
National Institute of Allergy and Infectious Diseases - NIH	$342,188	$349,716	Provide warehouse space for research
National Institute on Drug Abuse - NIH	$100,000	$102,200	Drug Discovery Support
Centers for Disease Control and Prevention	$236,500	$241,703	Develop a single Vaccine Adverse Events Reporting System
Centers for Disease Control and Prevention	$46,000	$47,012	Assess the safety & efficacy of Polio Antiviral Compounds
Centers for Disease Control and Prevention	$200,000	$204,400	Study the Isotopically Labeled Gonyautoxins
Centers for Disease Control and Prevention	$561,368	$573,718	Lab equiptment for Shelf Life
Centers for Disease Control and Prevention	$10,000	$10,220	Mouse Studies
Program Support Center	$345,858	$353,467	Implement and operate a customer call center
Office of Global Health Affairs	$187,030	$191,145	Participate in the Biotechnology Engagement Program Umbrella Agreement
Office of Public Health and Science	$603,725	$617,007	Provide research support to the National Vaccine Program
Office of Public Health and Science	$39,696	$40,569	Miscellaneous Services - Plain Lanugage
Office of the Secretary	$125,000	$127,750	Miscellaneous Services - PSC UFMS
Office of the Assistant Secretary for Public Health and Emergency Preparedness	$1,308,100	$1,336,878	Assess the Potency and Neutralization of Botulinum Neurotoxins
Office of the Assistant Secretary for Preparedness and Response	$50,000	$51,100	Facilitate the Critical Path and Medical Countermeasures for the FLU research
Healthcare Resources and Services Administration	$310,190	$317,014	Provide Library Services and Information Resources
DHHS total	**$22,539,053**	**$23,034,912**	
Environmental Protection Agency			
Environmental Protection Agency	$330,000	$337,260	Evaluate and Validate the AOAC Spricidial Activity Test
Environmental Protection Agency	$120,000	$122,640	Coordinate the state activities of the Radiation Control Program
EPA total	**$450,000**	**$459,900**	
Department of Defense			
Defense Medical Standardization Board	$1,500,000	$1,533,000	Conduct a program for testing the shelf-life of stored medical items
Defense Advance Research Projects Agency	$50,000	$51,100	Assist in the test bed development for deep bleeder acoustic coagulation program
Defense Advance Research Projects Agency	$450,000	$459,900	Develop a customized Intro to Product Development course
Defense Advance Research Projects Agency	$57,000	$58,254	Blood Pharming Program
Defense Advance Research Projects Agency	$50,000	$51,100	Faster Accimation to High Altitutde by Targeting T
Navy Medical Research Center	$48,205	$49,266	Provide core Facility Biotechnology Services
Navy Systems Management Activity	$123,713	$126,435	Biological Serosol Test Method & Ppe Decontamination Procedure
DOD total	**$2,278,918**	**$2,329,054**	
Department of Homeland Security			
Department of Homeland Security	$180,000	$183,960	Provide Training and Technical Transfer for Biological Countermeasures
Federal Emergency Management Agency	$50,000	$51,100	Support the Radiological Emergency Preparedness Program
DHS total	**$230,000**	**$235,060**	
Nuclear Regulatory Commission	**$125,000**	**$127,750**	Provide support to the conference for Radiation Control Program Directors
National Oceanic and Atmospheric Administration	**$75,000**	**$76,650**	Support the Shellfish Safety Assistance Project
Department of Justice	**$10,249,200**	**$10,474,682**	Purchase investigative equipment
Consumer Product Safety Commission	**$2,000**	**$2,044**	Ocular and Dermal Irritation Testing and Oral Toxicity Testing
TOTAL	**$35,949,171**	**$36,740,053**	

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) or President's Management Agenda *(depending upon context)*
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

Food and Drug Administration
Senate Conference Report and Appropriations Bill
Significant Items

Senate Significant Items
Contained in Senate Report 110 – 426 (July 17, 2008)

Item 1 – **Agricultural Products Food Safety Laboratory** – The Committee recommendation includes $1,757,000 (NOTE: The Conference Report changed this amount to $1,650,000.) for the FDA's contract with New Mexico State University's Physical Sciences Laboratory to operate the Food Technology Evaluation Laboratory, which conducts evaluation and development of rapid screening methodologies, technologies, and instrumentation; and provides technology deployment, modeling, and data analysis for food safety and product safety, including advanced risk-based systems for screening and inspection, to facilitate FDA's regulations and responsibilities in food safety, product safety, homeland security, bioterrorism, and other initiatives. (p.109)

Action taken or to be taken

During FY 2009, FDA will continue to support this activity at the funding level recommended by the Committee.

Item 2 – **Inspection of Imported Shrimp** – The Committee is concerned about the contamination of farmraised 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 State testing programs, a program for increasing the inspection of imported shrimp for banned antibiotics. (p.109)

Action taken or to be taken

The use of unapproved drugs in farm-raised seafood raises significant public health concerns. FDA is actively working to ensure that farmed raised shrimp and other aqua cultured products are free from unapproved chemotherapeutics residues. FDA has a continuous monitoring program to test for animal drugs in imported and domestic seafood products. FDA expanded this program during the past two years to give special attention to products and sources. It is estimated that 90 percent of shrimp, the most consumed seafood in the U.S., is imported. Therefore, shrimp is a high priority product in FDA's testing program.

FDA focuses on ensuring the control of food safety hazards associated with unapproved aquaculture drugs in imported seafood through the Seafood Hazard Analysis and Critical Control Point (HACCP) program. Under the HACCP program, the importer and the foreign processor share the responsibility for preventative controls and are required to verify that the products they offer for entry comply with the requirements of FDA seafood regulation, including controls of aquaculture drug hazards. FDA continues to

take regulatory actions against imports where positive samples are found in order to prevent adulterated fishery products from entering domestic commerce.

The FDA Field Offices will continue to work closely with States in sampling and testing programs that detect banned antibiotics and to share methods and sampling results with states and other stakeholders.

Item 3 – Budget Justification – The Committee directs the agency to submit the fiscal year 2010 budget request in a format that follows the same account structure as the fiscal year 2009 budget request unless otherwise approved by the Committee. (p.109)

Action taken or to be taken
FDA is meeting this request by submitting a fiscal year 2010 budget request in a format that is consistent with the Fiscal Year 2009 Congressional Budget Justification.

Item 4 – Codex Alimentarius – Within the total funding available, at least $2,495,000 is for FDA activities in support of Codex Alimentarius. (p.109)

Action taken or to be taken
During FY 2009, FDA intends to continue to participate in Codex at the funding level recommended by the Committee.

Item 5 – Collaborative Drug Safety Research –The Committee recommendation includes $559,000 (NOTE: The Conference Report changed this amount to $525,000.) to continue the collaborative research agreement on cardiac biomarkers between FDA, the Critical Path Institute, and the University of Utah. The Committee notes that this research project has been extremely successful and has developed a genetic test that will help guide warfarin, a commonly prescribed blood thinner, dosing. It is estimated that integrating genetic testing into warfarin therapy could allow Americans to avoid 85,000 serious bleeding events and 17,000 strokes annually, reducing health care spending by approximately $1,000,000,000 annually. (p.109)

Action taken or to be taken
During FY 2009, FDA will continue to support this Critical Path priority at the funding level recommended by the Committee.

Item 6 – Critical Path and Modernizing Drug Safety – The Committee recommendation includes $16,000,000 for critical path initiatives, including not less than $4,000,000 for competitive contracts or grants to universities and non-profit organizations to support critical path projects. The Committee expects that this funding will be used to further FDA's work on critical path opportunities, including the 76 opportunities published in 2006 and other opportunities identified since 2006, and to promote collaborations with other Government agencies, academia, patient groups, and other interested parties including, but not limited to, the Predictive Safety Testing Consortium, the National Institute for Pharmaceutical Technology and Education, the

Coalition Against Major Diseases, and the Clinical Trials Transformation Initiative. (p. 110)

Action taken or to be taken

During FY 2009, FDA will continue to support important Critical Path activities in the FDA centers and in the Office of the Commissioner at the funding level recommended by the Committee. These Critical Path activities will include the opportunities identified in 2006 and additional opportunities identified since 2006. FDA will continue to promote collaborations with other Government agencies, academia, patient groups, and other interested parties, such as those identified in the Committee report. FDA intends to make the designated funds available for competitive contracts and grants to universities and non-profit organizations to support critical path projects.

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Item 7 – Demonstration Grants for Improving Pediatric Device Availability – The Committee recommendation includes $2,000,000 for Demonstration Grants for Improving Pediatric Device Availability, as authorized by the Food and Drug Amendments Act of 2007. The Committee is aware that medical device products are developed for adults, limiting children's access to safe and effective medical devices. This program will provide grants to nonprofit pediatric medical device consortia, which will assist scientists and innovators with technical and financial resources to improve the number of medical devices available to children. (p. 110)

Action taken or to be taken

FDA recognizes that children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices not suited for use in children may not accommodate the unique needs of children, such as allowing for expandable growth, and accommodating their active lifestyles and differing metabolism.

During FY 2009, FDA will support this activity at the funding level recommended by the Committee. FDA will do so in a way that protects against conflicts between grant activities authorized by section 305 of the FDA Amendments Act and the review of device applications. To implement this program, FDA will rely on the expertise of the Office of Orphan Products.

Item 8 – Dietary Supplements – FDA has indicated that the ability to identify and analyze specific components in ingredients, including botanical ingredients, is an essential component of research and regulatory programs directed at ensuring the safety and effectiveness of dietary supplements. The Committee recommendation includes $1,713,000 (The Conference Report changed this amount to $1,608,000.) for review of botanicals in dietary supplements. This work is being carried out by FDA in collaboration with the National Center for Natural Products Research, Oxford, Mississippi. (p. 110)

Action taken or to be taken

During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 9 – Generic Drugs –The Committee recommendation includes no less than $81,526,000 for the generic drugs program at FDA, of which $41,358,000 is for the Office of Generic Drugs. (p. 110)

Action taken or to be taken
During FY 2009, FDA will support the generic drugs program and the Office of Generic Drugs at the funding levels recommended by the Committee.

Item 10 – InVitro High Throughput Immune Response Assessment Technologies – The Committee is aware of rapid in vitro high throughput immune response assessment technologies for evaluating the human immune response to vaccines. These technologies may facilitate the rapid screening of novel vaccine candidates, thus reducing the time and cost associated with development. Specifically, these approaches may be highly useful for conducting potency testing and predicting the performance of new vaccines. The Committee directs FDA to continue to evaluate these technologies to determine how they might be used to rapidly facilitate vaccine development and FDA review. (p. 110)

Action taken or to be taken
FDA appreciates the Committees' interest in facilitating the rapid screening of novel vaccine candidates to reduce the time and cost associated with development. In vitro high throughput immune response assessment technologies are still in the early stages of development. The accuracy of these technologies has not yet been determined and the technologies cannot be used to evaluate all vaccines.

FDA will continue to evaluate new technologies to determine how they might be used to rapidly facilitate vaccine development review.

Item 11 –Mammography Funding – The Committee recommends no less than the fiscal year 2008 level in appropriated funds for activities related to the Mammography Quality Standards Act [MQSA]. (p. 111)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 12 – MQSA Report – On June 26, 2008, the Committee received a report, as requested by Senate Report 110–134, on actions being taken to implement recommendations made in the Institute of Medicine report entitled ‘‘Breast Imaging Quality Standards’’. The report stated that FDA held an open public meeting on September 28 and 29, 2006, and has been considering potential amendments to MQSA, which would address the IOM report, since this meeting. To date, FDA has not acted on any of these recommendations. The Committee believes this is an unacceptable delay, and directs the FDA to report back within 120 days of enactment of this Act on which amendments that FDA will propose to MQSA, if any, in response to the IOM report recommendations and provide a timeline for these amendments. (p. 111)

Action taken or to be taken
In FDA's June 26, 2008 report to the committee, FDA stated that, in response to the IOM recommendations, it was "drafting amendments to the MQSA regulations. These amendments are undergoing consideration within FDA." FDA points out that, at this time, FDA is planning amendments to the regulations implementing MQSA, not to the Mammography Quality Standards Act itself. In response to the Committee's request, FDA is developing a report that will contain more specific information regarding the draft regulations that address the IOM recommendations.

Item 13 – National Center for Food Safety and Technology – With the growing threat of food borne illness to the public health, the Committee believes that collaborative research in food safety should continue among Government, academia, and private industry. The national model for that collaboration has been the National Center for Food Safety and Technology [NCFST] in Summit-Argo, Illinois. The Committee recommendation includes $2,212,000 (The Conference Report changed this amount to $2,077,000.) for NCFST to continue the important work done there. This funding should be exclusive of any initiative funds which the FDA may provide in addition to NCFST. **(p. 111)**

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

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 $5,000,000 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. 111)**

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 15 – Orphan Products Grants – The Committee recommendation includes $14,035,000 for the Orphan Products Grants Program within the Center for Drug Evaluation and Research. **(p. 111)**

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 16 – **Pediatric Cancer** – The Committee notes the poor survival rates and lack of new therapies associated with many pediatric cancers, including high-risk neuroblastoma. The Committee encourages the FDA to prioritize review of new treatments and clinical trials for pediatric oncology patients and requests a report on these activities within 120 days of the enactment of this act. (p. 111)

Action taken or to be taken

FDA is preparing a report that addresses FDA actions to encourage new therapies and new labeling information for treatments for pediatric cancers, including high-risk neuroblastoma.

Item 17 – **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. 112)

Action taken or to be taken

FDA is working closely with the National Fisheries Institute and maintains communication with State regulators as well as counterparts in NOAA's National Marine Fisheries Service about these economic fraud issues. FDA works to take action on economic fraud, consistent with other food safety priorities The FDA Field force also considers information obtained from States when pursuing activities related to mislabeling or substitution of species.

Item 18 – Interstate Shellfish Sanitation Conference and Vibrio Vulnificus Education – The Committee supports the ongoing work of the Interstate Shellfish Sanitation Conference [ISSC] and its joint efforts with the FDA and the shellfish industry to formulate shellfish safety regulations through the National Shellfish Sanitation Program. The Committee recommendation includes $148,000 (The Conference Report changed this amount to $139,000.) for the Office of Seafood Inspection to continue these activities and $185,000 (The Conference Report changed this amount to $174,000.) be directed to the ISSC for the *VibrioVulnificus* Education Program. (p. 112)

Action taken or to be taken

During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 19 – **Standardized Food Safety Certification** – The Committee is aware that the Hawaii Department of Agriculture has proposed a State-wide standardized food safety certification system. The Committee encourages the FDA to work with the State of Hawaii on this system and to provide funding if appropriate. (p. 112)

Action taken or to be taken

The Committee is aware of the standardized food safety certification system proposed by the Hawaii Department of Agriculture. FDA supports certification activities by Hawaii and other states.

On April 2, 2008, FDA published a notice in the Federal Register requesting comments on the use of third-party certification programs. FDA is working to develop certification systems that have the broadest application in all 50 states and territories, and in the District of Columbia, and will work with all interested parties to develop certification systems.

Item 20 – Standards of Identity – The Committee is aware of the ongoing debate surrounding increased importation and use of milk protein concentrate. The Committee remains concerned with FDA's current lack of enforcement of standards of identity as it relates to the potential use of milk protein concentrate in standardized cheese and the labeling thereof. (p. 112)

Action taken or to be taken

FDA continues to monitor to ensure that milk protein concentrates (MPCs) are not being used in standardized cheeses and cheese products. FDA routinely conducts inspections of food manufacturers, including manufacturers of standardized cheese products. During inspections, FDA investigators ensure that the ingredients that are being used to make a standardized cheese product are permitted under the standard of identity for the cheese. FDA has not received any complaints alleging that MPCs are used to manufacture standardized cheese products. FDA will continue to follow up on any complaints relating to the use of MPCs in standardized cheeses and will take action as appropriate.

Item 21 – Waste Management Education and Research Consortium —The Committee recommendation includes $73,000 (NOTE: The Conference Report changed this amount to $69,000.) for the FDA to continue its support for the Waste Management Education and Research Consortium and its work in food safety technology verification and education. (p. 112)

Action taken or to be taken

During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 22 – Western Region FDA Center of Excellence – The Committee recommendation includes $1,490,000 (NOTE: The Conference Report changed this amount to $1,399,000.) for the Western Region FDA Center of Excellence at the University of California at Davis [UCD]. California and the western States provide the majority of the Nation's fruits, vegetables, and specialty crops, and lead the Nation in import and export of food products. This Center is a cooperative research center with FDA and UCD and addresses food safety and security areas of focus identified by FDA to be of greatest need in the Western United States. (p. 112)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Joint Explanatory Statement for
HR 1105
February 23, 2009

Item 23 – FY 09 Quarterly Expenditure Report – To ensure that FDA efficiently applies this funding increase to its most pressing needs, FDA is directed to provide an expenditure report to the Committees no later than 15 days after the end of each fiscal year quarter following the date of enactment of this Act. This report shall include specific information for:

-The number of new hires and their estimated costs;

-The number of inspections and their estimated costs; and

-Information technology acquisition and development spending. All cost estimates and spending in the quarterly reports must be shown on a center/field basis. To provide a basis of comparison for the new activities in these reports, FDA is directed to include information on base funding, FTEs, inspections, and any other applicable base activity levels for each activity that has received increased funding. Finally, the reports must include up-to-date dollar obligation data for each enhanced activity. (OBFP and DBEC will lead this reporting effort.) (p. 42)

Action taken or to be taken
FDA will provide the quarterly reports to the Committee.

Item 24 – Cosmetics and Colors – The bill provides an increase of $1,000,000 for the Office of Cosmetics and Colors. (p. 43)

Action taken or to be taken
CFSAN will increase resources within the Office of Cosmetics and Colors by $1,000,000.

Item 25 – Medical Product Safety Plan – The bill provides an increase of $114,211,000 for medical product safety. An increase of more than $21,000,000 for medical product safety was provided in fiscal year 2008, and FDA received an additional $58,000,000 in supplemental funds during fiscal year 2008 for medical product safety. As noted above, it is expected that this funding will result in safer drugs, devices, and biologic products for consumers. Similar to a recent approach FDA has taken to address overall food safety issues, FDA is directed to prepare and provide to the Committees on

Appropriations a comprehensive approach to ensuring the safety of medical products from the manufacturing of raw ingredients or components to consumer use. (TBD) (p. 43)

Action taken or to be taken
FDA will develop and provide the Medical Product Safety Plan requested by the Committee.

Item 26 – Critical Path – The bill provides $16,000,000 for the critical path initiative, including not less than $4,000,000 for competitive contracts or grants to universities and nonprofit organizations to support critical path projects. Funding for critical path activities is distributed throughout FDA's program areas, and the Office of Critical Path Programs (OCPP) is responsible for coordinating these activities at the agency. It is understood that OCPP, working with FDA's centers, will play a primary role in determining which critical path efforts the agency will undertake. (p. 44)

Action taken or to be taken
During FY 2009, FDA will continue to support important Critical Path activities in the FDA centers and in the Office of the Commissioner at the funding level recommended by the Committee. These Critical Path activities will include the opportunities identified in 2006 and additional opportunities identified since 2006. FDA will continue to promote collaborations with other Government agencies, academia, patient groups, and other interested parties, such as those identified in the Committee report. FDA intends to make the designated funds available for competitive contracts and grants to universities and non-profit organizations to support Critical Path projects.

Item 27 – DDMAC – The bill provides an increase of $6,620,000 for the Division of Drug Marketing, Advertising and Communication in CDER. The funding provided is to be used for the review of direct-to-consumer advertisements and is equal to the amount of funding that the budget estimated would have been raised by the fee in fiscal year 2009. (p. 44)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Part of FDA’s mission is to protect the public health by assuring that prescription drug information is truthful, balanced and accurately communicated. FDA has adopted a comprehensive, multi-faceted, risk-based strategy for regulating consumer-directed advertising of medical products. FDA is in the process of hiring additional staff to better support advisory review of materials prior to public dissemination and enforcement actions on promotional materials already in use. The resulting enforcement actions stop misleading promotion and call for the correction of violations in promotion. The resources also strengthen FDA’s efforts to increase voluntarily compliance by developing guidance for industry, providing advisory comments on proposed materials, and conducting research on the public health effects of prescription drug promotion.

Item 28 – Demonstration Grants for Improving Pediatric Device Availability – The bill provides $2,000,000 for Demonstration Grants for Improving Pediatric Device Availability, as authorized by the Food and Drug Administration Amendments Act of 2007, in the Center for Devices and Radiological Health. Medical device products are typically developed for adults, limiting children's access to safe and effective medical devices. This program will provide grants to nonprofit pediatric medical device consortia, which will assist scientists and innovators with technical and financial resources to improve the number of medical devices available to children. The Office of Orphan Products Development will be responsible for carrying out this program. (p. 44)

Action Taken or to be Taken

FDA recognizes that children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices not suited for use in children may not accommodate the unique needs of children, such as allowing for expandable growth, and accommodating their active lifestyles and differing metabolism.

During FY 2009, FDA will support this activity at the funding level recommended by the Committee. FDA will do so in a way that protects against conflicts between grant activities authorized by section 305 of the FDA Amendments Act and the review of device applications. To implement this program, FDA will rely on the expertise of the Office of Orphan Products.

Item 29 – Office of Women's Health – The bill provides $6,000,000 for the Office of Women's Health, an increase of $1,000,000. (p. 45)

Action taken or to be taken

FDA will increase resources within the Office of Women's Health by $1,000,000.

Item 30 – Inspection of Imported Shrimp – There is concern about the contamination of farm-raised shrimp imports with banned antibiotics. FDA currently inspects less than two percent of imported shrimp. FDA is strongly encouraged to develop, in cooperation with state testing programs, a program for increasing the inspection of imported shrimp for banned antibiotics. (p. 45)

Action taken or to be taken

The use of unapproved drugs in farm-raised seafood raises significant public health concerns. FDA is actively working to ensure that farmed raised shrimp and other aqua cultured products are free from unapproved chemotherapeutics residues. FDA has a continuous monitoring program to test for animal drugs in imported and domestic seafood products. FDA expanded this program during the past two years to give special attention to products and sources. It is estimated that 90 percent of shrimp, the most consumed seafood in the U.S., is imported. Therefore, shrimp is a high priority product in FDA's testing program.

FDA focuses on ensuring the control of food safety hazards associated with unapproved aquaculture drugs in imported seafood through the Seafood Hazard Analysis and Critical

Control Point (HACCP) program. Under the HACCP program, the importer and the foreign processor share the responsibility for preventative controls and are required to verify that the products they offer for entry comply with the requirements of FDA seafood regulation, including controls of aquaculture drug hazards. FDA continues to take regulatory actions against imports where positive samples are found in order to prevent adulterated fishery products from entering domestic commerce.

The FDA Field Offices will continue to work closely with States in sampling and testing programs that detect banned antibiotics and to share methods and sampling results with states and other stakeholders.

Item 31 – Blood Safety – FDA is encouraged to conduct workshops and engage in other forms of communication with federal agencies, organizations involved in blood collection and others, to ensure that those organizations and the public understand the latest scientific information available on blood safety issues. (p. 45)

Action taken or to be taken

FDA is a science-based organization and places great value on obtaining the latest scientific information on blood safety issues and on ensuring that the public and all stakeholders understand the scientific basis of FDA policies and decisions. FDA will continue to conduct workshops and communicate with other federal agencies and organizations involved in blood collection to ensure that the public and all stakeholders understand the latest scientific information available on blood safety issues. FDA plans to hold several workshops this year including the workshop that was held in March 2009 on Improving Endpoints, Improving Care: Alpha-1 Antitrypsin Augmentation Therapy and Clinical Trials, as well as a licensing workshop and a workshop on the risk of arboviruses to blood safety.

Item 32 – Pediatric Cancer – There are poor survival rates and a lack of new therapies associated with many pediatric cancers, including high-risk neuroblastoma. FDA is encouraged to prioritize review of new treatments and clinical trials for pediatric oncology patients and a report on these activities. (p. 45)

Action taken or to be taken

FDA is preparing a report that addresses FDA actions to encourage new therapies and new labeling information for treatments for pediatric cancers, including high-risk neuroblastoma.

Item 33 – MQSA Report – The bill provides no less than the fiscal year 2008 level in appropriated funds for activities related to the Mammography Quality Standards Act (MQSA). Appropriations for this program fund research grants and various activities to develop and enforce quality standards for mammography service. On June 26, 2008, the Committees received a report on actions being taken to implement recommendations made in the Institute of Medicine report entitled "Breast Imaging Quality Standards." The report stated that FDA held an open public meeting on September 28 and 29, 2006, and has been considering potential amendments to MQSA, which would address the 10M

report, since this meeting. To date, FDA has not acted on any of these recommendations. This is an unacceptable delay. FDA is directed to report to the C6mmittees on which amendments that FDA will propose to MQSA, if any, in response to the 10M report recommendations, and provide a timeline for these amendments. (p. 45)

Action taken or to be taken
FDA will provide the Committee with the report as requested.

Item 34 – Seafood Economic Integrity – The importance of seafood to a healthy diet is recognized, but there are concerns that FDA does not focus sufficient attention on economic integrity issues, particularly with respect to mislabeling of species, weights, country of origin, and treatment. FDA is encouraged to work with states to more aggressively combat fraud in parts of the seafood industry. (p. 45)

Action taken or to be taken
FDA is working closely with the National Fisheries Institute and maintains communication with State regulators as well as counterparts in NOAA's National Marine Fisheries Service about these economic fraud issues. FDA works to take action on economic fraud, consistent with other food safety priorities. The FDA Field force also considers information from States on mislabeling or substitution of species, laboratory testing or other information related to the seafood industry.

Item 35 – Standardized Food Safety Certification – The Hawaii Department of Agriculture has proposed a state-wide standardized food safety certification system. FDA is encouraged to work with the State of Hawaii on this system and to provide funding if appropriate. (p. 45)

Action taken or to be taken – The Committee is aware of the standardized food safety certification system proposed by the Hawaii Department of Agriculture. FDA supports certification activities by Hawaii and other states.

On April 2, 2008, FDA published a notice in the Federal Register requesting comments on the use of third-party certification programs. FDA is working to develop certification systems that have the broadest application in all 50 states and territories, and in the District of Columbia, and will work with all interested parties to develop certification systems.

Item 36 – MRSA – Serious concerns have been raised about illnesses and deaths from Methicillin Resistant *Staphylococcus aureus* (MRSA). Estimates suggest that tens of thousands of persons develop serious MRSA infections in the United States each year and thousands die. While both FDA and USDA fund research on this issue, more may need to be done. FDA is encouraged to work with USDA and CDC, through the National Antibiotic Resistance Monitoring System and the Antibiotic Resistance Interagency Task Force, to address the issue of the prevalence of MRSA in domestic farm animals. (p. 45)
Action taken or to be taken

FDA agrees that MRSA needs to be studied and is working closely with USDA and CDC to address its prevalence. FDA is in the midst of a pilot study that is testing retail meat samples for MRSA and will use the results of this study to determine the correlation, if any, to clinical cases of infection.

Item 37 – Agricultural Products Food Safety Laboratory – The bill provides funding for the following item: $1,650,000 for the Agricultural Products Food Safety Laboratory at New Mexico State University. (p. 46)

Action taken or to be taken
During FY 2009, FDA will to support this activity at the funding level recommended by the Committee.

Item 38 – Collaborative Drug Safety Research – The bill provides funding for the following item: $ 525,000 for collaborative drug safety research at the Critical Path Institute and the University of Utah. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 39 – Dietary Supplements – The bill provides funding for the following item: $1,608,000 for the dietary supplements research at the National Center for Natural Products Research in Mississippi. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 40 – National Center for Food Safety and Technology – The bill provides funding for the following item: $2,077,000 for the National Center for Food Safety and Technology, Summit-Argo, Illinois. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 41 – Interstate Shellfish Sanitation Conference – The bill provides funding for the following item: $139,000 for the Interstate Shellfish Sanitation Conference (ISSC). (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 42 – Vibrio Vulnificus Education – The bill provides funding for the following item**: $**174,000 for ISSC *vibrio vulnificus* education. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 43– Waste Management Education and Research Consortium –The bill provides funding for the following item: $69,000 for the Waste Management Education and Research Consortium at New Mexico State University. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 44 –Western Region FDA Center of Excellence – The bill provides funding for the following item: for the Western Region Center of Excellence at the University of California-Davis. (p. 46)

Action taken or to be taken
During FY 2009, FDA will support this activity at the funding level recommended by the Committee.

Item 45 – **B & F Allocation Plan** – The bill provides $12,433,000 for FDA buildings and facilities, as requested in the amended budget. This funding shall be used to upgrade FDA facilities and laboratories that are currently below public safety standards and incapable of performing agency requirements. In providing this funding, specific projects are not approved, as the backlog of maintenance and repairs at FDA locations is significant. FDA is directed to prioritize this funding consistent with the backlog of maintenance and repairs and improve the average facility condition index at FDA sites. Within 30 days of the date of enactment of this Act, FDA is directed to provide a plan for allocating the funding to the Committees. The plan should include the methodology used to allocate the resources; the specific maintenance or repairs that will be conducted; whether the funding allocated to the site will complete a project or is partial funding for the project; and if partial funding for a project is provided, the full cost of completing the project. (p. 46)

Action taken or to be taken
FDA is preparing a plan for the committee on the allocation of funding for Buildings and Facilities.

Food and Drug Administration
Fact Sheet – Alaska

FDA Presence: 4 FDA employees in Alaska
Resident Post: Anchorage
reports to: Seattle District: Bothell, Washington, who
reports to: Pacific Region: Oakland, California

Industry Presence in State:
There are 484 FDA-regulated establishments in the State of Alaska
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 77 percent
Medical device and Radiological establishments – 14 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.

State Partnerships
Alaska Department of Environmental Conservation
- Conduct inspections of the fish and fishery products processing industry for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations.
- Conduct mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms in the State of Alaska.

Food and Drug Administration
Fact Sheet – Alabama

FDA Presence: 8 employees in Alabama
Resident Posts: Birmingham, Mobile, and Montgomery
reports to: New Orleans District (currently located in Nashville, TN), who
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State:
There are 1,635 FDA-regulated establishments in the State of Alabama
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 31 percent
Medical Device and radiological establishments – 31 percent
Human Drug establishments – 20 percent
Animal drug and feed establishments – 11 percent
Biological establishments (includes blood banks) – 7 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 – Alabama's primary food industry includes Gulf shrimp, crab, and oysters from the coast and farm-raised catfish
- Agriculture – Poultry, timber, cattle, cotton, soybeans, and peanuts are major agricultural crops.
- There is considerable medical device presence, as well as a wide range of clinical research activity through medical university settings.
- Biologics presence is in the form of regional blood testing facilities.
- 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.

Contracts, Partnerships & Local Activities:
State Contracts
Alabama Department of Public Health
- Conduct inspections of food manufacturers for sanitation.

Alabama Department of Agriculture and Industries
- Conduct BSE inspections

State Partnerships
None

Special Programs
- Active Food Safety Task Force, which includes: AL Department of Public Health; AL Department of Agriculture; Auburn Cooperative Extension Service; AL Restaurant Association; AL Grocers' Association; and AL Retail Foods Association.

Food and Drug Administration
Fact Sheet – American Samoa

FDA Presence: Overseen by 10 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:
There are 4 FDA-regulated establishments in American Samoa
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 33 percent
Animal drug and feed establishments – 33 percent
Human drug establishments - 17 percent
Biologic establishments (includes blood banks) - 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% of the land is communally owned.

Food and Drug Administration
Fact Sheet – Arizona

FDA Presence: 30 employees in Arizona
Resident Posts: Phoenix and Tucson
reports to: Los Angeles District, Irvine, California, who
reports to: Pacific Region, Oakland, California
Southwest Import District Resident Post: Nogales (13 employees) and San Luis, Arizona (3 employees) report to the Southwest Import District, Dallas, Texas

Industry Presence in State:
There are 2,267 FDA-regulated establishments in the State of Arizona
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:
- There are 5 firms in Arizona that produce human biological products including 6 plasmapheresis centers and 4 American Red Cross facilities.
- There are more than 10 manufacturers of vitamin and mineral Over-the-Counter products.
- The Southwest Import District received 489,932 line entries for fiscal year 2008. The primary products are: Fresh Produce, Frozen Shrimp, and Medical Devices.

Contracts, Partnerships & Local Activities:
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: (2 investigators)
reports 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)
reports to: Southwest Region, Dallas, Texas
Office of Shared Services (1), HHS (1)
National Center for Toxicological Research (NCTR/FDA), Jefferson (225 + 318 contractors)

Industry Presence in State:
There are 1,390 FDA-regulated establishments in the State of Arkansas
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 57 percent
Animal drug and feed establishments - 15 percent
Medical device and Radiological establishments - 14 percent
Human drug establishments – 11 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights:
- Retail/Warehousing- Wal-Mart World headquarters
- 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 07 was approximately 647. Primary products imported are alcoholic beverages, cosmetics, and animal drugs.

Contracts, Partnerships & Local Activities:
State Contracts
Arkansas Department of Health
- Conducts food sanitation inspections and inspections of mammography facilities.

Arkansas State Plant Board
- Conducts feed mill inspections; determines compliance with BSE Rule.

State Partnerships
Arkansas Department of Health
- Established a partnership with the Arkansas Department of Health to share oversight & authority of regulated dairy manufacturing facilities.
- 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 to the human; 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.

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: 464 FDA employees in California
Resident Posts: Fresno, Sacramento, San Jose, and Stockton.
reports to: San Francisco District, Alameda, who
reports to: Pacific Region, Oakland
Resident Posts: San Diego, Santa Barbara, San Pedro, LAX, Ontario and Canoga Park reports to: Los Angeles District, Irvine, who reports to: Pacific Region, Oakland
Pacific Region Laboratory Southwest, Irvine, who reports to: Pacific Region, Oakland

Southwest Import District Resident Posts (34 employees): Otay Mesa, Calexico, San Diego Seaport/Airport, and Tecate report to Southwest Import District, Dallas, Texas who report to the Southwest Region, Dallas, Texas

Industry Presence in State:
There are 18,801FDA-regulated establishments in the State of California
Food establishments (includes cosmetics) - 45 percent
Medical device and Radiological establishments - 35 percent
Human drug establishments - 10 percent
Animal drug and feed establishments - 7 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights:
- California has the greatest number of medical device and biotechnology firms of any area in the United States. 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% of all FDA regulated commodities imported into the United States, and contains the largest harbor complex in the country. One thousand, one hundred (1,100) ocean shipping containers, containing foodstuffs arrive each day in the Port of Los Angeles / Long Beach, increasing at approximately 20% annually. Additionally, with the international cargo from Los Angeles International Airport, courier hubs at regional airports, and the International mail processing facility for all of Southern California; a gateway for mail order imports of pharmaceuticals from outside the U.S. The district serves as the "Gateway to the Orient" for imports and exports and with the import operations along the U.S. Mexico border, a significant "Gateway to Mexico." A total of 70% 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 1,640,371 line entries in fiscal year 08.

Contracts, Partnerships & Local Activities:
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.
- Conduct inspections of feed mills and BSE.

California Department of Health Services (DHS)
- Conduct inspections of 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)

- Coordinate retail food protection efforts to promote HACCP principles for food safety
- Conduct inspections of all Acidified & Low Acid Canned Food processors.
- Conduct inspections of seafood processing facilities.
- 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.

DHS & DFA

- Coordinate cooperative agreement to support the California Egg Quality Assurance Plan.

<u>Other Partnerships in California</u>

- 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: 92 FDA employees in Colorado all in the Denver District Office. Denver District reports to the Southwest Region, Dallas, Texas
The Southwest Import District employs 1 Investigator located in the Denver District Office.

Industry Presence in State:
There are 2,255 FDA-regulated establishments in the State of Colorado
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 36 percent
Medical device and Radiological establishments - 28 percent
Human drug establishments – 17 percent
Animal drug and feed establishments - 14 percent
Biologic establishments (includes blood banks) - 5 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.
- Colorado also produces the largest amount of beer of any state
- Imports into Colorado - The Southwest Import District (SWID in Dallas) received 18, 703 line entries for fiscal year 08 through Colorado ports of entry. Primary products are medical devices, alcoholic beverages, cosmetics, and medical devices.

Contracts, Partnerships & Local Activities:
State Contracts
Colorado Department of Health
- Conduct food sanitation inspections.
- Conduct 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 Health & Environment
- Conduct inspections of artificial tanning facilities
- Conduct federal compliance testing of new assemblies or re-assemblies of x-ray equipment
- Southwest Import District Public Affairs Specialist: Focus on Import issues. Conducts education and outreach to the import industry, state, and other government officials and supports border health programs.

Food and Drug Administration
Fact Sheet – Connecticut

FDA Presence: 13 FDA employees in Connecticut
Resident Posts: Hartford (10 employees) and Bridgeport (3 employees)
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State:
There are 1,633 regulated establishments in the State of Connecticut
Food establishments (includes cosmetics) – 33 percent
Medical Device and Radiological establishments – 43 percent
Human drug establishments –18 percent
Animal drug and feed establishments – 2 percent
Biologic establishments (includes blood banks) – 4 percent

Industry Highlights:
- Connecticut has 20% of the District's Official Establishment Inventory of regulated firms with an emphasis on food and medical devices. New England District includes Maine, Massachusetts, Rhode Island, Vermont, New Hampshire, and Connecticut.
- 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 HACCP (Hazard Analysis and Critical Control Point) inspections
- Conduct juice HACCP inspections

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: 13 FDA employees in Delaware
Resident Post: Wilmington
reports to: Philadelphia District, Pennsylvania, who
reports to: Central Region: Philadelphia, Pennsylvania

Industry Presence in State:
There are approximately 223 FDA-regulated establishments in the State of Delaware
(Some firms are in more than one category)

- Food establishments (includes cosmetics) - 36 percent
- Medical device and radiological establishments – 34 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

- Participates in the Delaware Food Safety Council (DFSC), a partnership with the state and local government, academia, industry and USDA to address food safety issues. At the Jan. '07 DFSC quarterly meeting, PHI-DO led a discussion of FDA's ALERT initiative and disseminated ALERT materials. An invitation for future training was offered. The information was well received with inquiries made about future training opportunities.

Food and Drug Administration
Fact Sheet – Washington D.C.

FDA Presence: 13 employees in Washington D.C.
Resident Post: Falls Church Resident Post services Washington D.C, who
reports to: Baltimore District, Baltimore, Maryland, who
reports to Central Region, Chicago, Illinois.

Industry Presence in Washington D.C.:
There are 257 FDA-regulated establishments in Washington D.C.
Food establishments (includes cosmetics) - 49 percent
Medical device and Radiological establishments - 27 percent
Human drug establishments - 13 percent
Biologic establishments (includes blood banks) - 10 percent
Animal drug and feed establishments - 1 percent

Contracts, Partnerships & Local Activities:
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
Florida – Fact Sheet

FDA Presence: 130 employees in Florida (includes 2 student)
Resident Posts: Boca Raton, Ft. Myers, Jacksonville, Miami (Domestic), Tallahassee, Tampa, Miami (Imports), Port Everglades (co-located with USCBP)
Major Import Ports: Miami, Jacksonville, and Tampa
reports to: Florida District Office, Maitland, FL, who
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in Florida
There are 8,052 FDA-regulated establishments in the State of Florida
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 36 percent
Medical devices and Radiological establishments – 39 percent
Human drug establishments – 18 percent
Animal drug and feed establishments – 3 percent
Biologics establishments – 4 percent

Industry Highlights:
- 360 high risk food firms of which 215 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
- 341 class II & III medical device firms

Contracts, Partnerships & Local Activities
State Contracts
- Florida Department of Agriculture & Consumer Services (FDACS), Division of Food Safety (DFS) contracted to perform food safety and seafood HACCP inspections.
- Florida Department of Agriculture & Consumer Services (FDACS), Bureau of Compliance Monitoring (BCM) contracted to perform BSE inspections.

Partnership
- Florida Department of Agriculture & Consumer Services (FDACS), Bureau of Chemical Residue Laboratories share with FLA-DO all violative residue results obtained from produce of imported origin.
- Florida District works in conjunction with FDACS on establishment of rapid response team.

Collaborative Activities
- Collaborated with thirty-seven organizations throughout the state of Florida to distribute "Take Time to Care" educational materials from FDA's Office of Women's Health.

- Worked with other governmental agencies and industry to introduce FDA's Food Protection Plan and CFSAN's ALERT and Employee's FIRST initiatives to management and frontline employees of the food industry throughout Florida.

Food and Drug Administration
Fact Sheet – Georgia

FDA Presence: 263 FDA employees in Georgia
Resident Posts in Georgia: Middle Georgia, Savannah, and Tifton
reports to: Atlanta District, Atlanta, who
reports to: Southeast Region, Atlanta
Southeast Regional Laboratory, Atlanta
reports to: Southeast Region, Atlanta
HQ employees in GA: Facilities-3; Financial Mgmt. Br.-8; OAGS-2;
OC–1; LMR-2; DHRD-1; CFSAN–2; DFS-1; DFI-1

Industry Presence in State:
There are 2,682 FDA-regulated establishments in the State of Georgia
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 42 percent
Medical Device and Radiological establishments – 33 percent
Human Drug establishments – 14 percent
Animal Drug and Feed establishments – 7 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 landport—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 Spelman 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: 10 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:
There are 35 FDA-regulated establishments in Guam
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 63 percent
Medical device and radiological establishments – 23 percent
Human drug establishments - 9 percent
Biologic establishments (includes blood banks) – 5 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: 10 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:
There are 579 FDA-regulated establishments in the State of Hawaii
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 59 percent
Medical device and radiological establishments - 29 percent
Human drug establishments - 7 percent
Biologic establishments (includes blood banks) - 3 percent
Animal drug and feed establishments - 2 percent

Industry Highlights:
- Staff an International Mail Facility in conjunction with DHS/CBP (Customs and Border Protection) to detain counter drugs via international mail.
- Seafood, domestic and imports, is the largest industry on the Islands.
- Importation of goods to and through Hawaii to the mainland accounts for 1/3 of FDA resources covering the review, inspection and sampling of products primarily from Asia.

Contracts, Partnerships & Local Activities:
State Contracts
Hawaii Department of Health
- Conduct inspections of mammography facilities.
- Conduct diagnostic x-ray field tests.

State Partnerships
Hawaii Department of Health
- Conduct inspections of new x-ray assemblies or re-assemblies.
- Support for a Food Safety Task Force for food safety.

Hawaii Department of Agriculture & Department of Health
- Support the Egg Quality Assurance Plan, an integrated voluntary food safety program designed to ensure quality and safety of eggs (with USDA, University of Hawaii and industry).

Local Activities
Ongoing public affairs cooperation with the
- Hawaii Food Manufacturers Association,
- University of Hawaii,
- Hawaii Cooperative Extension Service,
- Hawaii Dietetic Association,
- Hawaii Section/Institute of Food Technologists, and
- Hawaii Department of Health.

Food and Drug Administration
Fact Sheet – Idaho

FDA Presence: 8 FDA employees in Idaho
Resident Post: Boise, Eastport
reports to: Seattle District, Bothell, Washington, who
reports to: Pacific Region, Oakland, California

Industry Presence in State:
There are 866 FDA-regulated establishments in the State of Idaho
(Some firms are in more than one category)
Food establishments -(includes cosmetics) - 58 percent
Medical device and Radiological establishments -15 percent
Animal drug and feed establishments – 13 percent
Human drug establishments - 11 percent
Biologic establishments (includes blood banks) - 3 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 help to provide training to regional food processing companies

Food and Drug Administration
Fact Sheet – Illinois

FDA Presence: 92 FDA employees in Illinois
Resident Posts: Mt. Vernon, Gurnee, Peoria, Hinsdale, Springfield, and O'Hare
reports to: Chicago District, Chicago, Illinois, who
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State:
There are 5,184 FDA-regulated establishments in the State of Illinois
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 42 percent
Medical device and Radiological establishments - 37 percent
Human drug establishments - 12 percent
Animal drug and feed establishments - 5 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights:
- Pharmaceuticals – Home to several multi-national manufacturers
- In-vitro diagnostics – Largest manufacturer in the world
- Pumpkins – Nation's only pumpkin cannery
- Candy – Concentration of large manufacturers.
- Significant import operations with a cross-section of FDA regulated commodities.

Contracts, Partnerships & Local Activities:

State Contracts

Illinois Department of Agriculture
- Conduct inspections of feed mills to ensure safety and BSE control

Illinois Department of Public Health
- Conduct food safety inspections

State Cooperative Agreements (Grants)

Illinois Department of Agriculture
- Conduct 200 inspections of renderers, protein blenders, commercial animal feed manufacturers, distributors, transporters of animal feed and feed ingredients, on-farm mixers, and ruminant feeders to ensure safety and BSE control
- Collect and analyze 500 surveillance samples of feed from renderers, protein blenders, and feed mills to ensure safety and BSE control

State Partnerships

Illinois Department of Public Health
- Conduct inspections of low acid canned food and acidified food establishments and seafood under the Hazard Analysis and Critical Control Point (HACCP) requirements.
- Collect samples to test foods for contaminants including microbiology and pesticides.
- Conduct joint Seafood HACCP training

Local Activities
- Cooperative program with the City of Chicago Department of Health, the Illinois Department of Public Health, and USDA to test foods supplied to the Chicago Public School lunch program.
- Cooperative program with the City of Chicago Department of Health regarding testing for lead in imported foods.

Food and Drug Administration
2009 Fact Sheet – Indiana

FDA Presence: 20 FDA employees in Indiana including 14 District Investigators, an Investigational Assistant, a SCSO, a National Expert, a Regional Milk Specialist, an Assistant PAS and an IT Specialist. These employees are stationed in the following Resident Post offices.

Resident Posts: Indianapolis (16 employees), Evansville (1), and South Bend (3)

Industry Presence in State:

There are 2,470 active FDA-regulated establishments in the State of Indiana.

Food establishments (includes cosmetics) – 43 percent
Medical Device and Radiological establishments – 27 percent
Animal drug and feed establishments – 12 percent
Human Drug establishments (includes Medical Gas) – 13 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 Bristol Myers Squibb
- Federal Express Hub in Indianapolis

Contracts, Partnerships & Local Activities:

State Contracts

Indiana Board of Health:

- Conduct inspections of mammography facilities.

Purdue University

- Conduct medicated feed mill and BSE inspections.

State Partnerships

Indiana Department of Health:

- Coordinate inspection plan to increase consumer safety by coordinating inspectional information of non-retail food establishments.

Indiana State Board of Animal Health

- Share information on tissue residues in food producing animals

Food and Drug Administration
Fact Sheet – Iowa

FDA Presence: 6 FDA employees in Iowa
Resident Posts: Sioux City (1), Davenport (1), and Des Moines (4)
reports to: Kansas City District, Lenexa, Kansas, who
reports to: Southwest Region, Dallas, Texas

Industry Presence in State:
There are 1,700 FDA-regulated establishments in the State of Iowa
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 42 percent
Animal drug and feed establishments - 30 percent
Medical device and radiological establishments - 16 percent
Human drug establishments - 9 percent
Biologic establishments (includes blood banks) - 3 percent
The Southwest Import District is responsible for imported products into Iowa. The investigator is located in St. Louis, MO. SWID received approximately 252 entry lines for fiscal year 08. 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 rand 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
- IA, KS, NE, and MO have agreed to participate in a partnership to conduct program evaluations according to FDA's *Recommended National Retail Food Regulatory Program Standard #9*. Iowa is the lead state in this partnership. FDA has provided a grant to fund the program.
- Iowa Food Safety Task Force – Established under FDA-funded grant. 04/09/09

Food and Drug Administration
Fact Sheet – Kansas

FDA Presence: 117 FDA employees in Kansas
Resident Posts: Wichita (2)
reports to: Kansas City District, Lenexa, Kansas, who
reports to: Southwest Region, Dallas, Texas
Regional Staff: Lenexa (4)
Headquarters Staff: DFO/OITSS Staff: Lenexa (4); OFASS Staff: Lenexa (1) & DFI Staff: Lenexa (1)

Industry Presence in State:
There are 1,658 FDA-regulated establishments in the State of Kansas
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 46 percent
Animal drug and feed establishments - 24 percent
Medical device and radiological establishments - 18 percent
Human drug establishments – 9 percent
Biologic establishments (includes blood banks) - 3 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. SWID received approximately 96 entry lines for fiscal year 08.The primary products imported are grain, seafood, animal drugs/devices, fresh vegetables, and cosmetics. The entries are handled by an investigator located in St. Louis, MO

Contracts, Partnerships & Local Activities:
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: 12 FDA employees in Kentucky
Resident Post: Louisville
reports to: Cincinnati District, Cincinnati, Ohio, who
reports to: Central Region: Chicago, IL

Industry Presence in State:
There are 1,604 FDA-regulated establishments in the State of Kentucky
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 52 percent
Medical device and Radiological establishments - 23 percent
Human drug establishments - 13 percent
Biologic establishments (includes blood banks) - 4 percent
Animal drug and feed establishments - 8 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 Acidified Food training.
- FDA provided funding for a survey of Food Manufacturing Industry for potential firms that fall under BSE Regulations. Shared information with University of Kentucky Regulatory Services.
- CIN-DO developed a Tissue Residue Outreach Program to discuss illegal drug residues with farmers throughout the state.
- Participated in “Operation Crème Puff” inspections of food warehouses.

Local Activities
Kentucky Food Safety Task Force – Quarterly Meetings.
- Composed of State, Federal, Academic, and Industry Representatives with an interest in food safety and security.

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
reports to: New Orleans District (currently located in Nashville, TN), who
reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State:
There are 2,372 FDA-regulated establishments in the State of Louisiana
(Some firms are in more than one category.)
Food establishments –59 percent
Medical device and Radiological establishments – 20 percent
Human drug establishments – 13 percent
Biologic establishments (includes blood banks) – 5 percent
Animal drug and feed establishments – 3 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.

Contracts, Partnerships & Local Activities:
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 3/31/09

Food and Drug Administration
Fact Sheet – Maine

FDA Presence: 18 FDA employees in Maine
Resident Post: Augusta (8 employees) and
Border Stations: Houlton (4 employees) and Calais (6 employees)
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State:
There are 929 regulated establishments in the State of Maine
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 12% 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.

Contracts, Partnerships & Local Activities:
State Contracts
Maine Department of Agriculture
- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections

Maine Department of Human Services
- Conduct inspections of mammography facilities

Food and Drug Administration
Fact Sheet – Maryland

FDA Presence: 55 FDA employees in Maryland
Resident Posts: Dundalk Marine Terminal (imports) who
reports to: Baltimore District, Baltimore, Maryland, who
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 2,093 FDA-regulated establishments in the State of Maryland
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 37 percent
Medical device and Radiological establishments - 36 percent
Human drug establishments – 13 percent
Biologic establishments (includes blood banks) – 6 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 & Local Activities:
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 30 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.

Partnerships
There are currently no partnership agreements with the state of Maryland.

Food and Drug Administration
Fact Sheet – Massachusetts

FDA Presence: 163 FDA employees in Massachusetts including State Programs Branch (5) and WEAC (56 employees)
Resident Post: Worcester (5 employees)
Border Station: Boston (9 employees)
reports to: New England District, Stoneham, Massachusetts (88 employees)
reports to: Northeast Region, Jamaica, New York
Laboratory: Winchester Engineering and Analytical Center, Winchester, Massachusetts (56 employees)
reports to: Northeast Region, Jamaica, New York

Industry Presence in State:
There are 4,057 regulated establishments in the State of Massachusetts
Food establishments (includes cosmetics) – 48 percent
Medical Device and Radiological establishments – 33 percent
Human drug establishments – 13 percent
Animal drug and feed establishments – 2 percent
Biologic establishments (includes blood banks) – 4 percent

Industry Highlights:
- Houses almost one-half of the regulated industry in New England with special emphases in biotechnology and medical devices. 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 are performed at WEAC. In addition to the specialized analytical procedures for radionuclides in foods and radiopharmaceuticals, WEAC performs chemical and microbiological testing.

Contracts, Partnerships & Local Activities:
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

Local Activities
FDA is a participant in Massachusetts Partnership for Food Safety and the Massachusetts Coalition for Food Safety and Defense activities.

Food and Drug Administration
2009 Fact Sheet – Michigan

FDA Presence: 91 FDA employees in Michigan
Resident Posts: Grand Rapids, Kalamazoo, Detroit Ambassador Bridge, Port Huron and Sault Saint Marie
reports to: Detroit District Office, Detroit, MI
reports to: Central Region, Chicago, IL

Industry Presence in State:
There are 3,275 active FDA-regulated establishments in the State of Michigan.
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:
- 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 & Local Activities:
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 FY08).

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.

Cooperative Agreements
- BSE
- Rapid Response Team

Food and Drug Administration
Fact Sheet – Minnesota

FDA Presence: 76 FDA – Minneapolis District employees in Minnesota
Resident Post: International Falls
reports to: Minneapolis District: Minneapolis, who
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 4,428 FDA-regulated establishments in the State of Minnesota
Food establishments (includes cosmetics) - 36 percent
Medical device and Radiological establishments - 22 percent
Animal drug and feed establishments - 33 percent
Human drug establishments - 7 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 for processing, and turkeys
- Second in the nation in production of spring wheat, oats, sweet corn for processing and canola. Other key crops/products include corn, sunflowers, soybeans, barley, dry edible beans, 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 & Local Activities:
Minnesota Department of Agriculture (contracts)
- 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 Health Department (contract)
- Conduct MQSA audits of mammography facilities.

Minnesota Department of Agriculture (grants)
- 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: 8 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:
There are 820 FDA-regulated establishments in the State of Mississippi
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 39 percent
Medical device and Radiological establishments – 29 percent
Human drug establishments – 15 percent
Animal drug and feed establishments – 12 percent
Biologic establishments (includes blood banks) – 5 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.

Contracts, Partnerships & Local Activities:
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 IMSlisted 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: 37 FDA employees in Missouri.
Resident Posts: St. Louis (*10 assigned to ORA*), Springfield (2)
reports to: Kansas City District, Lenexa, Kansas, who
reports to: Southwest Region, Dallas, Texas
Import entries entering ports of entry in Missouri are handled by the Southwest Import District. There is one Southwest Import District import investigator stationed at the St. Louis Resident Post. The Southwest Import District reports to the Southwest Region.
CDER National Division of Pharmaceutical Analysis *(St. Louis – 25)*

Industry Presence in State:
There are 2,486 FDA-regulated establishments in the State of Missouri
Food establishments (includes cosmetics) – 35 percent
Medical device and Radiological establishments - 27 percent
Animal drug and feed establishments - 17 percent
Human drug establishments - 16 percent
Biologic establishments (includes blood banks) - 5 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 received 82,002 entry lines in FY08 . 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: 5 FDA employees in Montana
Resident Posts: Helena and Sweetgrass
reports to: Seattle District: Bothell, Washington, Who
reports to: Pacific Region: Oakland, California

Industry Presence in State:
There are 1,129 FDA-regulated establishments in the State of Montana
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 69 percent
Medical device and Radiological establishments – 11 percent
Human drug establishments – 7 percent
Animal drug and feed establishments – 11 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 & Local Activities:
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: 4 FDA employees in Nebraska
Resident Post: Omaha
Reports to: Kansas City District, Lenexa, Kansas
Reports to: Southwest Region, Dallas, Texas

Industry Presence in State:
There are 1,205 FDA-regulated establishments in the State of Nebraska
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 40 percent
Animal drug and feed establishments - 31 percent
Medical device and radiological establishments -15 percent
Human drug establishments -11 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, from the R/P in St. Louis, MO. The entry lines received for fiscal year 08 was 3, 361 lines. 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: 4 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:
There are 681 FDA-regulated establishments in the State of Nevada
(Some firms are in more than one category)
Medical device and radiological establishments – 46 percent
Food establishments (includes cosmetics) – 21 percent
Animal drug and feed establishments – 13 percent
Human drug establishments – 15 percent
Biologic establishments (includes blood banks) - 5 percent

Industry Highlights:

- Growth of tourism and entertainment industry is demonstrated by the fact that there are more than 7,000 food service establishments in Clark County (including Las Vegas) alone and by expansion of food-related industries in the state.

Contracts, Partnerships & 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: 5 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:
There are 583 regulated establishments in the State of New Hampshire
Food establishments (includes cosmetics) – 45 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) – 2 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.

Contracts, Partnerships & Local Activities
None

Food and Drug Administration
Fact Sheet – New Jersey

FDA Presence: 82 district employees stationed in New Jersey. Additionally we have 2 Team Biologics members,1 Regional Shellfish Specialist, 1 CDER CSO and 2 IT people.

A National Drug Expert and a BIMO Specialist are now part of the Office of International Programs, Office of the Commissioner.

Resident Posts: Voorhees (NJ), North Brunswick (NJ)
Reports to: New Jersey District, Parsippany, New Jersey, who
Reports to: Central Region, Chicago, IL

Industry Presence in State:
There are 4,751 FDA-regulated establishments in the State of New Jersey
Food establishments (includes cosmetics) – 46 percent
Medical Device and Radiological establishments – 32 percent
Human Drug establishments – 17 percent
Biological establishments (includes blood banks) – 2 percent
Animal drug and feed establishments – 3 percent

Industry Highlights:
- New Jersey is recognized internationally as the center of the global pharmaceutical industry. It is home to the headquarters of more pharmaceutical companies than any other state in the country, and any other country in the world. For several decades, New Jersey-headquartered pharmaceutical companies have discovered and developed more than 1/3 of the new drugs approved by FDA.
- The medical device industry is also a major industry in New Jersey, accounting for approximately 8% of U.S. medical technology sales.
- New Jersey also has a large and thriving seafood industry and is home to several major food-processing companies.

Contracts, Partnerships & Local Activities:
State Contracts
New Jersey Department of Health and Senior Services
- Conducts 411 food safety inspections, including general food, seafood, and juice HAACP inspections.

New Jersey Department of Environmental Protection
- Conducts inspections of mammography facilities

New Jersey Department of Agriculture
- Conducts 70 BSE, medicated feed, and tissue residue inspections.

State Partnerships
New Jersey Department of Health and Senior Services
- Various divisions assist in disseminating FDA messages to consumers and health professional organizations.

Food and Drug Administration
Fact Sheet – New Mexico

FDA Presence: 2 FDA employees in New Mexico at this time.
Albuquerque Resident Post with 1 employee reports to: Denver District Office in Denver, Colorado
Denver District Office Reports to Southwest Regional Office in Dallas Texas

Industry Presence in State:
There are 760 FDA-regulated establishments in the State of New Mexico
(Some firms are in more than one category)
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 piñon nuts, pinto beans, and chiles. Third in natural gas production, 2nd in onshore proven gas reserves and 1st 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.
- Southwest Import District: The entries received through the New Mexico ports are reviewed by SWID Investigators, located in El Paso and Santa Teresa. The number of line entries received during fiscal year 08 27,726 line entries. The primary imported products are alcoholic beverages and seafood.

Contracts, Partnerships & Local Activities:
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.
- Southwest Import District Public Affairs Specialist: Focus on Import issues. Conducts education and outreach to the import industry, state and other government officials and support border health programs.

Food and Drug Administration
Fact Sheet – New York

FDA Presence: 385 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 two permanent offices at the Port of Buffalo (Peace Bridge and Lewiston Bridge)

Reports 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:
There are 9018 regulated establishments in the State of New York.

Food establishments (includes cosmetics) - 39 percent
Medical Device and Radiological establishments - 37 percent
Human drug establishments - 14 percent
Animal drug and feed establishments - 7 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights:

- Imports - New York ports of entry include airports, a seaport and numerous border crossings along the Canadian border. Approximately 33% of the FDA regulated commodities enter the country through New York. Cheese, seafood, 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. 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, and with Customs and Border Protection.
- 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.

Contracts, Partnerships & Local Activities:

State Contracts

New York Department of Agriculture and Markets

- Conduct inspections of food firms including LACF, seafood HACCP, juice HACCP and food sanitation; BSE and medicated feed mills; and tissue residue inspections. NYSDAM audits its state inspectors under FDA contract.

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.

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 have agreed 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 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 to share information, in real time, when high risk violations are encountered. This offers enhanced consumer protection to both US and Canadian Consumers.

Food and Drug Administration
Fact Sheet – North Carolina

FDA Presence: 20 FDA employees in North Carolina
Resident Posts: Asheville, Charlotte, Greensboro, Greenville, Raleigh, and Wilmington
reports to: Atlanta District, Atlanta, Georgia, who
reports to: Southeast Region, Atlanta, Georgia
HQ employee: ORO-1

Industry Presence in State:
There are 2,276 FDA-regulated establishments in the State of North Carolina
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 34 percent
Medical Device and Radiological establishments – 33 percent
Human Drug establishments – 20 percent
Animal Drug and Feed establishments –9 percent
Biological establishments (includes blood banks) – 4 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.

North Carolina Department of Environment & Natural Resources
- Conduct inspections of new x-ray assemblies or reassemblies.

Local Activities
North Carolina Food Safety and Security Task Force

Food and Drug Administration
Fact Sheet – North Dakota

FDA Presence: 8 FDA - Minneapolis District employees in North Dakota
Resident Posts: Dunseith, Fargo, Pembina and Portal
reports to: Minneapolis District, Minneapolis, Minnesota, who
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 1,339 FDA-regulated establishments in the State of North Dakota
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 3 ND Northern border ports staffed by FDA in Pembina, Portal and Dunseith.

Industry Highlights:
- Agriculture – Leads the nation in the production of durum wheat, spring wheat, all wheat, honey, oats, barley, lentils, sunflowers, dry edible beans, dry edible peas, flaxseed, and canola. Other key crops include alfalfa hay, potatoes, soybeans, and sugarbeets.
- Raising of elk, deer and buffalo for meat is a rapidly expanding part of the state's agri-industry.
- North Dakota ranks ninth nationally in agricultural exports.

Contracts, Partnerships & Local Activities:
North Dakota Department of Agriculture (contracts)
- 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 (contract)
- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Ohio

FDA Presence: 141 FDA employees in Ohio
Cincinnati District Office and three Resident Posts: Brunswick (Cleveland area), Columbus, and Toledo
Forensic Chemistry Center: Cincinnati, Ohio, (56 total)
The Cincinnati District Office and the Forensic Chemistry Center are separate organizations, each report to the Central Region Office in Chicago, IL.

Industry Presence in State:
There are 4,194 FDA-regulated establishments in the State of Ohio
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 41 percent
Medical Device and Radiological establishments – 34 percent
Human drug establishments - 14 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
- 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 "Operation Crème Puff" inspections of food warehouses.

Ohio Department of Health
- Conduct federal compliance testing of new assemblies or re-assemblies of x-ray equipment.

Local Activities
- CIN-DO attends quarterly FORC-G Meetings with State and local officials on food safety issues.
- CIN-DO attends quarterly meetings with ODA to discuss issues and items of concerns to both agencies.

Food and Drug Administration
Fact Sheet – Oklahoma

FDA Presence: 4 FDA employees in Oklahoma
Resident Posts: Oklahoma City and Tulsa
reports 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:
There are approximately 1,691 FDA-regulated establishments in Oklahoma
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 50 percent
Animal drug and feed establishments - 22 percent
Medical device and Radiological establishments – 14 percent
Human drug establishments – 11 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 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 were 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: 25 FDA employees in Oregon
Resident Posts: Portland and Beaverton who
reports to: Seattle District, Bothell, Washington who
reports to: Pacific Region, Oakland, California

Industry Presence in State:
There are 2,858 FDA-regulated establishments in the State of Oregon
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 69 percent
Medical device and Radiological establishments - 18 percent
Human drug establishments - 7 percent
Animal drug and feed establishments - 4 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 92 employees in Pennsylvania
Residence Posts: Harrisburg, Pittsburgh, Scranton and a new RP to be opened in the summer of 2009 in Wilkes Barre - reports to: Philadelphia District, Philadelphia, which
reports to: Central Region, Philadelphia

Industry Presence in State::
There are 4,759 FDA-regulated establishments in the Commonwealth of Pennsylvania.
(Some firms are in more than one category)

- Food Establishments (includes cosmetics) – 42 percent
- Medical Device and Radiological establishments - 31 percent
- Human Drug establishments - 18 percent
- Animal drug and feed establishments – 4 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:
Pennsylvania Department of Agriculture

- Conduct inspections of medicated feed mills, including coverage of BSE.
- Pennsylvania Department of Environmental Research
- Conduct inspections of mammography facilities
- Conduct inspections of food manufacturers, 100 food firms in Pennsylvania inspected annually.

State Partnerships:

- Participate in the Pennsylvania Food Safety Council (PFSC), a partnership with the state and local government, academia, industry and USDA to address food safety issues.
- Pennsylvania Department of Agriculture:
  - Coordinate regulatory activities enforcing the Nutrition Labeling & Education Act.
  - Coordinate workplanning and inspectional activities to assure all non-medicated feed mills in Pennsylvania are inspected yearly to assure compliance with regulations designed to prevent the introduction of BSE
- Pennsylvania Departments of Agriculture & Health:
  - Assure consumers that eggs from Pennsylvania are of minimal risk to cause food-borne disease from *Salmonella enteriditis.*

MOU's:

- PA Dept. of Agriculture & PA Dept. of Health and a number of PA Egg Producers to do 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 Student
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, who
reports to: Southeast Region, Atlanta, GA
Office of Criminal Investigations (OCI): 5 FT employees- reports to OCI FLA-FO

Industry Presence in State:
There are 1,486 FDA-regulated establishments in San Juan
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 50 percent
Medical device and radiological establishments – 26 percent
Human drug establishments – 17 percent
Animal drug and feed establishments – 4 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 pharma 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.

International Work

- 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.

Contracts, MOUs & Partnerships

- P.R. Department of Health- Environmental Health Division:
- Contract to conduct inspections of food manufacturers for sanitation
- Pilot to share violative food inspections cases to leverage enforcement.
- MOU: Confers embargo and seizure powers to SJN-DO for inspection of regulated goods in response to natural disasters.
- Publication of the Federal Food Code Handbook in Spanish for Health Department to train their inspectors. 200 graduated in December 2006.
- Published a summary of the Food Code, both in Spanish and English, to train Puerto Rico and USVI food establishments' staff.
- P.R. Department of Health Radiological Health Division:
- Contract to conduct inspections of mammography facilities.
- P.R. Department of Agriculture:
- MOU on emergency relocation, complying with COOP requirements.
- Agrological Lab accepted into FERN.
- P.R. Department of Consumer Affairs
- Pilot to share information on violative dietary supplements and unapproved drugs, particularly in the area of ED and sexual enhancement drugs.
- 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: 6 FDA employees in Rhode Island
Resident Post: East Providence
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State:
There are 650 regulated establishments in the State of Rhode Island
Food establishments (includes cosmetics) – 52 percent
Medical Device and Radiological establishments – 30 percent
Human drug establishments – 13 percent
Animal drug and feed establishments – 2 percent
Biologic establishments (includes blood banks) – 3 percent

Industry Highlights:
- Rhode Island is responsible for 8% of the District's Official Establishment Inventory of FDA-regulated firms with an emphasis on foods and medical devices.

Contracts, Partnerships & Local Activities:
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.

Local Activities
Rhode Island has a Food Safety Task Force in which FDA is a participant.

Food and Drug Administration
Fact Sheet – South Carolina

FDA Presence: 11 employees in South Carolina
Resident Posts: Charleston, Columbia, and Greenville
reports to: Atlanta District, Atlanta, Georgia, who
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State:
There are 1,199 FDA-regulated establishments in the State of South Carolina
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 49 percent
Medical Device and Radiological establishments – 30 percent
Human Drug establishments – 13 percent
Biological establishments (includes blood banks) – 4 percent
Animal Drug and feed establishments – 4 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 - Minneapolis District employees in South Dakota
Resident Post: Sioux Falls
reports to: Minneapolis District, Minneapolis, Minnesota
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 1,035 FDA-regulated establishments in the State of South Dakota
Animal drug and feed establishments - 49 percent
Food establishments (includes cosmetics) - 36 percent
Medical device and Radiological establishments- 8 percent
Human drug establishments- 5 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 sunflowers and alfalfa hay.
- Other key crops/products include durum wheat, spring wheat, winter wheat, all wheat, corn, all other hay, sorghum, soybeans, flaxseed, oats, proso millet, and honey.
- Cattle and sheep ranching are also a significant parts of the State's economy.

State Contracts
South Dakota Department of Agriculture (contracts)
- 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 (contract)
- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – Tennessee

FDA Presence: 64 FDA employees in Tennessee
Office/Resident Posts: Nashville, Chattanooga, Knoxville and Memphis, who reports to: New Orleans District (currently located in Nashville, TN), who reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State:
There are 2,531 FDA-regulated establishments in the State of Tennessee
(Some firms are in more than one category)
Medical device and radiological establishments - 36 percent
Food establishments (includes cosmetics) – 31 percent
Human drug establishments - 18 percent
Biologic establishments (includes blood banks) - 6 percent
Animal drug and feed establishments - 9 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 area.
- 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 & Local Activities:
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
reports to: Southwest Import District (SWID) (55 employees in Texas), Dallas
reports to: Southwest Region, Dallas
Domestic Resident Posts: Austin, El Paso, Houston, Ft. Worth, San Antonio
reports to: Dallas District (101), Dallas
reports to: Southwest Region (25), Dallas
Office of Regulatory Affairs HQ (4) and Office of Shared Services (13)

Industry Presence in Texas
There are 8,451 FDA-regulated establishments in the State of Texas
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 50 percent
Medical devices and Radiological establishments – 21 percent
Human drug establishments –13 percent
Animal drug and feed establishments – 12 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-Cellanese, 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.

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: 6 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:
There are 1,182 FDA-regulated establishments in the State of Utah
(Some firms are in more than one category)
Food establishments (includes cosmetics) - 37 percent
Medical device and radiological establishments - 29 percent
Human drug establishments –19 percent
Animal drug and feed establishments – 10 percent
Biologic establishments (includes blood banks) - 5 percent

Industry Highlights:
- Agriculture is dependent on irrigation, and more than 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, Canyonlands, 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 (Brian Head).
- The Southwest Import District is responsible for imported products into Utah. There is one investigator, who is located in Denver that is responsible for reviewing the entries. SWID received 9,748 entry lines for fiscal year 08. Primary products are cosmetics and medical devices.

Contracts, Partnerships & Local Activities:
State Contracts
Utah Department of Health
- Conduct inspections of mammography facilities.

Utah Department of Agriculture
- Conduct inspections of feed mills for medicated feed and BSE

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: 5 FDA employees in Vermont
Border Station: Highgate Springs
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State:
There are 539 regulated establishments in the State of Vermont
Food establishments (includes cosmetics) – 71 percent
Medical Device and Radiological establishments – 12 percent
Human drug establishments – 8 percent
Animal drug and feed establishments – 7 percent
Biologic establishments (includes blood banks) – 3 percent

Industry Highlights:
- Vermont has 7% 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.

Vermont Department of Health
- Conduct inspections of mammography facilities.
- Conduct food sanitation inspections.

Food and Drug Administration
Fact Sheet – U.S. Virgin Islands

FDA Presence: 1FDA employee in US Virgin Islands
Resident Post: St. Thomas
reports to: San Juan District Office
reports to: Southeast Region, Atlanta, GA

Industry Presence in State:
There are 77 FDA-regulated establishments in US Virgin Islands
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 73 percent
Medical device and radiological establishments – 10 percent
Human drug establishments – 15 percent
Biologic establishments (includes blood banks) - 2 percent

Industry Highlights:
- Small businesses employ almost 60 percent of the workforce and account for approximately 40 percent of the gross domestic product
- There are 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, Partnerships & Local Activities:
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: 33 FDA employees in Virginia
Resident Posts: Falls Church, Norfolk, Norfolk Import Terminal, Richmond, and Roanoke who
reports to: Baltimore District, Baltimore, Maryland who
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 2,331 FDA-regulated establishments in the State of Virginia
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 44 percent
Medical device and Radiological establishments – 33 percent
Human drug establishments - 10 percent
Animal drug and feed establishments - 8 percent
Biologic establishments (includes blood banks) – 5 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 & Local Activities:
State Contracts
Virginia Department of Agriculture and Consumer Services

- Conduct 14 inspections of feed mills
- Bovine Spongiform Encephalopathy (BSE): Contract includes 48 inspections of feed manufacturers, retail operations, haulers
- Food/Seafood: Contract includes 470 inspections of food/seafood manufacturers, repackers, distributors, and warehouses

Virginia Department of Health

- Conduct inspections of mammography facilities.

State Partnerships
Virginia Department of Agriculture and Consumer Services

- Collect and analyze food commodities grown for pesticides and industrial chemicals.

Virginia Department of Health Professions

- Inspect human and veterinary drug manufacturers, repackers and distributors

Virginia Department of Health

- Conduct inspections of the crabmeat processing industry.
- Collect and analyze clam and ocean quahog samples for marine biotoxins.

Virginia Bureau of Radiological Health

- Conduct testing of new and re-assembled x-ray equipment.

Food and Drug Administration
Fact Sheet – Washington

FDA Presence: 194 FDA employees in Washington
Resident Posts: Blaine, Seattle, Spokane, Yakima, Oroville, and Tacoma
reports 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:
There are 4,908 FDA-regulated establishments in the State of Washington
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 67 percent
Medical device and Radiological establishments – 17 percent
Human drug establishments – 6 percent
Animal drug and feed establishments – 8 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.

Contracts, Partnerships & Local Activities
State Contracts
Washington Department of Agriculture
- Conduct inspections for food sanitation.
- Conduct investigations of reported violative residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Washington Department of Health
- Conduct inspections of mammography facilities. Conduct inspections of new X-ray assemblies or re-assemblies.

State Partnerships
Washington Department of Agriculture
- Coordinate the regulation for food safety by work sharing, data sharing and educational exchange, including all current and future inspectional and sampling contracts.
- Coordinate the regulation of the fish and fishery products processing industry.
- Participate in a cooperative program, which encourages work sharing, data sharing, and educational exchange concerning animal feed safety.

Local Activities
- Member of the Food Safety Review Council. The group works in partnership with the Department of Health in developing advisory technical interpretations of the state food service regulations and other matters.
- Member of the Washington State Subcommittee on Agricultural and Food Safety. The group works to reduce the vulnerability to a terrorist 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:
There are 663 FDA-regulated establishments in the State of West Virginia
(Some firms are in more than one category)
Food establishments (includes cosmetics) – 46 percent
Medical device and Radiological establishments - 25 percent
Animal drug and feed establishments - 14 percent
Human drug establishments - 11 percent
Biologic establishments (includes blood banks) – 4 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 & Local Activities:
State Contracts
West Virginia Department of Health and Human Services
- 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 150 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: 33 Minneapolis District employees in Wisconsin
Resident Posts: Milwaukee, Madison, Green Bay, La Crosse and Stevens Point
reports to: Minneapolis District, Minneapolis, Minnesota
reports to: Central Region, Chicago, Illinois

Industry Presence in State:
There are 4,214 FDA-regulated establishments in the State of Wisconsin
Food establishments (includes cosmetics) - 54 percent
Animal drug and feed establishments- 19 percent
Medical device and Radiological establishments- 16 percent
Human drug establishments- 8 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 and butter production.
- Cranberries - Wisconsin ranks first in cranberry production.
- Low Acid Canned Foods - Ranks first in snapbeans. 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, corn for silage, maple syrup, 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 & Local Activities:
Wisconsin Department of Agriculture, Trade & Consumer Protection (Contracts)
- 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 (Contract)
- Conduct inspections of mammography facilities

Wisconsin Department of Agriculture (Grant)
- 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
The Southwest Import District is responsible for any imported products into Wyoming.
The SWID investigator located in Denver is responsible for the shipments entered through this port.

Industry Presence in State:

There are 262 FDA-regulated establishments in the State of Wyoming
(Some firms are in more than one category)

- Food establishments (includes cosmetics) – 49 percent
- Human Drug establishments – 21 percent
- Medical Device and Radiological establishments – 15 percent
- Animal drug and feed establishments – 11 percent
- Biological establishments (includes blood banks) – 4 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.
- The Southwest Import District did not receive any entry lines for fiscal year 08.

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.