DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2015

Food and Drug Administration

Justification of
Estimates for
Appropriations Committees

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

I am pleased to present the Administration's FY 2015 Budget for the Food and Drug Administration (FDA).

FDA protects and promotes the health and well-being of the American people in an increasingly complex, globalized environment. FDA oversees the safety of four-fifths of the Nation's food supply and is responsible for assessing the safety, effectiveness, and quality of medical products to ensure that advances in science and technology translate into products with meaningful benefits to patients and consumers. FDA also regulates the manufacturing, marketing, and distribution of tobacco products and seeks to reduce the use of tobacco products by minors.

A strong FDA is critical not only to the public health, but also to the U.S. economy, the balance of trade, and homeland security. The implementation of FDA's mission promotes innovation in the industries it regulates and affects costs in the broader economic and health care systems. These innovations help make medicines effective, safe, and affordable, create jobs, and position the domestic industries to compete in the global marketplace. FDA works to ensure the safety of the food supply and of medical products, and fosters development of medical products to respond to both deliberate and naturally emerging public health threats.

Over the last five years, Congress has enacted four statutes, all supported by the Administration, that give FDA significant new tools to advance its mission and to address new challenges. These statutes include: the Family Smoking Prevention and Tobacco Control Act of 2009; the Food Safety Modernization Act of 2011; the Food and Drug Administration Safety and Innovation Act of 2012; and the Drug Quality and Safety Act of 2013.

FDA is constantly seeking new ways to obtain the most public health value for the federal dollar as we implement these expanded authorities. Over the past year, we moved significantly forward in several priority areas, including; creating a system that will reduce foodborne illness; approving novel medical products in cutting-edge areas of science; and continuing to develop our new tobacco control program. We worked successfully with Congress and with regulated industry to reach agreement on a number of difficult issues, such as oversight of compounding pharmacies and the tracking of drugs throughout the global supply chain, while continuing to use the law to the full extent possible to protect consumers and advance public health.

However, the magnitude of the new responsibilities we have been asked to take on urgently requires additional resources if FDA is to uphold its track record of public health protection and continue to meet its core responsibilities. Therefore, in FY 2015, we request $4.7 billion, an increase of $358 million over the FY 2014 Enacted level. This request is targeted to maximize the impact of every dollar and to build capacity in critical areas of need – oversight of compounding pharmacies and food safety.

As a science-based regulatory agency with a public health mission, FDA plays a unique and essential role in promoting and protecting health and safety. We are committed to meeting the needs and expectations of the American people.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

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TABLE OF CONTENTS

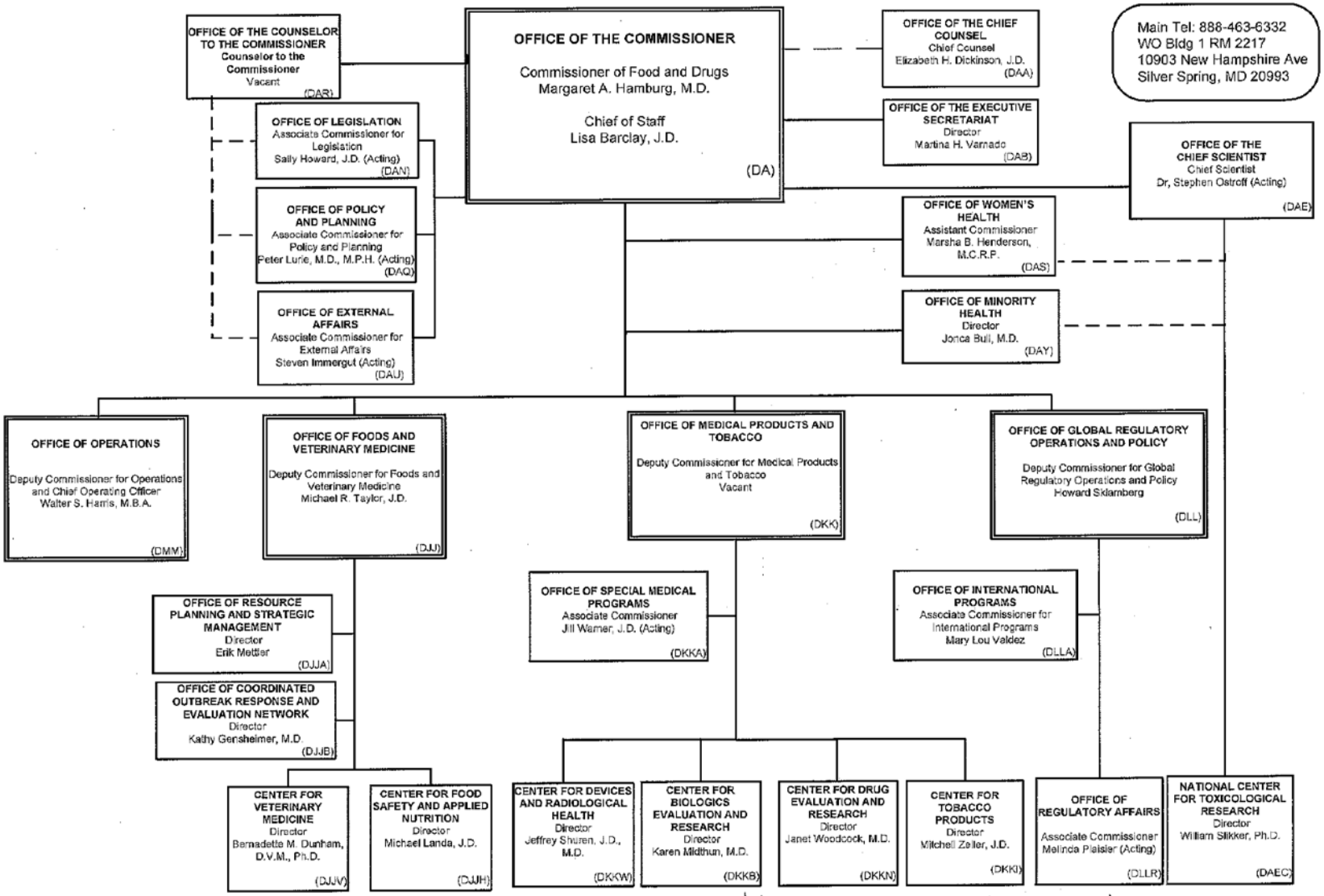
SUPPLEMENTARY TABLES

SIGNIFICANT ITEMS

FDA SPECIFIC ITEMS

GLOSSARY OF ACRONYMS

FOOD AND DRUG ADMINISTRATION



Vanessa Starks 2/11/16

Approved by the FDA Reorganization Coordinator
and Principal Delegation Control Officer

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INTRODUCTION AND MISSION

FDA promotes and protects public health by overseeing the safety, efficacy, quality, and security of human and veterinary drugs, biological products, medical devices, foods, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors.

FDA advances public health by expediting innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

FDA supports the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products and countermeasures to respond to deliberate and naturally emerging public health threats.

FDA's Scope is Vast, Complex, and Evolving Rapidly

FDA plays a vital role in the health of American citizens and regulated industries. Congress has given FDA responsibility for a range of products that are central to the health and well-being of every American. The products FDA regulates represent over 20 cents of every consumer dollar spent on products in the United States.

The food and drug supply chains FDA oversees are both increasingly global and complex as business models evolve throughout the manufacturing and distribution channels. To address these challenges, working with Congress, FDA is implementing significant new authorities to safeguard America's food supply, modernize medical product safety and innovation, and reduce the harms of tobacco use. Public trust in FDA oversight breeds confidence in regulated industries, at home and in the global market place.

FDA is a Bargain

Every American pays about $8 per year for the vast array of protections and services FDA provides. For this amount, FDA ensures that the food that Americans serve their families every day is safe and that Americans have access to life-saving medicines that are approved as fast as or faster than anywhere in the world. In addition, Americans can have confidence that the medical products that they rely on, ranging from toothpaste to cancer drugs, will provide the expected health benefits. FDA is a sound investment for the American people.

FDA Delivers Results

FDA delivers significant, quantifiable results that help Americans every day. FDA's drug approval system continues to lead the world in both quality and speed. Three quarters of all significant pharmaceutical advances that were approved anywhere in the world in 2013 were approved first by FDA. FDA approved 27 drugs that are entirely new to medicine in 2013, including advances in the treatment of rare forms of cancer and a "game-changing" virtual cure for Hepatitis C, as well as another five major new therapeutic advances, such as a new influenza vaccine using biotechnology and an Avian flu vaccine for the national stockpile. FDA also achieved significant reductions in medical device application review times and application back logs.

FDA issued all seven foundational proposed rules required by the Food Safety Modernization Act (FSMA) between January 2013 and February 2014. When implemented, these science-based standards will ensure the safety of all foods produced for the U.S. market, whether they come from the United States or from other countries. FDA has also made substantive progress in implementing the new tobacco control legislation, including first decisions on "substantial equivalence" of new tobacco products and the creation of 14 Tobacco Centers of Regulatory Science in collaboration with the National Institutes of Health.

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OVERVIEW OF THE BUDGET REQUEST

The fiscal year (FY) 2015 President's Budget Request for FDA is $4.74 billion for the total Program Level, which is $358 million above the FY 2014 Enacted level. Of the total funding, $2.58 billion is budget authority and $2.16 billion is user fees. The FY 2015 increase consists of $23 million in budget authority and $335 million in user fees. The growth in user fee funding stems from several new programs, along with increased collection authority for many of FDA's existing programs.

FDA is facing an environment of dramatic technological and market-based changes that require new ways of responding to the market place. FDA has carefully targeted FY 2015 investments to strengthen oversight of the pharmacy compounding industry, support food safety and implementation of FSMA, advance medical countermeasures, and maintain the integrity of operations and infrastructure.

Food and Drug Administration
Major Activities
(Dollars in Thousands)

Program	FY 2014 Enacted				FY 2015 President's Budget				FY 2015 +/- FY 2014			
	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	FS	MPS	MCM	Total*
Budget Authority:												
Salaries and Expenses Account												
Foods	882,817			882,817	903,403			903,403	20,586			20,586
Human Drugs		460,354	6,020	466,374		473,658	6,020	479,678		13,304	---	13,304
Biologics		208,533	2,395	210,928		207,359	2,395	209,754		-1,174	---	-1,174
Animal Drugs and Feeds	112,892	28,674		141,566	113,869	30,708		144,577	977	2,034		3,011
Devices and Radiological Health		316,824	4,001	320,825		313,936	4,001	317,937		-2,888	---	-2,888
National Center for Toxicological Research.	10,233	52,261		62,494	5,900	53,098		58,998	-4,333	837		-3,496
FDA Headquarters	70,331	81,464	10,312	172,107	73,285	81,763	10,312	175,360	2,954	299	---	3,253
FDA White Oak Consolidation		58,044		58,044		43,044		43,044		-15,000		-15,000
Other Rent and Rent Related	36,503	37,235	936	74,674	36,682	35,703	911	73,296	179	-1,532	-25	-1,378
GSA Rental Payments	75,341	85,847	888	162,076	78,622	89,849	865	169,336	3,281	4,002	-23	7,260
Subtotal, Salaries and Expenses Account...	**1,188,117**	**1,329,236**	**24,552**	**2,551,905**	**1,211,761**	**1,329,118**	**24,504**	**2,575,383**	**23,644**	**-118**	**-48**	**23,478**
Building and Facilities Account...				**8,788**				**8,788**				---
Total Budget Authority...	**1,188,117**	**1,329,236**	**24,552**	**2,560,693**	**1,211,761**	**1,329,118**	**24,504**	**2,584,171**	**23,644**	**-118**	**-48**	**23,478**
Total User Fees...	**29,559**	**1,255,128**		**1,825,965**	**269,310**	**1,316,562**		**2,160,827**	**239,751**	**61,434**	---	**334,862**
Total Program Level...	**1,217,676**	**2,584,364**	**24,552**	**4,386,658**	**1,481,071**	**2,645,680**	**24,504**	**4,744,998**	**263,395**	**61,316**	**-48**	**358,340**

* Total contains China Initiative, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification resources not included in Food Safety, Medical Product Safety, and Medical Countermeasures actitities.

** ADUFA and AGDUFA are currently included in Medical Product Safety. However, ADUFA and AGDUFA also support drug review for food producing animals.

PROGRAM CHANGES:

Medical Product Safety (+$61 million)

The FY 2015 Budget provides a program level of $2.6 billion, which is $61 million above the FY 2014 Enacted level, to continue core medical product safety activities across FDA programs. Within this amount, FDA will invest $25 million in budget authority to enhance pharmacy compounding oversight activities in FY 2015, which will significantly benefit public health and safety. This request also includes $4.6 million for proposed International Courier user fees.

Pharmacy Compounding

In 2012, a fungal meningitis outbreak associated with a compounded sterile drug resulted in 64 deaths and over 750 cases of infections across 20 States. Since September 26, 2012, FDA is aware that 28 firms ceased sterile operations, in some cases voluntarily after FDA inspections, and in other cases due to partial or full shutdowns imposed by state licensing authorities. Since that time, FDA has also learned of at least 20 compounders that may have shipped contaminated drug products, and FDA has received at least 125 reports of adverse events, including serious infections, associated with drugs produced by

compounders. As of February 18, 2014, 33 firms had conducted recalls overseen by FDA and seven firms had conducted recalls overseen by a State. These statistics demonstrate the magnitude of the problems that continue to be seen with compounders' sterile operations. Oversight of these firms requires significant FDA resources to investigate and take action to protect consumers. Further, in November 2013, President Obama signed the Drug Quality and Security Act (DQSA), Public Law 113-54, which provides FDA with additional responsibilities to oversee compounding activities. This is a major public health focus for FDA.[1]

During FY 2013, in response to adverse event reports and other complaints about compounded drugs, FDA proactively inspected additional pharmacies suspected of being at higher risk of making substandard products. FDA must follow up on findings from the inspections and must continue its inspection and enforcement efforts for the foreseeable future, as adverse events and seriously deficient sterile compounding practices continue to be discovered. FDA must also develop numerous regulations and other policy documents necessary to implement the new legislation and provide standards for the compounding industry. Without the resources for these activities, FDA will not be able to implement the new legislation and protect the public from substandard compounded products.

The DQSA provides FDA with additional authorities and responsibilities to strengthen oversight of compounding. The new law creates a new Section 503B in the Food, Drug, and Cosmetics (FD&C) Act. Under Section 503B, a compounder can become an "outsourcing facility." If certain conditions are met, an outsourcing facility will be able to qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use. Outsourcing facilities are not exempt from the requirement to comply with Current Good Manufacturing Practice (cGMP), among other applicable requirements under the FD&C Act.

Under the DQSA, compounding firms that register as outsourcing facilities must pay a user fee and, under certain circumstances, a reinspection fee. However, because registration as an outsourcing facility is not required, FDA will not be able to rely on projected user fees to sustain the increased pace of inspections and investigations. Further, the DQSA explicitly states that compounding fees must supplement and not supplant non-user fee money for oversight of outsourcing facilities, and fees collected can only be used for oversight of outsourcing facilities. Therefore, the user fees collected cannot be used to oversee the thousands of pharmacies that will choose not to register as outsourcing facilities.

The return on investment for the pharmacy compounding initiative is expected to be high, delivering results that enable FDA to sustain and expand its mission of protecting and promoting the health and well-being of the American people. The investment of $25 million is necessary to successfully implement and support the activities for this initiative. This regulatory oversight will help prevent outbreaks and mitigate potential public health risks that could result in injuries or possible deaths to the American public.

The requested resources will be devoted to the following main activities.

Inspections and Enforcement: FDA must have an increased inspection and enforcement presence with regard to compounding pharmacies to protect the public health regardless of whether firms elect to register as outsourcing facilities and pay fees. FDA intends to continue conducting for-cause inspections in response to adverse event reports, product quality complaints, and State requests. In addition, the FY 2015 Budget seeks additional resources to conduct additional proactive inspections of high-risk pharmacies, as well as additional follow-up inspections of pharmacies identified as needing to take corrective actions during previous inspections. In addition to direct inspection resources, these inspections will require significant staff support for case management. This work will include writing the inspection assignments, handling issues that arise during the inspections such as the need to obtain an

[1] http://www.fda.gov/NewsEvents/Testimony/ucm348120.htm

administrative warrant to access records, assessing the inspection results, and bringing any necessary regulatory or enforcement actions.

Policy Development: FDA will be engaged in the development of policy documents establishing the framework for the oversight of pharmacy compounding. To implement Sections 503A and 503B, FDA intends to draft and publish additional regulations and guidances. Since Section 503A does not cover the compounding of animal drugs, FDA also intends to develop separate guidance that sets out its enforcement priorities with respect to animal drug compounding.

State Collaboration and Coordination: During hearings following the outbreak, Congress and other stakeholders criticized FDA for inadequately coordinating and collaborating with States that license pharmacies and oversee their day-to-day operations. The new law requires the Secretary to establish a mechanism to receive submissions from state boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to Section 503A. This section will be implemented in consultation with the National Association of Boards of Pharmacy (NABP). In addition, state boards of pharmacy must be notified when the Secretary receives certain state submissions or makes a determination that a compounding pharmacy is acting contrary to Section 503A. Given the states' regulatory role, FDA must expend more resources developing better cooperative relationships and communication tools to improve interactions with the states on pharmacy compounding. This also includes working with state inspectors on inspections of sterile compounding operations for compliance with appropriate quality standards. FDA also intends to enhance its intergovernmental relations activities to provide strategic oversight and strengthen relationships with state officials at all levels of state government, working with associations of state officials, and facilitating interactions with the FDA program offices with substantive program knowledge.

Proposed International Courier User Fee

FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. Almost 80 percent, or $4.6 million, of this proposed fee will support imported medical product safety. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Food Safety (+$263 million)

The FY 2015 Budget provides a program level of $1.48 billion for food safety, which is $263 million above the FY 2014 Enacted level. Within this amount, FDA will invest $24 million in budget authority to further advance recent gains in food safety modernization through implementation of FSMA. This request also includes $255 million in proposed new user fees.

Food Safety Modernization

FDA will continue to make critical investments to implement FSMA. With the requested increase in budget authority, FDA will be able to increase the technical staffing and other capacity needed to develop guidance and provide technical assistance for industry and provide technical support for FDA inspectors, as well as planning and initial implementation of training for FDA and state inspectors. If the proposed user fee revenue is authorized and appropriated, FDA will be able to undertake the wider array of activities needed to fulfill the food safety modernization goals of FSMA, as outlined below, including comprehensive retraining of the federal and state inspection force to ensure inspection quality and consistency; training and technical assistance for small and mid-size growers and processors; and building the modern import oversight system mandated by FSMA. A central theme of these investments is supporting and leveraging the food safety efforts of both public and private partners to make the most effective use of available resources.

The implementation of the broad preventive controls framework mandated in FSMA will reduce instances of foodborne illness seen recently as a result of *E. coli* O157 contamination of pre-packaged salads,

Salmonella and *Listeria* contamination of cheese products, and *Listeria* contamination in cantaloupe. Implementation will also reduce the large number of recalls seen yearly for undeclared allergens in food products. A lack of additional funding to support these efforts will limit FDA's ability to protect consumers by reducing or preventing these types of incidents, including the illnesses and deaths linked with them, and to minimize the market disruptions and economic costs inflicted by illness outbreaks and significant contamination incidents.

These resources will provide FDA with needed long-term funding for implementation of the modernized food safety Congress called for in enacting FSMA. The requested resources will be devoted to the following activities.

Standard Setting: FDA will finalize the most significant rulemakings mandated by FSMA, including preventive controls for human and animal food, produce safety, and foreign supplier verification.

Technical Support for FSMA Implementation: FDA will invest in staff and contractor support for ongoing FSMA guidance development, in collaboration with the food industry, federal and state partners, and other experts, to ensure that the requirements of the new FSMA rules are well understood as they apply to a wide range of commodities and processing operations. FDA will hire additional staff with food safety expertise in produce commodities and processing operations subject to new FSMA standards. FDA needs the technical capacity and expertise to support FDA and state inspectors and the food industry, and to work collaboratively with a broad range of food industry experts to ensure food safety standards are well understood, up-to-date, effective, and efficient.

Training: FDA will increase training and certification activities to ensure that federal, state, local, tribal, territorial, and international partners conducting food safety inspections and other food safety oversight activities have the skills and new orientation needed to conduct high quality and consistent oversight under FSMA's new prevention-oriented and systems-based public health regulatory framework.

Federal-State Integration: In addition to supporting training for state partners, this funding also supports state capacity building, FDA-state joint work planning and data sharing, and collaborative agreements, such as the Manufactured Food Regulatory Program Standards, which allows for the development of a uniform basis for measuring and improving the performance of state manufactured food regulatory programs.

Risk Analysis: FDA will increase data gathering and analytical capacity to support risk-based priority setting and resource allocation, including automating and expediting risk analysis and integration of risk information into decision-making tools. FDA will continue to adapt these tools for use by the public and industry, which will increase the precision of risk evaluation of FDA-regulated commodities and associated hazards.

Antimicrobial Resistance: FDA will implement its initiative to phase out animal production uses of medically important antimicrobial drugs and bring remaining legitimate animal health uses under veterinary supervision. To support this initiative, FDA will collect use data and conduct other research to better understand antimicrobial drug use practices in animals and the public health impacts on antimicrobial resistance. FDA will use this funding to enhance methods for characterizing bacteria, conduct studies to better understand drug effects on bacteria, and develop approaches to monitor and assess drug use and antimicrobial resistance trends.

Proposed Food Safety User Fees

FDA is proposing two user fees for Food Import ($169 million) and Food Facility Registration and Inspection ($60 million) to support implementation of FSMA, including improving FDA's import process and modernizing FDA's inspection system.

With the proposed import user fee, FDA will implement the FSMA mandate for a modern-prevention-oriented import oversight system that ensures imported food meets the same high safety standards as

domestically produced food, The new import fees target activities associated with implementing the Foreign Supplier Verification Program mandated by FSMA, including recruiting and training FDA import staff to assess the adequacy of importer supply chain management and verification programs. To ensure that the new import oversight system does not impede trade, FDA will also invest in the staff, information technology and process improvements needed to make timely import entry decisions. These fees will enhance both the safety protections for imported food and feed and the efficiency and speed of food and feed entry decisions, thus supporting international trade in safe food and feed.

Revenue from registration fees will target new and improved activities required by FSMA to modernize FDA's inspection system. The fees will enable FDA to increase the effectiveness of inspections through adoption of preventive controls, training of personnel to inspect against the new prevention standards, and developing new ways to educate and inform industry. Fees will also support improvements in food and feed safety science and risk analysis, so that knowledge of the methods of food and feed contamination can better prevent outbreaks, and ensure that resources are better focused on areas of greatest risk.

Proposed Food Contact Substance Notification User Fee
FDA is proposing a new user fee of $5.1 million to ensure that the Food Contact Substance Notification (FCN) program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations. FDA has statutory responsibility for the safety of all food contact substances in the United States. The Food and Drug Administration Modernization Act established a premarket notification process for food contact substances, known as the FCN program. The FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. However, Section 409(h)(5) of the FD&C Act specifies that the FCN program can operate only if adequately funded. The proposed user fee will provide greater predictability of program funding and operations.

Proposed Cosmetics User Fee
FDA is proposing a new user fee of $19.5 million to support FDA cosmetic safety responsibilities. The FD&C Act does not authorize FDA to collect user fees to support the Cosmetics Program. Consequently, the FDA Cosmetics Program is challenged to keep pace with industry growth in all areas. The proposed user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

Proposed International Courier User Fee
FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. Approximately 20 percent, or $1.2 million, of this proposed fee will support imported food safety. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Medical Countermeasures (-$48 thousand)

The FY 2015 Budget provides a program level of $24.5 million for continuation of Medical Countermeasures activities across FDA program, which is $48 thousand below the FY 2014 Enacted level due to decreased rent costs. FDA will continue to promote the development of medical countermeasures by establishing clear regulatory pathways for medical countermeasures, instituting effective regulatory policies and mechanisms to facilitate timely access to available medical countermeasures, and advancing medical countermeasures regulatory science.

NON-ADDS:

Infrastructure (+$6 million)

Within the funding for medical product and food safety, and medical countermeasures, FDA requests a program level increase of $5.8 million for infrastructure. Infrastructure includes GSA Rental Payments, Other Rent and Rent Related costs, and White Oak Consolidation.

Rental Payments
FDA requests a $20.6 million program level increase for GSA Rental Payments and Other Rent and Rent Related costs. The rental properties that provide office and laboratory space are essential facilities that allow FDA to perform its vital public health mission. The resources requested for GSA Rent cover the cost of rental payments to GSA for FDA's six million square feet of 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 activities includes commercial rent and rent-related charges that are not part of the GSA Rental account.

White Oak Consolidation
The FY 2015 Budget provides a program level of $47.1 million, $14.8 million below the FY 2014 Enacted level. The funding level supports ongoing and expanded operational and logistical functions for 9,000 employees on the White Oak Campus, including services vital to support of medical product safety, such as the new Life Sciences-Biodefense Complex.

Current Law User Fees (+$75 million)

Within the funding for medical product and food safety, FDA requests a$75.4 million increase for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The user fees collected will support the review and surveillance of human and animal drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases for many existing programs, which will expand the available options for treating and curing diseases and will fund strategies to reduce the burden of illness and death caused by tobacco products. Note that some of the amount requested supports infrastructure costs associated with current law user fee programs.

OVERVIEW OF PERFORMANCE

In April 2011, FDA published its five-year strategic plan, "Strategic Priorities 2011 – 2015."[2] In that document, FDA laid out the mission-critical areas of focus for modernizing FDA and committed to using the following cross-cutting priorities to "improve agency infrastructure, modernize regulatory processes, strengthen our workforce – and, ultimately, better promote and protect the health of the American people."

- Advance Regulatory Science and Innovation
- Strengthen the Safety and Integrity of the Global Supply Chain
- Strengthen Compliance and Enforcement Activities to Support Public Health
- Expand Efforts to Meet the Needs of Special Populations
- Advance Medical Countermeasures and Emergency Preparedness.

These goals and objectives focus efforts to achieve FDA's public health mission and to fulfill its role in supporting HHS' larger mission and strategic goals. The FDA Budget requests have since focused on these priorities and principles, and this FY 2015 Budget continues building FDA capacity in these key areas.

TRANSPARENCY AND ACCOUNTABILITY

In April 2011, FDA launched FDA-TRACK, which is the Agency-wide performance management system. FDA-TRACK monitors, analyzes, and reports monthly performance on all FDA program offices and on key cross-cutting initiatives. Each quarter, the FDA-TRACK team uses statistical models to analyze monthly performance data collected from each office and initiative. Face-to-face briefings are then conducted with the responsible office directors for each program presenting their performance data and results to FDA executive leadership.

These briefings stimulate discussion and facilitate better communication, decision-making, plan of action and ultimately, performance. Briefing summaries and performance results are then posted to the FDA-TRACK website, allowing FDA's stakeholders to monitor progress on more than 600 performance measures and 100 key projects.

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

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

The performance measures in FDA-TRACK represent the foundational activities and outputs produced by FDA employees. To better express how these activities and outputs contribute to FDA's overall public

[2] http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527.htm

health mission, an effort is in place to align each FDA-TRACK measure to the program's strategic plan, objectives**,** and budgets. Upon completion of this alignment, FDA leadership will be able to align performance with even better data-driven information.

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

Over 33,000 visitors subscribe to the FDA-TRACK monthly updates.

Evidence and Innovation Strategies

FDA harnesses data to improve program results and performance and to promote innovation within FDA and regulated industries. Examples of these strategies included in the FY 2015 Budget include:

- FDA-iRISK, an innovative risk-assessment tool that supports systematic, faster way of comparing and ranking risks in the food supply
- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) electronic screening tool for import operations, which helps focus FDA's resources using a risk-based approach
- Innovation Pathway 2.0, a priority program for device technologies that addresses unmet medical needs in disease treatment, diagnosis, and health care delivery
- Medical Device Innovation Consortium, to expand FDA's capacity for device-related regulatory science by creating a safe space for facile, creative, and ambitious medical device collaborations
- regulatory science activities to develop new methods for rapid-detection of contaminants in FDA-regulated compounds and accelerate FDA's capability to manage, analyze, and interpret research data generated from new technologies using bioinformatics.

ALL PURPOSE TABLE

(dollars in thousands)	FY 2013 Final	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Foods	813,223	796,638	900,259	1,124,277	224,018
Budget Authority	*796,642*	*796,638*	*882,817*	*903,403*	*20,586*
User Fees	*16,581*	---	*17,442*	*220,874*	*203,432*
Center	246,115	245,654	266,888	334,985	68,092
Budget Authority	245,654	245,654	266,408	279,994	13,586
User Fees	461	---	485	54,991	54,506
Voluntary Qualified Importer Program	---	---	---	*243*	*243*
Food and Feed Recall	*461*	---	*485*	*243*	*-242*
Food Facility Registration and Inspection	---	---	---	*28,279*	*28,279*
Food Import	---	---	---	*14,068*	*14,068*
Cosmetics	---	---	---	*12,499*	*12,499*
Food Contact Substance Notification	---	---	---	*4,639*	*4,639*
Field	567,108	550,984	633,366	789,292	155,926
Budget Authority	550,988	550,984	616,409	623,409	7,000
User Fees	16,120	---	16,957	165,883	148,926
Voluntary Qualified Importer Program	---	---	---	*4,320*	*4,320*
Food and Feed Recall	*9,388*	---	*9,823*	*1,000*	*-8,823*
Food Reinspection	*6,782*	---	*7,134*	*4,375*	*-2,339*
Food Facility Registration and Inspection	---	---	---	*27,376*	*27,376*
Food Import	---	---	---	*128,366*	*128,366*
International Courier	---	---	---	*730*	*730*
Cosmetics	---	---	---	*4,496*	*4,496*
FTE		3,626	3,805	4,236	431
Human Drugs	1,186,882	1,040,607	1,289,304	1,335,840	46,536
Budget Authority	*438,549*	*438,550*	*466,374*	*479,678*	*13,304*
User Fees	*748,333*	*602,057*	*822,930*	*856,162*	*33,232*
Center	1,007,540	904,802	1,097,515	1,136,290	38,775
Budget Authority	319,497	319,495	339,838	347,513	*7,675*
User Fees	688,043	585,307	757,677	788,777	*31,100*
Prescription Drug (PDUFA)	*460,774*	*486,148*	*534,526*	*561,252*	*26,726*
Generic Drug (GDUFA)	*192,721*	*99,159*	*207,475*	*211,625*	*4,150*
Biosimilars (BsUFA)	*14,548*	---	*15,676*	*15,900*	*224*
Field	179,342	135,805	191,789	199,550	7,761
Budget Authority	119,052	119,055	126,536	132,165	*5,629*
User Fees	60,290	16,750	65,253	67,385	*2,132*
Prescription Drug (PDUFA)	*9,611*	*7,244*	*10,908*	*11,453*	*545*
Generic Drug (GDUFA)	*49,253*	*9,506*	*53,023*	*54,083*	*1,060*
Biosimilars (BsUFA)	*1,226*	---	*1,322*	*1,348*	*26*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*501*	*501*
FTE		4,277	5,218	5,510	292
Biologics	308,010	296,866	337,543	342,639	5,096
Budget Authority	*194,673*	*194,638*	*210,928*	*209,754*	*-1,174*
User Fees	*113,337*	*102,228*	*126,615*	*132,885*	*6,270*
Center	266,608	257,415	292,586	297,773	5,187
Budget Authority	157,571	157,570	170,744	169,890	-854
User Fees	109,037	99,845	121,842	127,883	6,041
Prescription Drug (PDUFA)	*98,982*	*89,720*	*109,993*	*115,493*	*5,500*
Medical Device (MDUFA)	*9,369*	*10,125*	*10,301*	*10,549*	*248*
Generic Drug (GDUFA)	---	---	*774*	*1,052*	*278*
Biosimilars (BsUFA)	*736*	---	*774*	*789*	*15*
Field	41,402	39,451	44,957	44,866	-91
Budget Authority	37,102	37,068	40,184	39,864	-320
User Fees	4,300	2,383	4,773	5,002	229
Prescription Drug (PDUFA)	*4,121*	*1,926*	*4,581*	*4,810*	*229*
Medical Device (MDUFA)	*179*	*457*	*192*	*192*	---
Medical Products Reinspection	---	---	---	---	---
FTE		1,342	1,384	1,385	1
Animal Drugs and Feed	154,656	147,774	173,207	189,536	16,329
Budget Authority	*125,962*	*125,841*	*141,566*	*144,577*	*3,011*
User Fees	*28,694*	*21,933*	*31,641*	*44,959*	*13,318*
Center	102,272	98,726	115,461	119,339	3,878
Budget Authority	77,242	77,242	87,846	90,505	2,659
User Fees	25,030	21,484	27,615	28,834	1,219
Animal Drug (ADUFA)	*19,685*	*16,917*	*20,768*	*19,814*	*-954*
Animal Generic Drug (AGDUFA)	*4,827*	*4,567*	*6,302*	*5,995*	*-307*
Food and Feed Recall	*518*	---	*545*	---	*-545*
Food Facility Registration and Inspection	---	---	---	*1,537*	*1,537*
Food Import	---	---	---	*1,468*	*1,468*
Field	52,384	49,048	57,746	70,197	12,451
Budget Authority	48,720	48,599	53,720	54,072	352
User Fees	3,664	449	4,026	16,125	12,099
Animal Drug (ADUFA)	*339*	*291*	*472*	*404*	*-68*
Animal Generic Drug (AGDUFA)	*156*	*158*	*220*	*186*	*-34*
Food and Feed Recall	*635*	---	*668*	---	*-668*
Food Reinspection	*2,534*	---	*2,666*	*807*	*-1,859*
Food Facility Registration and Inspection	---	---	---	*1,038*	*1,038*
Food Import	---	---	---	*13,690*	*13,690*
Medical Products Reinspection	---	---	---	---	---
FTE		773	844	871	27

(dollars in thousands)	FY 2013 Final	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Devices and Radiological Health	**384,427**	**379,752**	**427,998**	**440,874**	**12,876**
Budget Authority	*296,240*	*296,393*	*320,825*	*317,937*	*-2,888*
User Fees	*88,187*	*83,359*	*107,173*	*122,937*	*15,764*
Center	295,854	294,156	332,528	342,241	9,713
Budget Authority	221,880	221,880	240,345	238,308	-2,037
User Fees	73,974	72,276	92,183	103,933	11,750
Medical Device (MDUFA)	*68,267*	*67,230*	*86,180*	*97,810*	*11,630*
Mammography Quality Standards Act (MQSA)	*5,707*	*5,046*	*6,003*	*6,123*	*120*
Field	88,573	85,596	95,470	98,633	3,163
Budget Authority	74,360	74,513	80,480	79,629	-851
User Fees	14,213	11,083	14,990	19,004	4,014
Medical Device (MDUFA)	*1,782*	*1,722*	*1,913*	*1,913*	---
Mammography Quality Standards Act (MQSA)	*12,431*	*9,361*	*13,077*	*13,339*	*262*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*3,752*	*3,752*
FTE	**2,041**	**2,077**	**2,167**	**2,234**	**67**
National Center for Toxicological Research (BA Only)	**54,965**	**54,965**	**62,494**	**58,998**	**-3,496**
FTE	**246**	**255**	**281**	**282**	**1**
Family Smoking Prevention and Tobacco Control Act	**458,580**	**848,807**	**501,476**	**531,527**	**30,051**
Center (UF Only)	449,644	835,090	486,487	515,640	29,153
Field (UF Only)	8,936	13,717	14,989	15,887	898
FTE		**496**	**640**	**773**	**133**
FDA Headquarters	**251,408**	**220,035**	**275,439**	**294,814**	**19,375**
Budget Authority	*160,114*	*160,112*	*172,107*	*175,360*	*3,253*
User Fees	*91,294*	*59,923*	*103,332*	*119,454*	*16,122*
Prescription Drug (PDUFA)	*41,665*	*37,107*	*46,323*	*48,639*	*2,316*
Medical Device (MDUFA)	*5,582*	*5,527*	*6,485*	*6,733*	*248*
Animal Drug (ADUFA)	*893*	*700*	*944*	*898*	*-46*
Animal Generic Drug (AGDUFA)	*224*	*175*	*293*	*277*	*-16*
Family Smoking Prevention and Tobacco Control Act	*14,446*	*11,012*	*19,500*	*20,668*	*1,168*
Voluntary Qualified Importer Program	---	---	---	*277*	*277*
Food and Feed Recall	*657*	---	*691*	*75*	*-616*
Food Reinspection	*3,374*	---	*3,549*	*480*	*-3,069*
Generic Drug (GDUFA)	*23,001*	*5,127*	*23,988*	*24,205*	*217*
Biosimilars (BsUFA)	*1,226*	---	*1,321*	*1,321*	---
Mammography Quality Standards Act (MQSA)	*226*	*275*	*238*	*243*	*5*
Food Facility Registration and Inspection	---	---	---	*4,576*	*4,576*
Food Import	---	---	---	*9,464*	*9,464*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*301*	*301*
Cosmetics	---	---	---	*1,020*	*1,020*
Food Contact Substance Notification	---	---	---	*277*	*277*
FTE		**1,041**	**1,307**	**1,388**	**81**
FDA White Oak Consolidation	**57,172**	**57,159**	**61,922**	**47,116**	**-14,806**
Budget Authority	*53,684*	*53,684*	*58,044*	*43,044*	*-15,000*
Prescription Drug (PDUFA)	*3,488*	*3,475*	*3,878*	*4,072*	*194*
Other Rent and Rent Related	**100,179**	**88,129**	**116,439**	**120,862**	**4,423**
Budget Authority	*64,058*	*64,058*	*74,674*	*73,296*	*-1,378*
User Fees	*36,121*	*24,071*	*41,765*	*47,566*	*5,801*
Prescription Drug (PDUFA)	*23,889*	*17,707*	*26,794*	*28,134*	*1,340*
Medical Device (MDUFA)	*2,802*	*2,208*	*3,546*	*4,027*	*481*
Animal Drug (ADUFA)	*276*	*62*	*236*	*225*	*-11*
Animal Generic Drug (AGDUFA)	*95*	*14*	*73*	*69*	*-4*
Family Smoking Prevention and Tobacco Control Act	*1,548*	*1,398*	*3,050*	*3,233*	*183*
Voluntary Qualified Importer Program	---	---	---	*170*	*170*
Food and Feed Recall	*246*	---	*259*	*43*	*-216*
Food Reinspection	*588*	---	*619*	*204*	*-415*
Generic Drug (GDUFA)	*6,129*	*2,482*	*6,598*	*6,730*	*132*
Biosimilars (BsUFA)	*548*	---	*590*	*602*	*12*
Food Facility Registration and Inspection	---	---	---	*827*	*827*
Food Import	---	---	---	*2,528*	*2,528*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*184*	*184*
Cosmetics	---	---	---	*524*	*524*
Food Contact Substance Notification	---	---	---	*66*	*66*

(dollars in thousands)	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+/- FY 2014
GSA Rental Payments	**198,645**	**190,151**	**219,907**	**236,076**	**16,169**
Budget Authority	*149,970*	*149,970*	*162,076*	*169,336*	*7,260*
User Fees	*48,675*	*40,181*	*57,831*	*66,740*	*8,909*
Prescription Drug (PDUFA)	*20,504*	*23,575*	*22,997*	*24,147*	*1,150*
Medical Device (MDUFA)	*4,915*	*4,460*	*6,216*	*7,058*	*842*
Animal Drug (ADUFA)	*1,479*	*630*	*1,180*	*1,123*	*-57*
Animal Generic Drug (AGDUFA)	*431*	*267*	*440*	*417*	*-23*
Family Smoking Prevention and Tobacco Control Act	*5,493*	*6,243*	*9,974*	*10,572*	*598*
Voluntary Qualified Importer Program	---	---	---	*290*	*290*
Food and Feed Recall	*432*	---	*454*	*73*	*-381*
Food Reinspection	*1,330*	---	*1,399*	*348*	*-1,051*
Generic Drug (GDUFA)	*13,133*	*5,006*	*14,138*	*14,421*	*283*
Biosimilars (BsUFA)	*958*	---	*1,033*	*1,054*	*21*
Food Facility Registration and Inspection	---	---	---	*1,467*	*1,467*
Food Import	---	---	---	*4,417*	*4,417*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*319*	*319*
Cosmetics	---	---	---	*918*	*918*
Food Contact Substance Notification	---	---	---	*116*	*116*
Subtotal	**3,968,147**	**4,120,883**	**4,365,988**	**4,722,559**	**356,571**
Color Certification	**7,443**	**7,631**	**7,278**	**8,955**	**1,677**
FTE		**38**	**37**	**37**	---
Export Certification	**4,604**	**3,885**	**4,604**	**4,696**	**92**
FTE		**18**	**22**	**22**	---
Priority Review Voucher	---	**4,582**	---	---	---
FTE	---	**28**	---	---	---
Food and Drug Safety -- No Year	**46,244**	**8,727**	---	---	---
Food Safety	36,995	6,666	---	---	---
Drug Safety	9,249	2,061	---	---	---
FTE	---	**3**	---	---	---
Buildings and Facilities (Budget Authority)	**4,920**	**5,635**	**8,788**	**8,788**	---
Total Program Level	**4,031,358**	**4,151,343**	**4,386,658**	**4,744,998**	**358,340**
Non-Field Activities	2,686,453	2,922,359	2,941,285	3,113,731	172,446
Field Activities	937,745	874,601	1,038,317	1,218,425	180,108
White Oak, Rent Activities, and B&F	360,916	341,074	407,056	412,842	5,786
Food and Drug Safety -- No Year	46,244	8,727	---	---	---
User Fees:					
Current Law					
Prescription Drug (PDUFA)	683,184	666,902	760,000	798,000	38,000
Medical Device (MDUFA)	92,896	91,729	114,833	128,282	13,449
Animal Drug (ADUFA)	22,672	18,600	23,600	22,464	-1,136
Animal Generic Drug (AGDUFA)	5,733	5,181	7,328	6,944	-384
Family Smoking Prevention and Tobacco Control Act	480,067	867,660	534,000	566,000	32,000
Voluntary Qualified Importer Program	---	---	---	5,300	5,300
Food and Feed Recall	12,287	---	12,925	1,434	-11,491
Food Reinspection	14,608	---	15,367	6,414	-8,953
Generic Drug (GDUFA)	284,237	121,280	305,996	312,116	6,120
Biosimilars (BsUFA)	19,242	---	20,716	21,014	298
Mammography Quality Standards Act (MQSA)	18,364	14,682	19,318	19,705	387
Color Certification	7,443	7,631	7,278	8,955	1,677
Export Certification	4,604	3,885	4,604	4,696	92
Priority Review Voucher	---	4,582	---	---	---
Subtotal, Current Law	**1,645,337**	**1,802,132**	**1,825,965**	**1,901,324**	**75,359**
Proposed					
Food Facility Registration and Inspection	---	---	---	60,120	60,120
Food Import	---	---	---	169,021	169,021
International Courier	---	---	---	5,807	5,807
Cosmetics	---	---	---	19,457	19,457
Food Contact Substance Notification	---	---	---	5,098	5,098
Subtotal, Proposed	---	---	---	**259,503**	**259,503**
Total User Fees	**1,645,337**	**1,802,132**	**1,825,965**	**2,160,827**	**334,862**
Total Budget Authority	**2,386,021**	**2,349,211**	**2,560,693**	**2,584,171**	**23,478**
Total Program Level	**4,031,358**	**4,151,343**	**4,386,658**	**4,744,998**	**358,340**
Total FTE		**13,974**	**15,705**	**16,738**	**1,033**

* The FY 2014 Enacted column does not includes user fees that were sequestered in FY 2013 and were restored in Section 747 of the Consolidated Appropriations Act, 2014.

** Estimates for Food and Feed Recall and Food Reinspection levels have been updated for FY 2015.

*** FTE figures do not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, and 9 IDDA FTE and the associated funds.

**** The Drug Quality and Security Act (P.L. 113-54) authorized three new FDA user fees: the outsourcing facility fees; the prescription drug wholesale distributer licensing and inspection; and, the third-party logistics provider licensing and inspection fees. It is expected that collections for FY 2015 will be minimal.

MAJOR ACTIVITIES

(dollars in thousands)	FY 2013 Final				FY 2014 Enacted				FY 2015 President's Budget				FY 2015 +/- FY 2014			
	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	Food Safety	Medical Product Safety	Medical Counter-measures	Total*
Budget Authority:																
Foods	**796,642**	---	---	**796,642**	**882,817**	---	---	**882,817**	**903,403**	---	---	**903,403**	**20,586**	---	---	**20,586**
Center	245,654			245,654	266,408			266,408	279,994			279,994	13,586	---	---	13,586
Field	550,988			550,988	616,409			616,409	623,409			623,409	7,000	---	---	7,000
Human Drugs	**---**	**433,374**	**5,175**	**438,549**	**---**	**460,354**	**6,020**	**466,374**	**---**	**473,658**	**6,020**	**479,678**	**---**	**13,304**	**---**	**13,304**
Center		314,322	5,175	319,497		333,818	6,020	339,838		341,493	6,020	347,513	---	7,675	---	7,675
Field		119,052	---	119,052		126,536	---	126,536		132,165	---	132,165	---	5,629	---	5,629
Biologics	**---**	**192,614**	**2,059**	**194,673**	**---**	**208,533**	**2,395**	**210,928**	**---**	**207,359**	**2,395**	**209,754**	**---**	**-1,174**	**---**	**-1,174**
Center		155,512	2,059	157,571		168,349	2,395	170,744		167,495	2,395	169,890	---	-854	---	-854
Field		37,102	---	37,102		40,184	---	40,184		39,864	---	39,864	---	-320	---	-320
Animal Drugs and Feeds	**97,304**	**28,658**	**---**	**125,962**	**112,892**	**28,674**	**---**	**141,566**	**113,869**	**30,708**	**---**	**144,577**	**977**	**2,034**	**---**	**3,011**
Center	52,989	24,253	---	77,242	61,711	26,135	---	87,846	62,688	27,817	---	90,505	977	1,682	---	2,659
Field	44,315	4,405	---	48,720	51,181	2,539	---	53,720	51,181	2,891	---	54,072	---	352	---	352
Devices and Radiological Health	**---**	**292,799**	**3,441**	**296,240**	**---**	**316,824**	**4,001**	**320,825**	**---**	**313,936**	**4,001**	**317,937**	**---**	**-2,888**	**---**	**-2,888**
Center		218,439	3,441	221,880		236,344	4,001	240,345		234,307	4,001	238,308	---	-2,037	---	-2,037
Field		74,360	---	74,360		80,480	---	80,480		79,629	---	79,629	---	-851	---	-851
National Center for Toxicological Research	**12,092**	**42,873**	**---**	**54,965**	**10,233**	**52,261**	**---**	**62,494**	**5,900**	**53,098**	**---**	**58,998**	**-4,333**	**837**	**---**	**-3,496**
FDA Headquarters	**60,283**	**80,293**	**9,538**	**160,114**	**70,331**	**81,464**	**10,312**	**172,107**	**73,285**	**81,763**	**10,312**	**175,360**	**2,954**	**299**	**---**	**3,253**
FDA White Oak Consolidation		**53,684**	**---**	**53,684**		**58,044**		**58,044**		**43,044**	**---**	**43,044**	**---**	**-15,000**	**---**	**-15,000**
Other Rent and Rent Related	**30,748**	**32,508**	**802**	**64,058**	**36,503**	**37,235**	**936**	**74,674**	**36,682**	**35,703**	**911**	**73,296**	**179**	**-1,532**	**-25**	**-1,378**
GSA Rental Payments	**71,986**	**77,220**	**764**	**149,970**	**75,341**	**85,847**	**888**	**162,076**	**78,622**	**89,849**	**865**	**169,336**	**3,281**	**4,002**	**-23**	**7,260**
Food and Drug Safety -- No Year	**36,995**	**9,249**	**---**	**46,244**				**---**				**---**				**---**
Food Safety	36,995			36,995				---				---				---
Drug Safety		9,249	---	9,249				---				---				---
Subtotal, Salaries and Expenses Account	**1,106,050**	**1,243,272**	**21,779**	**2,381,101**	**1,188,117**	**1,329,236**	**24,552**	**2,551,905**	**1,211,761**	**1,329,118**	**24,504**	**2,575,383**	**23,644**	**-118**	**-48**	**23,478**
Building and Facilities Account				**4,920**				**8,788**				**8,788**				**---**
Total Budget Authority	**1,106,050**	**1,243,272**	**21,779**	**2,386,021**	**1,188,117**	**1,329,236**	**24,552**	**2,560,693**	**1,211,761**	**1,329,118**	**24,504**	**2,584,171**	**23,644**	**-118**	**-48**	**23,478**
Total User Fees	**28,162**	**1,129,665**		**1,645,337**	**29,559**	**1,255,128**		**1,825,965**	**269,310**	**1,316,562**		**2,160,827**	**239,751**	**61,434**		**334,862**
Prescription Drug (PDUFA)		683,184		683,184		760,000		760,000		798,000		798,000	---	38,000		38,000
Medical Device (MDUFA)		92,896		92,896		114,833		114,833		128,282		128,282	---	13,449		13,449
Animal Drug (ADUFA)		22,672		22,672		23,600		23,600		22,464		22,464	---	-1,136		-1,136
Animal Generic Drug (AGDUFA)		5,733		5,733		7,328		7,328		6,944		6,944	---	-384		-384
Family Smoking Prevention and Tobacco Control Act				480,067				534,000				566,000	---	---		32,000
Voluntary Qualified Importer Program	---	---		---	---	---		---	5,300	---		5,300	5,300	---		5,300
Food and Feed Recall	12,287			12,287	12,925			12,925	1,434			1,434	-11,491	---		-11,491
Food Reinspection	14,608			14,608	15,367			15,367	6,414			6,414	-8,953	---		-8,953
Generic Drug (GDUFA)		284,237		284,237		305,996		305,996		312,116		312,116	---	6,120		6,120
Biosimilars (BsUFA)		19,242		19,242		20,716		20,716		21,014		21,014	---	298		298
Mammography Quality Standards Act (MQSA)		18,364		18,364		19,318		19,318		19,705		19,705	---	387		387
Color Certification				7,443				7,278				8,955	---	---		1,677
Export Certification	1,267	3,337		4,604	1,267	3,337		4,604	1,267	3,429		4,696	---	92		92
Priority Review Voucher	---	---		---	---	---		---	---	---		---	---	---		---
Food Facility Registration and Inspection				---					60,120			60,120	60,120	---		60,120
Food Import				---					169,021			169,021	169,021	---		169,021
International Courier				---					1,199	4,608		5,807	1,199	4,608		5,807
Cosmetics				---					19,457			19,457	19,457	---		19,457
Food Contact Substance Notification				---					5,098			5,098	5,098	---		5,098
Total Program Level	**1,134,212**	**2,372,937**	**21,779**	**4,031,358**	**1,217,676**	**2,584,364**	**24,552**	**4,386,658**	**1,481,071**	**2,645,680**	**24,504**	**4,744,998**	**263,395**	**61,316**	**-48**	**358,340**

* Total contains China Initiative, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification resources not included in Food Safety, Medical Product Safety, and Medical Countermeasures actitities.
** ADUFA and AGDUFA are currently included in Medical Product Safety. However, ADUFA and AGDUFA also support drug review for food producing animals.

BUDGET AUTHORITY CROSSWALKS

(dollars in thousands)	FY 2013 Final	Changes from FY 2013				FY 2014 Enacted
		Food Safety	Medical Product Safety	Medical Counter-measures	Sub-Total	
Salaries and Expenses Account						
Foods	**796,642**	**86,175**	---	---	**86,175**	**882,817**
Center	245,654	20,754	---	---	20,754	266,408
Field	550,988	65,421	---	---	65,421	616,409
Human Drugs	**438,549**	---	**26,980**	**845**	**27,825**	**466,374**
Center	319,497	---	19,496	845	20,341	339,838
Field	119,052	---	7,484	---	7,484	126,536
Biologics	**194,673**	---	**15,919**	**336**	**16,255**	**210,928**
Center	157,571	---	12,837	336	13,173	170,744
Field	37,102	---	3,082	---	3,082	40,184
Animal Drugs and Feeds	**125,962**	**15,588**	**16**	---	**15,604**	**141,566**
Center	77,242	8,722	1,882	---	10,604	87,846
Field	48,720	6,866	-1,866	---	5,000	53,720
Devices and Radiological Health	**296,240**	---	**24,025**	**560**	**24,585**	**320,825**
Center	221,880	---	17,905	560	18,465	240,345
Field	74,360	---	6,120	---	6,120	80,480
National Center for Toxicological Research	54,965	-1,859	9,388	---	**7,529**	**62,494**
FDA Headquarters	160,114	10,048	1,171	774	**11,993**	**172,107**
FDA White Oak Consolidation	53,684	---	4,360	---	**4,360**	**58,044**
Other Rent and Rent Related	64,058	5,755	4,727	134	**10,616**	**74,674**
GSA Rental Payments	149,970	3,355	8,627	124	**12,106**	**162,076**
Total Salaries and Expenses Account	**2,334,857**	**119,062**	**95,213**	**2,773**	**217,048**	**2,551,905**
Buildings and Facilities Account	**4,920**	---	---	---	---	**8,788**
Total Budget Authority	**2,339,777**	**119,062**	**95,213**	**2,773**	**217,048**	**2,560,693**
Non-Field Activities	1,236,923	37,665	62,679	2,515	102,859	1,339,782
Field Activities	830,222	72,287	14,820	---	87,107	917,329
Rent Activities, Building and Facilities, and White Oak	272,632	9,110	17,714	258	27,082	303,582

* FY 2013 Final does not include Food and Drug Safety No Year funding.

(dollars in thousands)	FY 2014 Enacted	Changes from FY 2014				FY 2015 President's Budget
		Food Safety	Medical Product Safety	Medical Counter-measures	Sub-Total	
Salaries and Expenses Account						
Foods	**882,817**	**20,586**	---	---	**20,586**	**903,403**
Center	266,408	13,586	---	---	13,586	279,994
Field	616,409	7,000	---	---	7,000	623,409
Human Drugs	**466,374**	---	**13,304**	---	**13,304**	**479,678**
Center	339,838	---	7,675	---	7,675	347,513
Field	126,536	---	5,629	---	5,629	132,165
Biologics	**210,928**	---	**-1,174**	---	**-1,174**	**209,754**
Center	170,744	---	-854	---	-854	169,890
Field	40,184	---	-320	---	-320	39,864
Animal Drugs and Feeds	**141,566**	**977**	**2,034**	---	**3,011**	**144,577**
Center	87,846	977	1,682	---	2,659	90,505
Field	53,720	---	352	---	352	54,072
Devices and Radiological Health	**320,825**	---	**-2,888**	---	**-2,888**	**317,937**
Center	240,345	---	-2,037	---	-2,037	238,308
Field	80,480	---	-851	---	-851	79,629
National Center for Toxicological Research	**62,494**	**-4,333**	**837**	---	**-3,496**	**58,998**
FDA Headquarters	**172,107**	**2,954**	**299**	---	**3,253**	**175,360**
FDA White Oak Consolidation	**58,044**	---	**-15,000**	---	**-15,000**	**43,044**
Other Rent and Rent Related	**74,674**	**179**	**-1,532**	**-25**	**-1,378**	**73,296**
GSA Rental Payments	**162,076**	**3,281**	**4,002**	**-23**	**7,260**	**169,336**
Total Salaries and Expenses Account	**2,551,905**	**23,644**	**-118**	**-48**	**23,478**	**2,575,383**
Buildings and Facilities Account	**8,788**	---	---	---	---	**8,788**
Total Budget Authority	**2,560,693**	**23,644**	**-118**	**-48**	**23,478**	**2,584,171**
Non-Field Activities	1,339,782	13,184	7,602	---	20,786	1,360,568
Field Activities	917,329	7,000	4,810	---	11,810	929,139
Rent Activities, Building and Facilities, and White Oak	303,582	3,460	-12,530	-48	-9,118	294,464

APPROPRIATION LANGUAGE

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding Section 521 of Public Law 107–188; **[**$4,346,670,000**]**[3] *$4,430,203,000: Provided,* That of the amount provided under this heading, **[**$760,000,000**]** *$798,000,000* shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, and shall be credited to this account and remain available until expended; **[**$114,833,000**]** *$128,282,000* 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; **[**$305,996,000**]** *$312,116,000* shall be derived from human generic drug user fees authorized by 21 U.S.C. 379j–42, and shall be credited to this account and remain available until expended; **[**$20,716,000**]** *$21,014,000* shall be derived from biosimilar biological product user fees authorized by 21 U.S.C. 379j–52, and shall be credited to this account and remain available until expended; **[**$23,600,000**]** *$22,464,000* shall be derived from animal drug user fees authorized by 21 U.S.C. 379j–12, and shall be credited to this account and remain available until expended; **[**$7,328,000*] $6,944,000* shall be derived from animal generic drug user fees authorized by 21 U.S.C. 379j–21, and shall be credited to this account and remain available until expended; **[**$534,000,000**]** *$566,000,000* shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s, and shall be credited to this account and remain available until expended **[**; $12,925,000 shall be derived from food and feed recall fees authorized by 21 U.S.C. 379j–31, and shall be credited to this account and remain available until expended; $15,367,000 shall be derived from food reinspection fees authorized by 21 U.S.C. 379j–31, and shall be credited to this account and remain available until expended; and amounts derived from voluntary qualified importer program fees authorized by 21 U.S.C. 379j–31 shall be credited to this account and remain available until expended**]**: *Provided further,* That in addition and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees, medical device user fees, human generic drug user fees, biosimilar biological product user fees, animal drug user fees, and animal generic drug user fees that exceed the respective fiscal year **[**2014**]** *2015* limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, human generic drug, biosimilar biological product, animal drug, and animal generic drug assessments for fiscal year **[**2014**]** *2015*, including any such fees collected prior to fiscal year **[**2014**]** *2015* but credited for fiscal year **[**2014**]** *2015*, shall be subject to the fiscal year **[**2014**]** *2015* limitations: Provided further, That the Secretary may accept payment during fiscal year **[**2014**]** *2015* of user fees specified under this heading and authorized for fiscal year **[**2015**]** *2016*, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year **[**2015**]** *2016* for which the Secretary accepts payment in fiscal year **[**2014**]** *2015* shall not be included in amounts under this heading: 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) $900,259,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $1,289,304,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $337,543,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $173,207,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $408,918,000 shall be for

[3] Please note that brackets indicate deleted text and italics indicate new text.

the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $62,494,000 shall be for the National Center for Toxicological Research; (7) $501,476,000 shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) not to exceed $178,361,000 shall be for Rent and Related activities, of which $61,922,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9) not to exceed $219,907,000 shall be for payments to the General Services Administration for rent; and (10) $275,201,000 shall be for other activities, including the Office of the Commissioner of Food and Drugs, the Office of Foods and Veterinary Medicine, the Office of Medical and Tobacco Products, the Office of Global and Regulatory Policy, the Office of Operations, the Office of the Chief Scientist, and central services for these offices:**]** *Provided further,* That not to exceed $25,000 of this amount shall be for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner: **[***Provided further,* That any transfer of funds pursuant to Section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) shall only be from amounts made available under this heading for other activities:**]** *Provided further,* That funds may be transferred from one specified activity to another with the prior **[**approval**]** *notification* 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, *food and feed recall fees, food reinspection fees, and voluntary qualified importer program fees authorized by 21 U.S.C. 379j-31, outsourcing facility fees authorized by 21 U.S.C. 379j-62, prescription drug wholesale distributor licensing and inspection fees authorized by 21 U.S.C. 353(e)(3), and third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1),* **[**may**]** *shall* be credited to this account, to remain available until expended.

BUILDINGS AND FACILITIES

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

SALARIES AND EXPENSES (LEGISLATIVE PROPOSAL)

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

LANGUAGE ANALYSIS

Language Provision	Explanation
Food Inspection and Facility Registration User Fee	The Administration will propose legislation to allow FDA to collect a fee for food establishment registration and inspection. The additional resources will generate an estimated $60,120,000 to support food safety modernization activities. Revenue would target new and improved activities required by FSMA, most significantly funding to modernize FDA's inspection system, by increasing the effectiveness of inspection through adoption of preventive controls and by training of personnel to inspect against the new prevention standards as well as developing new ways of educating
International Courier User Fee	The Administration will propose legislation to allow FDA to collect fees for international couriers. The additional resources are estimated at $5,807,000.
Cosmetic User Fee	The Administration will propose legislation to allow FDA to collect fees for cosmetic safety. The additional resources, estimated at $19,457,000, will allow FDA to establish and maintain a Cosmetic Registration
Food Contact Notification User Fee	The Administration will propose legislation to allow FDA to collect fees for food contact and notification. The additional resources, estimated at $5,098,000, will support FDA's efficient and timely review of food contact notifications.
Food Import Fee	The Administration will propose legislation to allow FDA to collect for food imports, which will generate an estimated $169,021,000 million to support FDA's food safety efforts. The fee will have exemptions for small importers and a maximum charge for large importers.
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, food and feed recall fees, food reinspection fees, and voluntary qualified importer program fees authorized by 21 U.S.C. 379j-31, outsourcing facility fees authorized by 21 U.S.C. 379j-62, prescription drug wholesale distributor licensing and inspection fees authorized by 21 U.S.C. 353(e)(3), and third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1), [may] shall be credited to this account, to remain available until expended.	This provision allows collection of the prescription drug wholesale distributor licensing and inspection fee and the third-party logistics provider licensing and inspection fee. This language also makes the current food fees indefinite.

AMOUNTS AVAILABLE FOR OBLIGATION

(dollars in thousands)	FY 2013 Actual	FY 2014 Enacted	FY 2015 President's Budget
General Fund Discretionary Appropriation:			
Appropriation	2,349,211	2,560,693	2,584,171
Total Discretionary Appropriation	**2,349,211**	**2,560,693**	**2,584,171**
Mandatory Appropriation:			
CRADA	2,000	2,000	2,000
Total Mandatory Appropriation	**2,000**	**2,000**	**2,000**
Offsetting Collections:			
Non-Federal Sources:	1,802,132	1,825,965	2,160,827
Total Offsetting Collections	**1,802,132**	**1,825,965**	**2,160,827**
Unobligated Balances Previously Unavailable:			
Sequestered fees from FY 2013[1]	---	78,691	---
Total Unobligated Balances Previously Unavailable	**---**	**78,691**	**---**
Total Obligations	**4,153,343**	**4,467,349**	**4,746,998**

[1] Estimate correct as of 09/30/13; subject to change based on actual collections.

SUMMARY OF CHANGES

(dollars in thousands)	Budget Authority	User Fees	Program Level	FTE
FY 2014 Enacted	**2,560,693**	**1,825,965**	**4,386,658**	**15,705**
FY 2015 Program Changes				
Budget Authority Changes				
Food Safety Modernization	23,644		23,644	
Medical Product Safety	-118		-118	
Medical Counter Measures	-48		-48	
Total Budget Authority Changes	**23,478**		**23,478**	**209**
User Fee Changes				
Current Law				
Prescription Drug (PDUFA)		38,000	38,000	13
Medical Device (MDUFA)		13,449	13,449	58
Animal Drug (ADUFA)		-1,136	-1,136	---
Animal Generic Drug (AGDUFA)		-384	-384	---
Family Smoking Prevention and Tobacco Control Act		32,000	32,000	135
Voluntary Qualified Importer Program		5,300	5,300	---
Food and Feed Recall		-11,491	-11,491	-26
Food Reinspection		-8,953	-8,953	-49
Generic Drug (GDUFA)		6,120	6,120	231
Biosimilars (BsUFA)		298	298	---
Mammography Quality Standards Act (MQSA)		387	387	---
Color Certification Fund		1,677	1,677	---
Export Certification		92	92	---
Subtotal, Current Law		**75,359**	**75,359**	**362**
Proposed				
Food Facility Registration and Inspection Fee		60,120	60,120	69
Food Import		169,021	169,021	301
International Courier		5,807	5,807	21
Cosmetics		19,457	19,457	63
Food Contact Substance Notification		5,098	5,098	8
Subtotal, Proposed		**259,503**	**259,503**	**462**
Total User Fee Changes		**334,862**	**334,862**	**824**
Net Program Changes	**23,478**	**334,862**	**358,340**	**1,033**
Total FDA Request for FY 2015	**2,584,171**	**2,160,827**	**4,744,998**	**16,738**

* FTE column does not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, and 9 IDDA FTE and the associated funds.

BUDGET AUTHORITY BY ACTIVITY

(dollars in thousands)	FY 2013 Actuals	FY 2014 Enacted	FY 2015 President's Budget
Salaries and Expenses Account:			
Foods	**796,638**	**882,817**	**903,403**
Center	245,654	266,408	279,994
Field	550,984	616,409	623,409
Human Drugs	**438,550**	**466,374**	**479,678**
Center	319,495	339,838	347,513
Field	119,055	126,536	132,165
Biologics	**194,638**	**210,928**	**209,754**
Center	157,570	170,744	169,890
Field	37,068	40,184	39,864
Animal Drugs and Feeds	**125,841**	**141,566**	**144,577**
Center	77,242	87,846	90,505
Field	48,599	53,720	54,072
Devices and Radiological Health	**296,393**	**320,825**	**317,937**
Center	221,880	240,345	238,308
Field	74,513	80,480	79,629
National Center for Toxicological Research	**54,965**	**62,494**	**58,998**
FDA Headquarters	**160,112**	**172,107**	**175,360**
FDA White Oak Consolidation	**53,684**	**58,044**	**43,044**
Other Rent and Rent Related	**64,058**	**74,674**	**73,296**
GSA Rental Payments	**149,970**	**162,076**	**169,336**
Subtotal, Salaries and Expenses Account	**2,334,849**	**2,551,905**	**2,575,383**
Food and Drug Safety – No Year	**8,727**	**---**	**---**
Food Safety	6,666	---	---
Drug Safety	2,061	---	---
Buildings and Facilities Account	**5,635**	**8,788**	**8,788**
Total Budget Authority	**2,349,211**	**2,560,693**	**2,584,171**
FTE[1]	**9,798**	**10,325**	**10,534**

[1] Does not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, 9 IDDA FTE and the associated funds.

APPROPRIATIONS HISTORY

Salaries and Expenses

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropration*:				
FY 2006	1,849,676,000	1,837,928,000	1,841,959,000	1,843,751,000
FY 2007	1,916,329,000	1,914,382,000	1,941,646,000	1,790,368,000
FY 2008	2,051,801,000	1,683,405,000	2,276,262,000	2,235,876,000
FY 2009 1/	2,638,197,000		3,168,794,000	2,622,267,000
FY 2010	3,371,218,000	3,230,218,000	3,230,218,000	3,237,218,000
FY 2011	3,989,507,000		3,720,044,000	3,650,783,000
FY 2012	4,256,673,000	3,599,871,000	3,599,871,000	3,788,336,000
FY 2013				
Base	4,449,283,000	4,153,933,000	4,197,658,000	4,203,577,000
Sequestration	---	---	---	-207,550,000
Subtotal	4,449,283,000	4,153,933,000	4,197,658,000	3,996,027,000
FY 2014	4,613,104,000	4,280,164,000	4,346,670,000	4,346,670,000
FY 2015	4,702,854,000			

* Excludes Mammography Quality Standards Act, Color Certification, and Export Certification user fees.

1/ FY 2009 Appropriation does not include Supplemental Appropriation

Buildings and Facilities

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropration:				
FY 2006	7,000,000	5,000,000	7,000,000	7,920,000
FY 2007	4,950,000	4,950,000	4,950,000	4,950,000
FY 2008	4,950,000	4,950,000	4,950,000	2,433,000
FY 2009	2,433,000		12,433,000	12,433,000
FY 2010	12,433,000	12,433,000	12,433,000	12,433,000
FY 2011	12,433,000		9,980,000	9,980,000
FY 2012	13,055,000	8,788,000	8,788,000	8,788,000
FY 2013				
Base	5,320,000	---	5,320,000	5,176,000
Sequestration	---	---	---	-256,000
Subtotal	5,320,000	---	5,320,000	4,920,000
FY 2014	8,788,000	---	11,000,000	8,788,000
FY 2015	8,788,000			

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FOODS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Foods	**813,223**	**796,638**	**900,259**	**1,124,277**	**224,018**
Budget Authority	***796,642***	***796,638***	***882,817***	***903,403***	***20,586***
User Fees	***16,581***	---	***17,442***	***220,874***	***203,432***
Center	246,115	245,654	266,893	334,985	68,092
Budget Authority	245,654	245,654	266,408	279,994	13,586
User Fees	461	---	485	54,991	54,506
Voluntary Qualified Importer Program	---	---	---	*243*	*243*
Food and Feed Recall	*461*	---	*485*	*243*	*-242*
Food Facility Registration and Inspection	---	---	---	*23,279*	*23,279*
Food Import	---	---	---	*14,088*	*14,088*
Cosmetics	---	---	---	*12,499*	*12,499*
Food Contact Substance Notification	---	---	---	*4,639*	*4,639*
Field	567,108	550,984	633,366	789,292	155,926
Budget Authority	550,988	550,984	616,409	623,409	7,000
User Fees	16,120	---	16,957	165,883	148,926
Voluntary Qualified Importer Program	---	---	---	*4,320*	*4,320*
Food and Feed Recall	*9,338*	---	*9,823*	*1,000*	*-8,823*
Food Reinspection	*6,782*	---	*7,134*	*4,575*	*-2,559*
Food Facility Registration and Inspection	---	---	---	*27,376*	*27,376*
Food Import	---	---	---	*123,366*	*123,366*
International Courier	---	---	---	*750*	*750*
Cosmetics	---	---	---	*4,496*	*4,496*
FTE		**3,626**	**3,805**	**4,236**	**431**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Food Additives Amendment of 1958; Color Additives Amendments of 1960; The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Food Allergen Labeling and Consumer Protection Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Modernization Act of 2011 (Public Law 111-353); Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C. 379aa-1)

Allocation Methods: Direct Federal/intramural; Contract; Competitive grant

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Foods Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The mission of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety and proper labeling of the American food supply, animal feed, and cosmetics, as well as the safety and effectiveness of animal drugs and devices. The FVM Program is comprised of the Foods and the Animal Drugs and Feeds Programs, and related field-based activities managed by the Office of Regulatory Affairs (ORA). The Foods and Animal Drugs and Feeds Programs are administered by the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) respectively. The Office of Foods and Veterinary Medicine provides leadership and strategic direction to the FVM Program, including direct oversight of all activities of CFSAN and CVM, and manages the crosscutting outbreak response and evaluation team.

The operations of the Foods and the Animal Drugs and Feeds Programs are administered by the Center for Food Safety and Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) respectively, both in collaboration with the Office of Regulatory Affairs (ORA). CFSAN is charged with ensuring the safety of the human food supply, dietary supplements, and cosmetics as well as ensuring proper labeling

of foods and cosmetics. CVM is responsible for ensuring the safety and effectiveness of animal drugs as well as ensuring the safety of animal feed.

The FVM Strategic Plan[4] provides a guiding strategic vision for FDA's food, feed, and veterinary medicine activities, including the implementation of the Food Safety Modernization Act (FSMA). The Plan contains one cross-cutting and seven programmatic goals and directly supports FDA's strategic priority to Advance Food Safety and Nutrition.

- Cross-cutting Goal: Improve Effectiveness and Efficiency Across All Levels of the FVM Program
- Goal One: Establish Science-Based Preventive Control Standards Across the Farm-to-Table Continuum
- Goal Two: Achieve High Rates of Compliance with Preventive Control Standards Domestically and Internationally
- Goal Three: Strengthen Scientific Leadership, Capacity, and Partnership to Support Public Health and Animal Health Decision Making
- Goal Four: Provide Accurate and Useful Information so Consumers Can Choose a Healthier Diet and Reduce the Risk of Chronic Disease and Obesity
- Goal Five: Encourage Food Product Reformulation and Safe Production of Dietary Supplements
- Goal Six: Improve Detection and Response to Foodborne Outbreaks and Contamination Incidents
- Goal Seven: Advance Animal Drug Safety and Effectiveness

FDA recognizes that outbreaks of foodborne illness and contamination events have a substantial impact on public health – an estimated 48 million foodborne illnesses occur every year resulting in an estimated 128,000 hospitalizations and 3,000 deaths.[5] Foodborne illnesses cost on average $1,626 per case and more than $75 billion per year in total.[6]

FDA faces unique food safety challenges in the 21st Century. FSMA enables FDA to better protect public health by strengthening the food and feed safety system and focuses FDA on preventing food and feed safety problems rather than relying primarily on reacting to problems after they occur. FSMA also provides FDA with new enforcement authorities designed to achieve high rates of compliance with prevention- and risk-based food and feed safety standards and to better respond to and contain problems when they do occur. Furthermore, FSMA gives FDA important new tools to hold imported food and feed to the same standards as domestic food and feed and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

The FVM Strategic Plan provides a framework for the implementation of FSMA and other legislative authorities and places high priority on the prevention of foodborne and feed-borne illness of unknown origins, as well as illness that can be specifically attributed to known sources. The Foods Program addresses food safety risks at multiple points of the food supply chain through a combination of regulations, guidance, technical assistance, training and outreach, model codes for food service establishments such as restaurants, and consumer information. The Foods Program ensures that nutrition labeling is informative and accurate and encourages the food industry to provide healthy and nutritious products.

[4] The strategic plan can be found on the FDA website.
[5] CDC. 2011.Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.
[6] Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," Journal of Food Protection, Volume 75, Number 1, January 2012, pp. 123-131(9).

In addition to the high-priority initiatives identified in the FVM Strategic Plan, the Foods Program conducts many other important food safety, nutrition, and cosmetic activities. These include review of infant formula notifications, pre- and post-market regulation of ingredients and packaging, monitoring for chemical contaminants, authorization of nutrient content and health claims, regulation of dietary supplements, cosmetics safety and labeling, and ongoing regulatory, enforcement, research, communications, education and outreach activities.

In addition to implementing FSMA, Foods Program priorities for FY 2014 include:

- taking initial steps to address the safety of trans fats from partially hydrogenated oils and caffeine as an additive in energy drinks and a range of other foods to which caffeine has not traditionally been added
- developing draft targets to support voluntary sodium reduction efforts by the packaged food and restaurant industries
- publishing draft risk assessment for arsenic in rice and rice products and determine whether guidance levels are needed for arsenic in rice or rice products
- publishing proposed rules to update the Nutrition Facts Label and Serving Sizes
- publishing final rules for requiring nutrition information on menus and on vending machines
- publishing final rule prohibiting the use of certain cattle material to address the potential risk of bovine spongiform encephalopathy in human food, including dietary supplements, and cosmetics
- refining the process to file product processes subject to FDA regulations to utilize current technology to ensure adequacy and food safety for low acid canned food products
- transitioning or otherwise incorporating advanced molecular technologies to modernize and augment field capacity
- advancing the use of whole genome sequencing to more accurately track foodborne outbreaks and contamination through the Genome Tracker network of state and federal laboratories.

The following, selected accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities within the context of current priorities and demonstrate progress towards the goals of the FVM Strategic Plan.

Standard Setting

The Foods Program sets and recognizes standards in many areas of its broad responsibility, as illustrated by the following examples.

FSMA Rules Published
In 2013, FDA proposed six new food safety rules under FSMA to modernize the food safety system and focus on preventing food safety problems, rather than relying primarily on responding to problems after they occur. In January 2013, FDA proposed two of the four new food safety rules on preventive controls for human food and standards for produce safety. The first proposed rule will require manufacturers of food to be sold in the United States, whether produced at a foreign or domestic based facility, to have written plans that identify hazards that are reasonably likely to occur; specify the steps that will be put in place to prevent or minimize the hazards; identify monitoring procedures; record monitoring results; and specify what actions will be taken to correct problems that arise. The second rule proposed enforceable science- and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms.

The third and fourth FSMA rules were proposed in July 2013 and aim to strengthen assurances that imported food meets the same safety standards as domestically produced food. Imported food comes to the United States from about 150 different countries. Under the proposed rule for Foreign Supplier Verification Programs (FSVP), importers would need to verify that their suppliers are meeting the same U.S. safety standards required of domestic producers. Requirements for verification activities will be primarily based on the type of food, nature of the hazard identified, and on who is best able to control the

hazard. Under the proposed rule for Accreditation of Third-Party Auditors, FDA will recognize accreditation bodies based on certain criteria such as competency and impartiality. The accreditation bodies, which could be foreign government agencies or private companies, will in turn accredit third-party auditors to audit and issue certifications for foreign food facilities.

The fifth FSMA rule was proposed in December 2013. This rule would require the largest food businesses in the United States and abroad to take steps to prevent facilities from being the target of intentional attempts to contaminate the food supply. The sixth FSMA rule focused on animal food safety and is discussed in the Animal Drugs and Feeds Program narrative.

In addition, on January 31, 2014, FDA published the seventh foundational FSMA proposed rule, which would require those who transport food to use sanitary transportation practices to ensure the safety of food.

Manufactured Food Regulatory Program Standards Alliance
To ensure an integrated food safety system (IFSS), FDA awards and oversees contracts to States and territories to perform a majority of the domestic inspections of food manufacturing facilities. These domestic regulatory partners perform current Good Manufacturing Practice inspections as well as inspections in high-risk industries such as low-acid canned foods, acidified foods, juice, and seafood under FDA's Hazard Analysis and Critical Control Point regulation. To ensure the development of a high-quality state manufactured food regulatory program, FDA created the Manufactured Food Regulatory Program Standards Alliance through a cooperative agreement to provide additional resources, training, and support to programs that are implementing these standards. Additionally, FDA's training grants promote consistency in the implementation and application of IFSS and FSMA training requirements as they relate to setting standards and administering training and education programs to state, local, territorial, and tribal food safety officials.

Import Safety Systems Recognition
To better ensure the safety of imported foods, the Foods Program completed in December 2012 the first pilot with New Zealand for a new tool called systems recognition (previously termed "comparability"). Approximately 15 to 20 percent of all foods consumed in the United States originate from foreign sources. For example, 80 percent of the seafood and 25 to 35 percent of the produce eaten by American consumers is imported. Systems recognition involves reviewing a foreign country's food safety regulatory system to determine if it provides a similar set of protections to that of FDA. The process includes a comprehensive review of the country's relevant laws and regulations, inspection programs, response to food-related illness and outbreaks, compliance and enforcement and laboratory support. The Foods Program is involved in a second pilot with Canada. Its geographical location makes Canada one of the largest exporters to the United States.

Compliance

Administrative Detention
The Foods Program evaluates industry compliance with safety standards throughout the production and handling stages of the global food and feed supply chain. Under FSMA, FDA received authorization to suspend a facility's registration if FDA determines that food and feed manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. In November 2012, the Foods Program exercised this new authorization by suspending the food facility registration of Sunland Inc., based in Portales, New Mexico. The manufacturer of nuts and nut and seed spreads was linked to an outbreak of *Salmonella* Bredeney that sickened 41 people in 20 States among numerous other peanut butter products. In December 2012, a U.S. District of New Mexico judge signed a consent decree imposing requirements on Sunland to keep potentially harmful products from entering the U.S. marketplace.

Arsenic
In July 2013, FDA proposed an "action level" for inorganic arsenic, the hazardous form of arsenic, in apple juice. The "action level" will establish threshold guidance to industry concerning the amount of inorganic arsenic in apple juice. The proposed level is the same set by the Environmental Protection Agency for arsenic in drinking water. Though FDA has been monitoring the presence of arsenic in apple juice for the past 20 years, new tools have allowed for a better understanding of the breakdown between organic and inorganic arsenic levels. If FDA finds that a food product exceeds the set threshold, it takes the "action level" into account when considering an enforcement action. In September 2013, FDA posted the results of testing for the presence of arsenic in approximately 1,300 samples of rice and rice products. These results include the approximately 200 samples of rice and rice products that FDA initially tested and released the findings in September 2012. While levels varied significantly depending on the product tested, agency scientists determined that the amount of detectable arsenic is too low in the rice and rice product samples to cause any immediate or short-term adverse health effects.

Foreign Inspections
The Foods Program recently developed a strategic plan to identify country and commodity combinations of interest based on identified risk factors and expert elicitation. The plan encompasses 26 commodity types in 54 countries and more than 3,700 potential foreign facilities. In order to address these areas, FDA leverages the work of the Dedicated Foreign Inspection Cadre, FDA inspection staff located at FDA's foreign offices, and district-based investigators to enhance overall coverage of the foreign establishment inventory. In FY 2013, the Dedicated Foreign Food Cadre completed more than 400 foreign inspections and FDA conducted more than 1,400 foreign food establishment inspections globally.

Enforcement Actions
When firms violate FDA safety requirements, FDA takes regulatory action and assists the firms in reaching full compliance while ensuring that products of concern do not reach U.S. consumers. When firms refuse to comply with FDA regulations, FDA takes further enforcement action to ensure unsafe products do not reach U.S. consumers and requests the firms' potential shut down of operations. In FY 2013, there were ten injunctions and five seizures against food and dietary supplement processors and manufacturers. FDA also monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. During FY 2013, FDA classified 309 Class I (most serious), 241 Class II, and 66 Class III human food recall events. FDA puts import controls into place when non-compliant food products are discovered or food manufacturers are determined to be manufacturing or shipping non-compliant products. In FY 2013, 1,006 such import alert notices were issued. Additionally, ORA's Office of Criminal Investigations protects the public by ensuring compliance with FDA procedures designed to keep the public safe from foodborne illnesses caused by adulterated and unsafe foods by applying effective criminal enforcement of the FD&C Act.

Risk Analysis and Regulatory Science

The Foods Program invests in advanced science and technologies to more efficiently address issues threatening the food supply.

FDA-iRISK
One of the most significant recent scientific advancements was the development and release of an innovative risk-assessment tool, FDA-iRISK. The tool automates the time and labor intensive process of developing mathematical models to simulate risk and intervention in food-production chains. FDA-iRISK allows for a more comprehensive, rapid risk ranking of many food-hazard combinations and potential solutions and provides regulatory and industry decision-makers with a systematic, faster way of comparing and ranking risks in the food supply and predicting best solutions. In addition, FDA-iRISK was one of six finalists in the 2013 HHS Innovates Awards, and received Honorable Mention at an awards event held in March 2013, where the "Secretary's Picks" were announced.

Pathogen Detection
Scientific partnerships help FDA with its public health decision making, and improve effectiveness and efficiency across the farm-to-table continuum. FDA partnered with the National Center for Biotechnology Information, the University of California, Davis, BGI America, and Agilent Technologies, Inc. to launch "The 100,000 Genome Project," a five-year effort to more quickly identify the source contamination in foodborne illness outbreaks and to keep additional contaminated product from entering the market. The project will entail the genome sequencing of approximately 100,000 subtypes of common pathogens such as *Salmonella*, *Listeria*, and *Escherichia coli*. The project was honored as a recipient of the "Secretary's Pick" for the 2012 HHS Innovates Award.

FDA annually invests $12 million to equip its field laboratories with cutting edge technology. FDA uses methods for regulatory testing that are sophisticated analyses that scan for multiple contaminants in a single analytical run. This approach enables FDA to extract the maximum amount of information from a single collected sample which translates into effective protection of public health.

Response

Food Emergency Response Network
In preparation for food-related emergencies and high-profile events, FDA provides direct oversight to the Food Emergency Response Network (FERN) and utilizes FDA's field laboratories as well as Center and FERN laboratories. FERN grants provide state-of-the-art equipment, analytical platforms, methodology, training, and proficiency testing that can be used for surge capacity, outbreak sampling, and large surveillance assignments. FERN support also includes the FERN training program that provides courses for both Federal and state laboratory analysts. This program increases the FERN capacity and analytical capability for chemical, microbiological, and radiological testing that enhances the response to food emergency events (including food safety and food defense). FDA has awarded 15 microbiological, 14 chemistry, and five radiochemistry cooperative agreement grants.

Nutrition and Food Labeling

Infant Formula
In April 2013, the Foods Program proposed a rule to add selenium to the list of required nutrients for infant formulas and to establish both minimum and maximum levels of selenium in infant formulas. Selenium is an essential nutrient for infants, and formula often serves as a sole source of nutrition for infants. The proposed rule will also amend the labeling requirements for infant formula to require the listing of selenium per 100 kilocalories. By amending regulations to add and establish a safe range of selenium in infant formula, FDA is able to require manufacturers marketing infant formula in the United States to add selenium within this safe range, and require any manufacturer newly entering the U.S. market to adopt this practice as well.

Gluten-free Labeling
The Foods Program regulates food labels to provide accurate and useful information to consumers so that they can make healthier diet decisions and reduce the risk of chronic disease and obesity. In August 2013, FDA published a new regulation defining the term and the threshold for products labeled "gluten-free," including dietary supplements, to better protect consumers who are gluten sensitive or who suffer from celiac disease.

Food Product Reformulation

Trans Fat
In November 2013, the Foods Program proposed a preliminary determination that partially hydrogenated oils (PHOs), a major source of artificial trans-fat in processed foods, are not generally recognized as safe (GRAS) for use in food. The determination to remove GRAS status from PHOs will mean they are considered food additives and could not be used in food unless authorized by regulation. The Centers for

Disease Control and Prevention estimates that eliminating artificial trans-fat in processed foods could prevent up to 7,000 deaths from heart disease each year and up to 20,000 heart attacks each year.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$836,244,000	$836,244,000	$0
FY 2012 Actual	$866,920,000	$866,920,000	$0
FY 2013 Actual	$796,638,000	$796,638,000	$0
FY 2014 Enacted	$900,259,000	$882,817,000	$17,442,000
FY 2015 Budget Request	$1,124,277,000	$903,403,000	$220,874,000

BUDGET REQUEST

The FY 2015 Budget for the Foods Program is $1,124,277,000, of which $903,403,000 is budget authority and $220,874,000 is user fees. This is $224,018,000 above the FY 2014 Enacted level. The Center portion is $334,985,000 and the Field portion is $789,292,000.

In FY 2015 the Foods Program will continue carrying out FDA's food safety, nutrition, and animal health activities which becomes more challenging every year as globalization, advances in science and technology, and shifts in consumer expectations drive change throughout the human and animal food systems. The Foods Program has prioritized the activities of greatest public health importance in order to best protect the American people as outlined in the FVM Strategic Plan.

The implementation of FSMA is a continued priority of the Foods Program, and FDA will work to improve compliance and inspection programs to ensure successful implementation of the FSMA final rules for preventive controls for human food and for produce safety. The Foods Program will execute integrated food safety strategies in partnership with states, establish oversight of the third party audit program, continue to support foreign inspection planning and related enforcement cases, and expedite the integration of risk-based decision-making.

Also in support of FSMA, the Foods Program will continue to develop new risk assessment methodology, expand existing risk tools (for example, FDA-iRISK), and collect data to enhance and refine existing and ongoing models as well as conduct risk prioritization and comparative risk assessment to better target use of FDA resources. The investment of these cutting-edge tools will significantly reduce the time to develop quantitative risk analysis models to respond to complex food safety issues that FDA faces each day. In addition, the Foods Program will continue the development of improved extraction, detection, and data analysis methods and procedures for the major classes of chemical contaminants and adulterants in foods.

The Foods Program will also develop guidance to assist industry in implementing final menu and vending machine labeling regulations. FDA will also continue monitoring existing front-of-pack labeling and will explore future front-of-pack nutrition labeling opportunities. Additionally, the Foods Program will be developing standards and guidance regarding the labeling of allergens in food in accordance with the Food Allergen Labeling and Consumer Protection Act.

At the FY 2015 Budget level, the Foods Program will increase the investment in staff and contractor support for guidance development to successfully implement the proposed rules related to FSMA. Additionally, the Foods Program will develop training and outreach material as well as tools for industry to support implementation, adoption, and compliance with FSMA standards. To achieve FSMA implementation, the Foods Program will invest in the technical capacity and expertise to be at the cutting edge of understanding food safety hazards and preventive measures; and will work collaboratively with a

broad range of food industry experts to ensure standards are well understood and are up- to-date, effective, and efficient in protecting the safety of food. The Foods Program will invest in a research strategy that aims to address high priority needs to ensure that implementation and compliance of the FSMA proposed rules is effectively achieved. This investment will allow the Foods Program to develop and validate rapid detective methods that will be shared with State and local government partners and industry to prevent adulteration of the foods supply as well as improve the ability of those partners and industry to identify the cause of foodborne outbreaks.

Food Safety

Food Safety Modernization: Standard Setting, FSMA Implementation, Training, and Federal-State Integration (+$20,586,000)

The Foods Program is creating a modern, prevention-focused, science and risk-based food safety system and implementing FSMA requirements.

With this funding increase, the Foods Program will be able to increase the technical staffing and other capacity needed to develop guidance and provide technical assistance for industry and provide technical support for FDA inspectors, as well as planning and initial implementation of training for FDA and state inspectors. These funds will allow the Foods Program to hire additional staff with critical expertise in the broad range of produce commodities and process operations subject to new FSMA standards. The initial investments in training of FDA and state inspectors will help ensure the quality and consistency of inspections within the new FSMA prevention framework.

Further details on this, as well as the other organizations involved in this initiative appear in the Overview of Budget Request narrative, the Animal Drugs and Feeds Program narrative, the Office of Regulatory Affairs narrative, and the FDA Headquarters narrative.

Proposed Food Import User Fee (+$137,454,000)

One of the most transformative aspects of FSMA is the new set of import authorities and mandate to FDA to create a modern, prevention-oriented import oversight system that can meet the challenges of the global food system, with its complex supply chains and increasing volume of imports. The FSMA provisions create new obligations for food importers to have a risk-based foreign supplier verification program in place to ensure that their suppliers produce food in compliance with appropriate risk-based preventive controls that provide the same level of protection as U.S. standards.

With this funding increase FDA will provide technical assistance and training for industry, the import community, other federal agencies (domestic and foreign) involved in the import process, and FDA personnel to achieve compliance with the new import obligations under FSMA, including successful implementation of the Foreign Supplier Verification Program (FSVP) requirement. FSVP shifts the paradigm for import oversight from response to prevention by making importers responsible for verifying that the food they import into the United States is safe and meets FSMA's food safety standards. Successful implementation of FSVP will greatly increase assurances to consumers that imported food is safe.

To help ensure successful implementation of FSVP and facilitate the import of safe food, FDA will also implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process. The national call center initiative will improve responsiveness to inquiries concerning the import process or the status of imports. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. The implementation of expanded port and border hours will increase port and border coverage by adding staff and expanding hours of operation, thus providing improved screening for food safety while speeding up the overall entry admissibility process for safe products. Moreover, capital

investments will be directed to acquire additional space at various border locations to support this effort. These investments will increase efficiency, improve industry and FDA communication, reduce time to resolve problems, and improve movement of trade in safe food.

Improving the information technology available during import reviews will allow FDA to utilize enhanced risk information and thus allow for risk-based decision making for import personnel. Modern IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives. FDA also plans to utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA. FDA will research, test, validate, and purchase analytical tools for rapid screening of products at the border. The tools will allow for improved risk analytics by permitting the targeting of products with the highest probability of being violative and the rapid release of all others into U.S. commerce. This investment will also allow for the development of FDA's fee collection system that supports the design, testing, and implementation of a system to administer the import user fee program.

Proposed Food Facility Registration & Inspection User Fee (+$50,655,000)

With this investment, FDA will continue to develop and implement a modern, prevention-oriented inspection and compliance program and an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. FDA will implement and enforce preventive controls in food processing facilities, and begin training more than 3,400 (1,100 FDA and 2,300 State) inspection personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. Finally, FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

FDA will provide funding to Federal, state, local, territorial, and tribal regulatory and public health partners in the form of at least 20 grants or cooperative agreements, contracts, or inter-agency agreements between federal agencies. A minimum of 16 of the state grants, contracts, cooperative agreements or inter-agency agreements between federal agencies would be funded with a combination of existing and new budget authority and four (state contracts) would be funded with user fees. FDA also plans to improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations. The resources allocated to planning and response will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

Additionally, FDA will work with government and industry partners to develop new trace-back tools and new systems that unify information received from FDA regulatory partners and private industry. FDA will develop and administer food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard.

Additional resources will be provided to ensure programmatic objectives and implementation of the integrated food safety system are coordinated and provides support for the governance structure. FDA staff will also serve as field State liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards. Moreover, FDA will develop and validate certification testing instruments, serve as Official Establishment Inventory (OEI) Coordinators for the field and support the States as FDA moves to national standards for laboratories.

Proposed Food Contact Substances Notification User Fee (+$4,639,000)

With resources funded by user fees, FDA will expand and develop the Food Contact Notification Program (FCN) to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable FDA to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Proposed Cosmetics Safety User Fee (+$16,995,000)

FDA will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. FDA will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist it in its safety evaluations and product modifications. The user fees will also enable FDA to meaningfully participate in international harmonization efforts for cosmetic standards. With this investment, FDA will refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities. As a result, FDA will be better positioned to fulfill its public health mission and will promote greater safety and understanding of cosmetic products consumers regularly use.

Proposed International Courier User Fee (+$750,000)

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

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

With this new user fee, FDA will:

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

PERFORMANCE

The Foods Program's performance measures focus on premarket application review, incidence of foodborne pathogens, regulatory science activities, and postmarket inspection and import screening activities in order to ensure the safety and proper labeling of the American food supply and cosmetics, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2013: 92% Target: 80% (Target Exceeded)	80%	80%	maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)*	FY 2013 :563 enrolled Target: 564 enrolled (Target Not Met)	584 enrolled	604	+ 20
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2012: 14.3 cases/100,000 CY 2011 Target: 11.9 cases/100,000 (Target Not Met)	11.4 cases/ 100,000	11.0 cases/ 100,000	- 0.4 cases/ 100,000
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2012: 1.12 cases/100,000 CY 2011 Target: 1.09 cases/100,000 (Target Exceeded)	1.00 cases/ 100,000	0.95 cases/ 100,000	- 0.05 cases/ 100,000
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2012: 0.25 cases/100,000 CY 2011 Target: 0.29 cases/100, (Target Exceeded)	0.27 cases/ 100,000	0.27 cases/ 100,000	maintain
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2012: 16.42 cases/100,000 CY 2011 Target: 14.5 cases/100,000 (Target Not Met)	13.9 cases/ 100,000	13.6 cases/ 100,000	- 0.3 cases/ 100,000
212409: Reducing foodborne illness in the population. By December 31, 2013, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 2.1 cases per 100,000. (*Outcome*)	CY 2012: 2.6 cases/100,000 Target: 2.3 cases/100,000 (Target Not Met)	2.0 cases/ 100,000	1.9 cases/ 100,000	- 0.1 cases/ 100,000

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY2013: 5 working days Target: 5 working days (Target Met)	4 working days	4 working days	maintain
214207: The number of systems recognition, assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	FY 2013: 7 assessments completed Target: 8 (Target Not Met)	10	12	+ 2
214201: Number of prior notice import security reviews. *(Output)*	FY 2013: 81,199 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2013: 187,819 Target: 160,158 (Target Exceeded)	160,000	160,000	maintain
214203: Number of Filer Evaluations. (Output)	FY 2013: 1,300 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2013: 10,405 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2013: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	maintain
214209: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 19,500 firms) every three years. *(Output)*	FY 2013: 100% Target: 100% of approximate inventory every three years based on 22,000 firms (Target Met)	33%	67%	+33%
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2013: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	maintain

The following selected items highlight notable results and trends detailed in the performance table.

Pathogen Detection

FDA scientists are evaluating commercially available instrumentation that can be adapted to improve the ability of FDA to more quickly and effectively detect foodborne pathogens. The improvements in sample throughput, along with the high degree of specificity built into this technology, will dramatically improve FDA's response and trace back capabilities. When fully deployed, this technology holds the promise of reducing the time to conduct these analyses from 14 days to less than a week. In FY 2013, FDA met the target of reducing the average number of days to serotype priority pathogens in foods to five days.

Voluntary National Retail Food Regulatory Program Standards

Strong and effective regulatory programs at the state, local and tribal level are needed to prevent food borne illness and reduce the occurrence of food borne 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 food borne illness. FDA missed its FY 2013 target by one enrollee, because while the number of new enrollees (35) exceeded the expected number for FY 2013, the number of jurisdictions that dropped their enrollment (19) was higher than expected.

System Recognition

FDA developed the Systems Recognition tool to support both the establishment of regulatory partnerships and the identification of opportunities to leverage resources, aligning well with key strategies of FDA's Pathway to Global Product Safety and Quality. Systems recognition provides objective criteria and a robust process for determining which food safety systems provide a level of assurance whereby FDA can confidently leverage the work conducted by food safety authorities in countries with comparable food safety systems, while focusing FDA resources where most needed. System recognition assessments of regulatory food safety systems include reviews of self-assessments provided to FDA by foreign governments, as well as in-country audits. In FY 2013, FDA missed the target by one self-assessment because, due to circumstances outside of FDA's control, one country that had requested FDA to initiate a systems recognition assessment, and was considered a viable candidate for systems recognition, had not yet completed their self-assessment.

Foodborne Illness

FDA's Priority Goal for decreasing the rate of *Salmonella* Enteritidis is a long-term outcome goal that reflects the Foods Program focus on better addressing foodborne illness from farm to table. Although FDA has not yet met the target for this goal, the rate of incidence is decreasing, and the partnership with the Centers for Disease Control and Prevention has been beneficial in improving data collection and attribution.

FSMA High Risk Domestic Inspection Coverage

FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world. ORA plays a critical role in the implementation of FSMA; and the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting 100 percent of the high-risk domestic inventory every three years. The FY 2014 target represents the first year of a three-year cycle. This goal serves to cumulatively track the progress over the three year period as the coverage of inventory approaches the FSMA requirement of 100 percent. At the time of enactment, the legislation permitted a five-year cycle to meet the level of inspection coverage; and 100 percent of coverage to be met in three-year cycles thereafter. The close of FY 2013 marked a milestone in which FDA met the five year high-risk goal in three years.

Increase Laboratory Surge Capacity

A critical component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of sample of potentially contaminated foods for the presence of contaminants. Maintaining 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.

PROGRAM ACTIVITY DATA

Foods Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Food and Color Additive Petitions			
Petitions Filed [1]	15	10	10
Petitions Reviewed [2]	12	7	7
Substances			
Notifications Received	111	114	114
Notifications Reviewed [3]	109	100	100
Infant Formula Notifications			
Notifications Received [4]	32	40	40
Notifications Reviewed [5]	32	40	40
FDA Review Time	90 Days	90 Days	90 Days
New Dietary Ingredient Notifications [6]			
Submissions Received [7]	29	50	75
Submissions Reviewed [8]	29	50	75
FDA Review Time	75 Days	75 Days	75 Days

[1] This number is for the cohort of petitions filed in the FY.

[2] Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.

[3] Number reviewed includes notifications that became effective or were withdrawn.

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

[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 has received at least 15 notifications that pertain to 2 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 are 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 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,658***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,403	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	210		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	232		
Domestic Fish & Fishery Products (HACCP) Inspections	1,012		
Import (Seafood Program Including HACCP) Inspections	135		
Juice HACCP Inspection Program (HACCP)	146		
Interstate Travel Sanitation (ITS) Inspections	904		
Domestic Field Exams/Tests	2,272	3,945	3,945
Domestic Laboratory Samples Analyzed	10,466	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,403*** [1]	***1,200***	***1,200***
All Foreign Inspections	1,403	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,061***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	187,819	160,200	160,200
Import Laboratory Samples Analyzed	29,810	35,300	35,300
Import Physical Exam Subtotal	**217,629**	**195,500**	**195,500**
Import Line Decisions	11,502,065	12,201,809	12,201,809
Percent of Import Lines Physically Examined	1.89%	1.60%	1.60%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	81,199	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,355***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***269***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,137	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	967	1,104	1,104
State Contract Juice HACCP	89	103	103
State Contract LACF	75	68	68
State Partnership Inspections	269	273	273
State Contract Foods Funding	$13,741,087	$13,076,000	$13,076,000
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$18,455,000	$18,455,000	$18,455,000
Total State & Annual FERN Funding	**$32,196,087**	**$31,531,000**	**$31,531,000**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,685***	***20,496***	***20,496***

[1] The FY 2013 actual unique count of foreign inspections includes 65 OIP inspections (45 for China and 20 for India).

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**100**	**100**	**100**
Domestic Inspections	125	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**0**	**0**	**0**
Foreign Inspections	5	0	0
IMPORTS			
Import Field Exams/Tests	2,925	1,600	1,600
Import Laboratory Samples Analyzed	461	540	540
Import Physical Exam Subtotal	**3,386**	**2,140**	**2,140**
Import Line Decisions	2,433,747	2,883,187	2,883,187
Percent of Import Lines Physically Examined	0.14%	0.07%	0.07%
GRAND TOTAL COSMETICS ESTABLISHMENT	**130**	**100**	**100**

HUMAN DRUGS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Human Drugs	**1,186,882**	**1,040,607**	**1,289,304**	**1,335,840**	**46,536**
Budget Authority	***438,549***	***438,550***	***466,374***	***479,678***	***13,304***
User Fees	***748,333***	***602,057***	***822,930***	***856,162***	***33,232***
Center	1,007,540	904,802	1,097,515	1,136,290	38,775
Budget Authority	319,497	319,495	339,838	347,513	*7,675*
User Fees	688,043	585,307	757,677	788,777	*31,100*
Prescription Drug (PDUFA)	*480,774*	*486,148*	*534,526*	*561,252*	*26,726*
Generic Drug (GDUFA)	*192,721*	*99,159*	*207,475*	*211,625*	*4,150*
Biosimilars (BsUFA)	*14,548*	---	*15,676*	*15,900*	*224*
Field	179,342	135,805	191,789	199,550	7,761
Budget Authority	119,052	119,055	126,536	132,165	*5,629*
User Fees	60,290	16,750	65,253	67,385	*2,132*
Prescription Drug (PDUFA)	*9,811*	*7,244*	*10,908*	*11,453*	*545*
Generic Drug (GDUFA)	*49,253*	*9,506*	*53,023*	*54,083*	*1,060*
Biosimilars (BsUFA)	*1,226*	---	*1,322*	*1,348*	*26*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*501*	*501*
FTE	**4,277**		**5,218**	**5,510**	**292**

Authorizing Legislation: 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[2]; 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[2]; Public Health Service Act of 2010 (42 U.S.C. 262); Protecting Patients and Affordable Care Act of 2010[2]; Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA); Drug Quality and Security Act (2013)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA's Human Drugs Program is responsible for ensuring the safety and efficacy of prescription, generic, and over-the-counter (OTC) drug products that are available to the American public, monitoring marketed drug products to ensure patient safety, and monitoring drug quality to ensure the safety of the drug supply chain. The Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) field drugs program are the two components of the Human Drugs Program, which operates with funding from appropriations and user fees.

The Program's mission is to promote and protect public health by ensuring safe and effective drugs are available to Americans. The Human Drugs Program supports the FDA priorities of improving health care quality and reducing health care costs.

Promoting Patient Access to FDA-Regulated Medical Products

The goal of the Human Drugs Program is to promote the health of the public by ensuring that prescription and over the counter (OTC) human drug products, including brand and generic products, are safe and effective. In addition, FDA aims to ensure that novel prescription drugs become available in a timely manner without compromising high standards of safety and efficacy. The Human Drugs Program aligns to FDA's strategic goal of promoting public health by advancing the safety and efficacy of medical

products. The following selected accomplishments demonstrate the Human Drugs Program's delivery of its regulatory and public health responsibilities within the context of current priorities.

FDA has achieved significant recent accomplishments with implementing several components of the Food and Drug Safety and Innovation Act (FDASIA). Accomplishments include implementing two new user fee programs, the Generic Drug User Fee Amendments (GDUFA) and the Biosimilars User Fee Act (BsUFA), as well as the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

PDUFA V, GDUFA, and BsUFA launched on October 1, 2012. GDUFA and BsUFA will deliver tremendous public health benefits resulting from the availability of generic drugs and biosimilar biological drugs which provide patients with more affordable treatments. PDUFA V ensures that FDA will continue to receive consistent funding from FY 2013 through FY 2017 that will enhance the capacity to fulfill its mission of bringing to market novel drug products for patients.

Generic drug review is a high priority for the Human Drugs Program and the review function supports the larger FDA mission of promoting and protecting public health. With increasing healthcare costs, many Americans face challenges in acquiring the drug products necessary for proper medical treatment. The availability of generic drugs directly impacts public health by making safe, affordable drug products accessible to the public, making it possible for more patients to afford essential medicines. In FY 2013, FDA successfully surpassed the performance goal to hire and train at least 25 percent of GDUFA reviewers, inspectors, and support staff to reduce review times, build and enhance systems, and achieve other key performance goals for the generic drug review program.

In FY 2013, FDA also produced additional draft guidance for industry, Biosimilar Initial Advisory and Biosimilar Product Development (BPD) Phase Meetings. This guidance was negotiated as part of the Biosimilar Biological Product Authorization Performance Goals and Procedures for FY 2013 through FY 2017 and was published a year in advance of the agreed goal for publication. Also in FY 2013, FDA held two *FDA Basics* webinars, providing an overview of biological products and biosimilar products for consumers as part of FDA's biosimilar educational outreach efforts.

At U.S. borders, FDA determines product admissibility by performing entry reviews, field exams, and sample collections to ensure that products coming into the United States are from approved sources and are properly registered. In FY 2013, FDA performed field/label examinations and sample collections on 22,775 and 355 import entry lines, respectively, of human drug products and refused more than 16,035 import entry lines of violative products. Additionally, after screening 264 imported dietary supplement products, FDA investigators found 225 of the products screened positive for the presence of Sibutramine, an active pharmaceutical ingredient. FDA worked with U. S. Customs and Border Protection (CBP) to seize a number of these products; FDA refused admission to those products that were not seized by CBP. All were denied entry into the U.S.

FDA conducts inspections of both domestic and foreign high-risk drug establishments on a periodic basis for surveillance purposes. In FY 2013, field investigators have inspected 443 domestic high-risk drug establishments and 365 high-risk foreign drug establishments. As a result of these foreign inspections, 43 Good Manufacturing Practices (GMP) based warning letters were issued.

Ensuring Product Quality and Patient Safety

The Human Drugs Program provides comprehensive regulatory coverage of the production and distribution of drug products and manages inspection programs designed to minimize consumer exposure to defective or harmful drug products. FDA evaluates the findings of inspections that examine the conditions and practices in facilities where drugs are manufactured, packed, tested, and stored. FDA also monitors the quality of finished drug products in distribution through sampling and analysis.

FDA's post market safety activities exist to monitor the safety and efficacy of drugs that are available to consumers. FDA also aims to identify and communicate risks associated with approved drugs. The

ongoing activities associated with post market safety allow FDA to discover risks associated with drug products that could not have been discovered during pre-market review. These efforts aim to protect patients from adverse events or improper use of drug products that could result in potentially harmful effects. The Food and Drug Administration Amendments Act (FDAAA) required FDA to establish an active surveillance system for monitoring drugs using data from electronic healthcare information. FDA's response to that requirement was the launch of the Sentinel Initiative. The Sentinel Initiative provides significant public health benefits by developing new approaches and methods to monitor the safety of marketed medical products to complement existing FDA surveillance capabilities. Increased access to large quantities of data enhances FDA's ability to detect and understand safety signals to better inform patients and healthcare providers on the safe use of regulated products. In FY 2013, the Human Drugs Program expanded surveillance to 149 million patients, which is an 18 percent marginal growth increase of 23 million patients from FY 2012. To date, Sentinel has contributed to several drug safety communications and labeling changes to better inform patients and providers on safe use.

FDA is also responsible for reviewing prescription drug information to ensure that healthcare professionals and consumers receive drug information that is truthful, balanced, and accurate. Prescription drug information available to physicians and consumers is critical for the safe and effective use of these products. FDA analyzes Direct-To-Consumer (DTC) advertisements (intended for consumers) and professional promotions (intended for healthcare professionals) to ensure that information presented to the intended audiences is truthful and presents both the benefits and risks of drugs.

FDA monitors recalls of human drugs that have been found to present safety concerns, and assures the adequacy of a firm's ability to recall and effectively remove defective products from commerce. In FY 2013, FDA classified and issued 46 Class I, 192 Class II, and 101 Class III drug recall events. In FY 2013 there were five injunctions and one seizure against drug manufacturers. In FY 2013, FDA's Office of Criminal Investigations made 303 drug-related arrests and secured 273 drug-related convictions with fines, restitutions, and other monetary penalties in excess of $2.3 billion.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$949,645,000	$477,502,000	$472,143,000
FY 2012 Actual	$954,596,000	$477,623,000	$476,973,000
FY 2013 Actual	$1,040,607,000	$438,550,000	$602,057,000
FY 2014 Enacted	$1,289,304,000	$466,374,000	$822,930,000
FY 2015 Budget Request	$1,335,840,000	$479,678,000	$856,162,000

BUDGET REQUEST

The FY 2015 Budget for the Human Drugs Program is $1,335,840,000, of which $479,678,000 is budget authority and $856,162,000 is user fees. This is $46,536,000 above the FY 2014 Enacted level. The Center portion is $1,136,290,000 and the Field portion is $199,550,000. This level of funding will support FDA's ability to fulfill its mission of ensuring safe and effective drugs are available to patients including novel, generic, and biosimilar biological human drug products. The FY 2015 Budget will allow the Human Drugs Program to uphold its public health mission of improving health care quality and reducing health care costs as well as enhance FDA's oversight of pharmacy compounding.

The Human Drugs Program will promote the health of the public by ensuring that prescription and over the counter (OTC) human drug products, including brand and generic products, are safe and effective. FDA will support the safety and efficacy of human drug products throughout the entire drug lifecycle. This will be accomplished by reviewing new drug applications to make sure that safety and efficacy are

demonstrated, a process that draws on the expertise of a wide range of medical and health services personnel, and then by monitoring drugs after they are released to the market for signs that could not have been detected in clinical trials.

Even when safe and effective drugs are made to exacting standards, misuse (intentional or accidental) can still occur. FDA is working to improve the safe use of medical products by examining the communications of risks and benefits associated with those products.

The Human Drugs Program will continue to focus on ensuring that drugs meet FDA standards of quality. FDA's drug oversight activities begin when sponsors test drug products in animals and continue throughout the drug lifecycle, including post market safety activities. CDER also scrutinizes generic drug products to ensure they demonstrate equivalent performance to the innovator product. FDA is fully engaged in enforcement actions against drug products that exist outside of the FDA approval system, such as counterfeit and marketed unapproved products.

The Human Drugs program will also focus on post market safety activities to monitor the safety and efficacy of drugs that are currently available to consumers. FDA aims to identify and communicate risks associated with approved drugs. The ongoing activities associated with post market safety allow FDA to discover risks associated with drug products that could not have been discovered during pre-market review. These efforts aim to protect patients from adverse events or improper use of drug products.

The FY 2015 Budget will also support inspections of drug manufacturers to ensure that products are made according to FDA standards of quality. FDA evaluates the findings of inspections that examine the conditions and practices in facilities where drugs are manufactured, packed, tested, and stored. FDA also monitors the quality of finished drug products in distribution through sampling and analysis.

The FY 2015 Budget will allow FDA field offices to conduct mission-critical testing and inspection activities on drugs in all stages of development and distribution to ensure their safety and efficacy before entering the U.S. market. These activities include clinical support of the NDAs and INDs, field exams, entry reviews, sample collections, laboratory analysis, and inspections of both domestic and foreign facilities.

Additionally, the FY 2015 Budget includes an initiative to enhance FDA's oversight of pharmacy compounding.

Medical Product Safety

Pharmacy Compounding: Inspections and Enforcement, Policy Development, and State Collaboration and Coordination (+$16,989,000)

The Pharmacy Compounding Initiative component of the Human Drugs Program is part of a multi-program initiative to provide more appropriate and effective oversight of pharmacy compounding through investments in inspections and enforcement, policy development, and state coordination. Further details on this initiative as well as the other organizations involved in this initiative appear in the Overview of the Budget Request narrative, Biologics Program narrative, Animal Drugs and Feeds Program narrative, Office of Regulatory Affairs narrative, and FDA Headquarters narrative.

FDA will support case management for inspections of human drug compounding pharmacies including writing the inspection assignments, handling issues that arise during the inspections such as the need to obtain an administrative warrant to access records, assessing the inspection results, and bringing any necessary regulatory or enforcement actions. FDA will continue conducting for-cause inspections in response to adverse event reports, product quality complaints, and state requests. The FY 2015 Budget seeks additional resources to conduct additional proactive inspections of high-risk human drug compounding pharmacies, as well as follow-up inspections of pharmacies identified as needing to take corrective actions during previous inspections.

FDA's additional resources will also support the establishment of the regulatory policy framework to effectively oversee the human drug compounding industry, and enhance FDA's ability to coordinate the regulation of human drug compounding with the states. FDA will support the development of additional regulations and guidance to implement the new legislation and provide standards for the compounding industry.

PERFORMANCE

The Human Drugs Program's performance measures focus on premarket and post market activities, generic drug review actions, drug safety and promotion activities in order to ensure that human drugs are safe and effective and meet established quality standards, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
223210: Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60 day filing date. *(Output)*	N/A New Goal	90%	90%	maintain
223211: Review and act on 90 percent of priority NME NDA and original BLA submissions within 6 months of the 60 day filing date. *(Output)*	N/A. New Goal	90%	90%	maintain
223212: Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt. *(Output)*	FY 2012: 96% (Historical Actual) New Goal	90%	90%	maintain
223213: Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt. *(Output)*	FY 2012: 100% (Historical Actual) New Goal	90%	90%	maintain
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year *(Output)*	FY 2013: 1,302 Target: 2,000 (Target Not Met)	1,350	1,450	+100
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2013: 808 Target: 750 (Target Exceeded)	750	750	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel*pilots. *(Outcome)*	FY 2013: 149 million Target: 135 million (Target Exceeded)	150 million	150 million	maintain
222302: Percentage of television advertisements requiring submission reviewed within 45 days. *(Output)*	FY 2012: Draft guidance issued (Target Met)	Issue final guidance and establish a baseline.	30%	N/A

The following selected items highlight notable results and trends detailed in the performance table.

Review Goals

PDUFA V was authorized by Congress in July 2012. Review Goals 232210, 232211, 232212, 232213 were added in FY 2013 to align with the new PDUFA V performance commitments. Performance results will not be available until the review of the applications for the FY 2013 cohort is complete. The goal of the PDUFA V program is to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval.

The number of actions taken by CDER's generic drug review program has been on an upward trend for the last several years. In FY 2013, the actual number of actions taken on applications was not comparable to the previously developed FY 2013 target because of a new GDUFA program requirement which enhanced the process for issuing ANDA actions. Prior to GDUFA, individual deficiency letters were communicated to the sponsor from multiple disciplines (chemistry, bioequivalence, labeling, microbiology, etc.). Beginning in FY 2013, the GDUFA goals letter required a single complete response letter to convey deficiencies in an application as opposed to multiple deficiency letters from each discipline. This efficiency enhancement resulted in a different method of performing and measuring actions, preventing a comparison to the original FY 2013 target. In order to align the FY 2014 and FY 2015 targets with the latest process enhancements, the targets have been adjusted accordingly. The impact of this process improvement does not reflect a drop in program performance and will prove beneficial to the ANDA process moving forward.

Sentinel

The Sentinel Initiative presents significant public health benefits from expanding surveillance of drugs available to consumers. Access to large quantities of data enhances FDA's ability to detect safety signals and act on post market safety issues. In FY 2013, FDA exceeded the target and expanded surveillance to 149 million patients.

Drug Promotion

In FY 2012, FDA met the target to issue a draft guidance to communicate the categories of television advertisements it generally intends to require sponsors to submit under the provisions outlined in the Food and Drug Administration Amendments Act.

Domestic and Foreign High Risk Inspections

One critically important step toward enhanced consumer protection is FDA's development of a risk-based model to establish consistent, agency-wide priorities when developing annual domestic and foreign field

activities. Important features of the risk-based model 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; including both inherent risk (outbreaks, Class I recalls, adverse events) and compliance history. FDA continues to enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk firms enter the market, or the definition of high risk evolves based on new information on 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 or sample results. FDA has made inspecting high-risk domestic and foreign firms a priority, and has set multiple performance goals for these high-risk facilities. As a result of these efforts, in FY 2013 FDA has met or exceeded inspection targets for human drugs facilities.

PROGRAM ACTIVITY DATA

Human Drugs Program Activity Data (PAD)

CDER Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
New Drug Review			
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	128	128	128
Efficacy Supplements	124	124	124
Manufacturing Supplements	1,762	1,762	1,762
Commercial INDs (Drugs and Biologics) with Activity	5,776	5,776	5,776
Sponsor Requests: IND-Phase Formal Meetings	1,961	1,961	1,961
Sponsor Requests: Review of Special Study Protocols	212	212	212
Submissions of Promotional Materials	86,194	83,000	83,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	20	20	20
Reviews: Standard NDA/BLA	140	140	140
Approvals: Priority NDA/BLA	18	18	18
Approvals: Standard NDA/BLA	81	81	81
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	11	11	11
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	15	15	15
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	6	6	6
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	10	10	10
Reviews: NDA Supplementals	3,095	3,095	3,095
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	6,527	6,984	7,473
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	81	81	81
Receipts: IND/IDE Amendments (Biologics Only)	17,682	17,682	17,682
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	6	6	6
Approvals: PLA/BLA	4	4	4
Reviews: License Supplement (PLA/ELA/BLA)	333	333	333
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	992	992	992
Outputs – Reviews/Approvals			
Actions – ANDA **	1,302	1,350	1,450
Approval Actions - ANDA (both Tentative and Full Approvals)**	523	523	523
Median Review Time from ANDA Receipt to Approval (months) **	36	36	36
Actions - ANDA Supplementals (Labeling and Manufacturing) **	5,474	5,474	5,474
**Assumes GDUFA program implementation as of FY 2013			
Over-the-Counter Drug Review			
OTC Monographs Under Development***	28	28	28
OTC Monographs Published***	1	5	5
***Category includes Proposed Rules and Final Rules			
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	9	8	8
New Written Requests Issued	15	15	15
Pediatric Exclusivity Determinations made	5	7	7
Post Exclusivity Safety Report	8	9	9
Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	1,040,246	1,175,573	1,175,573
Electronic Submissions: % of Total Adverse Drug Reaction Reports	90%	95%	95%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	89%	86%	86%
Submissions: Drug Quality Reports	10,759	11,000	12,500
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	3,029	3,000	3,000
Number of drugs with Risk Communications	145	175	200
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	36	45	45
Number of FOI Requests	2,638	2,500	2,500
Number of FOI Requests Processed	2,805	2,700	2,700
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	91	92	92
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	183	175	175
Number of Citizen Petitions Completed [1/] (excluding suitability petitions and OTC monograph-related petitions)	105	100	100

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

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,851***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	112	171	171
Pre-Approval Inspections (ANDA)	117	216	216
Bioresearch Monitoring Program Inspections	526	563	563
Drug Processing (GMP) Program Inspections	967	591 [2]	591 [4]
Compressed Medical Gas Manufacturers Inspections	173	295	295
Adverse Drug Events Project Inspections	89	120	120
OTC Monograph Project and Health Fraud Project Inspections	59	79	79
Domestic Laboratory Samples Analyzed	1,840	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***827*** [1]	***999***	***999***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	163	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	141	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	190	255	255
Foreign Drug Processing (GMP) Program Inspections	604	843	843
Foreign Adverse Drug Events Project Inspections	6	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,678***	***2,855***	***2,855***
IMPORTS			
Import Field Exams/Tests	7,137	7,200	7,200
Import Laboratory Samples Analyzed	418	490	490
Import Physical Exam Subtotal	**7,555**	**7,690**	**7,690**
Import Line Decisions	590,079	911,465	911,465
Percent of Import Lines Physically Examined	1.28%	0.84%	0.84%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***30***	***0*** [3]	***0***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	0	0	0
State Partnership Inspections: GMP Inspections	30	0	0
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,708***	***2,855***	***2,855***

[1] The FY 2013 actual unique count of foreign inspections includes 67 OIP inspections (17 for China and 50 for India).

[2] The FY 2014 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2013 actuals, but the overall coverage is not changing, This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

[3] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

[4] The pharmacy compounding inspections were not included in the Field Human Drugs Program Activity Data Table (PAD) table because these inspections are not directly accounted for under the categories currently tracked in the PAD. The Good Manufacturing Practices (GMP) inspections line may include some inspections that happened to be conducted at pharmacy compounding facilities, but this number would only account for a subset of the total number of pharmacy compounding inspections.

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OFFICE OF ORPHAN PRODUCTS DEVELOPMENT[7]

	FY 2013Actual	FY 2014Enacted	FY 2015 Request
Program Level[8]	$23,139,897	$23,598,688	$23,598,688
Orphan Product Grants[9, 10]	$12,960,744	$14,035,060	$14,035,060
Pediatric Device Consortia Grants[11]	$3,000,000	$3,000,000	$3,000,000
Program Administration[12, 13]	$7,179,153	$6,563,628	$6,563,628

Authorizing Legislation: Federal Food, Drug and Cosmetic Act (21 U.S.C. 321-399); Orphan Drug Regulations (21 CFR 316); Humanitarian Use Device and Humanitarian Device Exemption Regulations (21 CFR 814 Subpart H); PHS Act (42 U.S.C. 241) Section 301; Safe Medical Device Act of 1990 (as amended) (21 U.S.C. 351-353, 360, 360c-360j, 371-375, 379, 379e, 381); Pediatric Medical Devices Safety and Improvement Act of 2007, Section 305; Food and Drug Administration Safety and Innovation Act of 2013, Section 620

Allocation Method: Direct Federal/Extramural Grants

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

Since its inception in 1982, the public health programs of the Office of Orphan Products Development (OOPD) have promoted and advanced the development of innovative products (drugs, biologics, medical devices, and medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions. An estimated 7,000 rare diseases, with a public health impact affect more than 25 million and many millions more of family members in the United States. Between 85 and 90 percent of these cases are serious or life-threatening.

OOPD administers major provisions of the 1983 Orphan Drug Act (ODA), relevant sections of the 1990 Safe Medical Devices Act, and other statutes, where Congress sought to provide incentives to promote the development of products for the treatment of rare diseases or conditions. OOPD's program activities directly support the Health and Human Services' priority to accelerate scientific advances in lifesaving cures and quality health outcomes. Further, OOPD activities support FDA's strategic priorities by enhancing the process of developing promising new products into safe, effective, and accessible treatments for patients. Specifically, OOPD programs address FDA Strategic Priority (SP) 2.1, "Advance Regulatory Science and Innovation," and SP 2.4, "Expand Efforts to Meet the Needs of Special Populations." One of FDA's signature initiatives in FDA's Strategic Plan is "Scientific Innovation for Rare Disease Therapies."

[7] 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.
[8] Assumes 50 percent of non-grant budget from user fees in FY 2015
[9] Orphan Product Grants are part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.
[10] FY 2013 amount reduced by sequestration and rescissions
[11] Pediatric Device Consortia (PDC) Grants are part of the aggregate amount of budget authority contained in the CDRH budget line item of the All Purpose Tables.
[12] Program Administration is part of the aggregate amount of budget authority contained in the Other Activities budget line item of the All Purpose Tables.
[13] FY 2013 included supplemental increases of $1,971,718 to support Orphan Product Grants and $600,000 to support PDC Grants. FY 2014 and FY 2015 include a supplemental increase of $1,200,000 to support Orphan Product Grants.

Orphan Product Grants Activity

The 1983 Orphan Drug Act created the Orphan Product Grants Program, which is administered by OOPD, to stimulate the development of promising products for rare diseases and conditions. 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. These grants support new and continuing extramural research projects that test the safety and efficacy of promising new drugs, biologics, devices, and medical foods through human clinical trials in very vulnerable populations often with life-threatening conditions.

Of the 650 clinical trials the Orphan Products Grants Program has funded, 54 grants have been used to bring more than 50 orphan products to marketing approval for 48 different serious or life threatening orphan indications. OOPD Grants Program has funded approximately 10 percent of orphan product approvals. In FY 2013, OOPD funded 15 new grants (out of 92 grant applications) and provided funding or continued support for approximately 60 other ongoing clinical study projects.

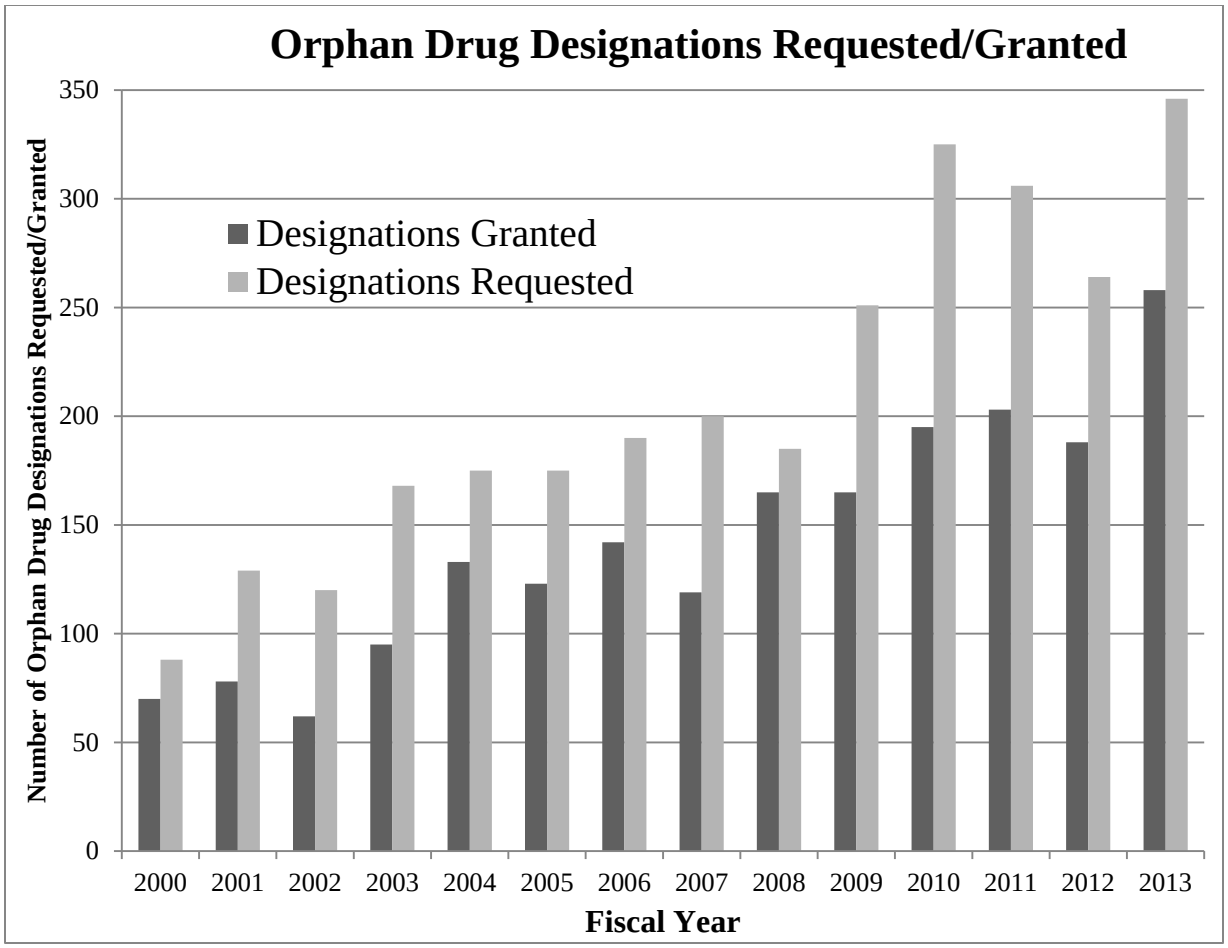
Grants are a very modest investment to better ensure that product development occurs in a timely manner. However, FDA grant funds are covering less and less of the total cost for conducting clinical trials, which continue to increase far faster than the rate of medical inflation. Recent budget cuts and increases in the costs of clinical trials have reduced the capacity of the program to provide the needed monetary support to researchers actively conducting clinical trials that increase the number of new, safe and effective diagnostic and therapeutic options for patients with rare diseases.

Orphan Drug Designation Activity

The 1983 Orphan Drug Act also created the orphan drug designation program which provides financial incentives to sponsors for developing drugs (and biologics) for rare diseases and conditions, which is generally defined as one affecting fewer than 200,000 persons in the United States. OOPD evaluates applications from sponsors who are developing drugs to treat rare diseases to determine eligibility for orphan drug designation. Sponsors whose drugs are designated as orphan are eligible for significant tax credits for clinical trial costs, user fee waiver of marketing applications, and seven years of marketing exclusivity upon approval.

Of the over 2,900 orphan drug designations OPPD issued since 1983, over 450 have resulted in marketing approval, the vast majority with orphan exclusivity. In contrast, the decade prior to 1983 saw fewer than ten such products developed by industry come to market. During FY 2013, OOPD received 3 new applications for orphan drug designation. These included potential treatments for many kinds of rare cancers and sickle cell disease. OOPD designated 235 orphan drugs in FY 2013. FDA approved 36 orphan designated drugs for marketing in FY 2013.

The number of requests for orphan designation has more than doubled since 2000. Not only are the requests increasing, but the complexity of the science associated with these orphan drugs is increasing due to advances in pharmacogenomics and personalized medicine. In FY 2013, 45 percent of all the new molecular entities (NME) FDA approved were orphan designated drugs and biologics.



Humanitarian Use Device Designation Activity

The purpose of the Humanitarian Use Device (HUD) program is to encourage the discovery, development, and use of medical devices intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The HUD program was authorized by the Safe Medical Devices Act and administered by OOPD.

OOPD reviews applications from sponsors requesting HUD designation. A device that has received HUD designation is eligible for humanitarian device exemption (HDE) approval if, among other criteria, the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of available devices or alternative forms of treatment. FDA approval of an HDE application authorizes the applicant to market the device. This marketing approval is subject to certain profit and use restrictions set forth in Section 520(m) of the Federal Food, Drug, and Cosmetic Act. Since 1990, 58 HUD devices have been approved for marketing through the HDE pathway.

Except in certain circumstances, HUDs approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (for profit). Under Section 520(m)(6)(A)(i) of the FD&C Act, as amended by Food and Drug Administration Safety and Innovation Act, a HUD is eligible to be sold for profit after receiving HDE approval if the device meets certain criteria. Currently, eight manufacturers have received approval to market their devices for profit and other sponsors have submitted requests to qualify for the exemption from profit prohibition.

In FY 2013, OOPD received 25 new HUD applications and designated twelve devices. An additional four devices were designated based on HUD applications originally submitted in prior years for a total of 16 HUD devices designated in FY 2013. In FY 2013, one device received an HDE approval from CDRH and five manufacturers received approval to market their devices for profit.

Pediatric Device Consortia Grants Activity

There is a significant public health need for medical devices designed specifically for children. This need is due in part to the lack of commercial incentives and market forces to drive pediatric medical device development, as well as the challenges of pediatric device development including differences in size, growth, development, and body chemistry that impact pediatric device requirements. The Section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (part of the 2007 FDAAA legislation) mandates demonstration grants for improving pediatric device availability through pediatric device consortia.

The FDA Pediatric Device Consortia Grant Program, administered in OOPD, supports nonprofit consortia that promote the development of pediatric medical devices. The program was re-authorized in FY 2013 in the Food and Drug Administration Safety and Improvement Act (FDASIA). In FY 2014, nine consortia are included in this program – seven were awarded grants in FY 2013 as part of a five year cycle, two others continue from the previous grant award cycle. The consortia are based out of Boston, Philadelphia, District of Columbia, Atlanta, Ann Arbor, Los Angeles, San Francisco, and Palo Alto.

Since the Program's inception in 2009, a total of $14.6 million have been awarded to the consortia in five years. Collectively, the consortia have supported the development of more than 240 potential pediatric devices, many of which are in the early stages of development. The success of the consortia has also garnered more than $14 million additional non-federal research dollars to support pediatric device development research.

Outreach Activity

OOPD participates in significant outreach activities by:

- providing information on incentives available to develop products for rare diseases to external stakeholders including industry, the patient community, advocacy groups, and international regulatory agencies
- speaking at meetings and conferences on the FDA designation and approval processes, the Orphan Products Grants Program, and the science of developing therapeutic products for rare diseases/conditions
- assisting patients and advocacy groups on issues of concern related to rare diseases and orphan products, such as drug shortages.

In FY 2013**,** OOPD received more than 51 invitations to speak and participate at orphan drug stakeholder meetings and including conferences. OOPD made presentations and participated in 36 of these meetings, often to explain how orphan drugs and humanitarian devices could be developed with ODA incentives and HDE provisions, as well as FDASIA requirements for rare diseases. At these meetings, the missions of OOPD and FDA were explained, and questions and concerns from stakeholders were addressed. Examples of public health related OOPD outreach activities in FY 2013 include conducting training courses for researchers and reviewers, workshops for drug and device sponsors, and presentations to national and international rare disease patient groups. In FY 2014 through FY 2016, OOPD will continue the outreach efforts to enhance all stages of the development and approval process for products to treat rare disease patients.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$22,785,290	$22,785,290	$0
FY 2012 Actual	$23,636,200	$23,636,200	$0
FY 2013 Actual	$23,139,897	$23,139,897	$0
FY 2014 Enacted	$23,598,688	$23,598,688	$0
FY 2015 Budget Request	$23,598,688	$23,598,688	$0

BUDGET REQUEST

The FY 2015 Budget for the Office of Orphan Products Development is $23,598,688 in budget authority, which is the same as the FY 2014 Enacted level. It will support eight Orphan Product Grants and seven Pediatric Consortia Grants (new and continuations).

PERFORMANCE

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
293207: Percentage of reviews of first-time and amended orphan drug designation applications completed in 90 days or less. *(Output)*	FY 2013: 91% (Historical Actual)	75%	75%	maintain
293208: Percentage of Humanitarian Use Device designation reviews completed in 45 days or less. *(Output)*	FY 2013: 100% (Historical Actual)	95%	95%	maintain

PROGRAM ACTIVITY DATA

PROGRAM WORKLOAD AND OUTPUTS	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Grants Programs			
New Orphan Product Grants Awarded	5	8	8
Total Pediatric Consortia Grants (New and Continuations)	7	7	7
Orphan Drug Requests, Designations, and Market Approvals			
New Designation Requests	330	270	270
Designations	235	189	189
FDA Marketing Approvals	36	20	20
HUD Requests and Designations			
New Designation Requests	25	25	25
Designations	14	14	14

BIOLOGICS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Biologics	**308,010**	**296,866**	**337,543**	**342,639**	**5,096**
Budget Authority	*194,673*	*194,638*	*210,928*	*209,754*	*-1,174*
User Fees	*113,337*	*102,228*	*126,615*	*132,885*	*6,270*
Center	266,608	257,415	292,586	297,773	5,187
Budget Authority	157,571	157,570	170,744	169,890	-854
User Fees	109,037	99,845	121,842	127,883	6,041
Prescription Drug (PDUFA)	*98,932*	*89,720*	*109,993*	*115,493*	*5,500*
Medical Device (MDUFA)	*9,369*	*10,125*	*10,301*	*10,549*	*248*
Generic Drug (GDUFA)	---	---	*774*	*1,052*	*278*
Biosimilars (BsUFA)	*736*	---	*774*	*789*	*15*
Field	41,402	39,451	44,957	44,866	-91
Budget Authority	37,102	37,068	40,184	39,864	-320
User Fees	4,300	2,383	4,773	5,002	229
Prescription Drug (PDUFA)	*4,121*	*1,926*	*4,581*	*4,810*	*229*
Medical Device (MDUFA)	*179*	*457*	*192*	*192*	--
Medical Products Reinspection	---	---	---	---	--
FTE		**1,342**	**1,384**	**1,385**	**1**

Authorization Legislation: Public Health Service Act; Federal Food, Drug, and Cosmetic Act; Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Medical Device Amendments of 1992; Food and Drug Administration Modernization Act of 1997; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness Response Act of 2002; Project BioShield Act of 2004; Medical Device User Fee Stabilization Act of 2005; Food and Drug Administration Amendments Act of 2007; Patient Protection and Affordable Care Act of 2010; Food and Drug Administration Safety and Innovation Act of 2012; and Drug Quality and Security Act of 2013.

Allocation Method: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Biologics Program was established in 1902 with the passage of the Biologics Control Act in the Department of Treasury's Hygienic Laboratory and later became part of the National Institutes of Health (NIH) in 1930. In 1972, the Biologics Program was transferred from NIH to FDA and became the Bureau of Biologics. In 1988, the Bureau became the Center for Biologics Evaluation and Research (CBER) which, with the Office of Regulatory Affairs' (ORA) field investigation program, comprises the FDA Biologics Program.

FDA is responsible for protecting and enhancing public health by ensuring the safety, purity, potency and effectiveness of biological products including vaccines and allergenic products, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries. FDA encompasses the review and approval of safe and effective biological products and works with other Federal agencies, foreign governments and their national regulatory authorities, and international organizations such as the World Health Organization (WHO).

FDA regulates complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science. The Biologics Program also plays an important role in protecting the public against the threat of emerging infectious diseases, neglected tropical diseases, and potential bioterrorism agents.

FDA's strategic goal to Advance Biologics Safety and Effectiveness is focused on four long-term objectives:

- ensure the safety of biological products
- enhance the ability of advances in science and technology facilitate development of safe and effective biological products

- increase the Nation's preparedness to address threats as a result of bioterrorism, pandemic, and emerging infectious diseases
- improve global public health through international collaboration, including research and information sharing.

Major accomplishments for FY 2013 through FY 2014 include:

- issuing a long-term strategic plan and proposed rule concerning drug and biologic product shortages, ensuring safe and effective influenza vaccines are available
- enhancing patient access to new medical treatments for serious conditions by issuing a draft guidance that provides a comprehensive reference for industry on fast track designation, accelerated approval, breakthrough designation, and priority review.

Ensure the Safety of Biological Products

FDA ensures the safety of biological products throughout their lifecycle. Under FDAAA, FDA gained additional authorities to enhance product safety through required postmarket studies, safety labeling changes, and risk evaluation and mitigation strategies. Implementing these tools, FDA carries out surveillance, compliance, and enforcement activities to ensure product safety.

In March 2013, FDA issued an Order to Cease Manufacturing to a fertility clinic responsible for determining the eligibility of anonymous and directed donors of reproductive human cells, tissues, and cellular and tissue-based products. Inspections revealed that the firm failed to provide adequate protections against the risks of communicable disease transmission.

In May 2013, the Biologics Program approved iTrace for Blood Centers, the first device employing Radio Frequency Identification technology cleared for use in blood establishments to track and monitor blood products, in conjunction with barcode identification and labeling processes in place. iTrace enhances blood safety and surveillance by streamlining blood collection and processing and aiding in product tracking and reconciliation, thus preventing the release of unsuitable blood products.

In May 2013, FDA also held a public workshop with NIH and the scientific-medical community to discuss scientific and regulatory challenges associated with the use of Fecal Microbiota for Transplantation (FMT). As a result of discussion during the workshop, the Biologics Program published a final guidance for industry.

In June 2013, the Biologics Program required safety labeling changes for immune globulin products "Immune Globulin Products (Human) intravenous, subcutaneous, and intramuscular." FDA also required safety labeling changes for Rotateq, a rotavirus vaccine, after assessing new safety data from its evaluation of rotavirus vaccines and intussusception. This evaluation was the first protocol-based assessment completed under the Mini- Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, and it demonstrated FDA's enhanced capability to integrate safety signal identification and evaluation with regulatory decision-making. PRISM is evaluating febrile seizures and influenza vaccines, venous thromboembolism and Gardasil (a human papilloma virus vaccine), Kawasaki Disease and Prevnar 13 (a pneumococcal conjugate vaccine). PRISM is also assessing the feasibility of addressing pregnancy and birth outcomes after influenza vaccines.

In September 2013, FDA collaborated with the Centers for Medicare and Medicaid Services (CMS) to monitor Guillain-Barré syndrome after seasonal influenza vaccines among Medicare beneficiaries in near real time using healthcare claims data; the results of the evaluation of Guillain-Barré syndrome after the 2009 H1N1 vaccine using medical chart confirmation in Medicare beneficiaries were published in the American Journal of Epidemiology. The Biologics Program continued development of the Blood Safety Continuous Active-Surveillance Network (BloodSCAN), to create an active pharmacovigilance system for blood and blood products by launching a protocol based evaluation of thromboembolic events and Immune Globulin Products (Human).

The Biologics Program also monitors recalls of biological products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. In FY 2013, FDA classified 4 Class I, 1103 Class II, and 426 Class III biologic recall events

In October 2013, FDA issued a long-term strategic plan to improve the agency's response to imminent or existing shortages, and for longer term approaches for addressing the underlying causes of drug and biologic product shortages and highlighting opportunities for manufacturers and others to prevent shortages by promoting and sustaining quality manufacturing. FDA issued a proposed rule requiring all manufacturers of biologic products to notify FDA of a permanent discontinuance or a temporary interruption of manufacturing likely to disrupt their supply.

In November 2013, FDA issued a Safety Communication and required a change to product labeling for hydroxyethyl starch solutions "Boxed Warning on increased mortality and severe renal injury, and additional warning on risk of the bleeding, for use of hydroxyethyl starch solutions in some settings."

Enhance the Ability of Advances in Science and Technology to Facilitate Development of Safe and Effective Biological Products

The Biologics Program addresses the use of advanced technologies, methods, and relevant scientific discoveries, such as newly identified clinical biomarkers, adaptive clinical trial designs, and genomics in regulatory guidance for industry. The program advances regulatory research that supports product review and the corresponding review processes to reflect the new generation of product evaluation tools and the innovative products FDA expects to see over the next decade. Accomplishments in the development of safe and effective biological products include the following items.

FDA issued draft guidance, "Expedited Programs for Serious Conditions – Drugs and Biologics," which provides a single source for industry on fast track, priority review, accelerated approval, and breakthrough designation, to help enhance accelerated patient access to new medical treatments for serious conditions. Also this year, CBER published seven draft and seven final guidances and provided input to over a dozen Agency guidances intended to facilitate development of safe and effective biological products, while taking into account advances in science and technology.[14]

In March 2013, FDA developed and validated a quantitative risk assessment on the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) in the United States by transfusion of red blood cells, drawing on recommendations made by FDA's Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC). Results were presented to TSEAC.

In April 2013, the Biologics Program approved Kcentra for the urgent reversal of vitamin K antagonist (VKA) anticoagulation in adults with acute major bleeding. Unlike plasma, Kcentra does not require blood group typing or thawing allowing it to be administered more quickly than frozen plasma. FDA held a Workshop on the Application of Advances in Nucleic Acid and Protein Based Detection, to hear scientific advances and encourage manufacturers to bring this technology for multiplex detection of transfusion- transmissible agents forward for approval.

In May 2013, FDA approved Allocord (St. Louis Cord Blood Bank of the SSM Cardinal Glennon Children's Medical Center) and approved HPC, Cord Blood, in June 2013 (LifeSouth Community Blood Centers, Inc.), increasing the total to five cord blood products available to treat patients with disorders affecting the hematopoietic system.

In June 2013, FDA approved RIXUBIS the first recombinant Factor IX product indicated for prophylaxis to reduce the frequency of bleeding events and the likelihood of disabling joint disease. It is also the

[14] Complete information on CBER guidances can be found at: http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances

second approved recombinant Factor IX product, adding to choices for treatment for Factor IX deficient patients and reducing the likelihood of shortages

In July 2013, the Biologics Program approved the second U.S. licensed blood typing and antibody detection and identification system using gel column agglutination technology; this system helps with the resolution of blood typing discrepancies. This approval was based on the review of sixteen Biologics License Applications (BLAs), one efficacy supplement, seven Prior Approval Supplements, and four 510(k)s for S.A. DGGel® cards.

In August 2013, FDA approved the first rapid diagnostic test to detect both Human Immunodeficiency Virus (HIV)-1 antigen and HIV-1/2 antibodies. The Alere Determine HIV1/2 Ag/Ab Combo Test is the first FDA-approved test that distinguishes test results for HIV-1 p24 antigen and HIV-1/2 antibodies in a single test and helps diagnose HIV infection at an earlier time point in outreach settings, allowing infected individuals to seek medical care.

In December 2013, FDA approved Tretten, Coagulation Factor XIII A-Subunit (Recombinant), the first recombinant product for use in the routine prevention of bleeding in adults and children who have a serious, rare clotting disorder, known as congenital Factor XIII A-subunit deficiency.

In January 2014, the Biologics Program held workshops entitled "Strategies to Address Hemolytic Complications of Immune Globulin Infusions" and "Complex Issues in Developing Drug and Biological Products for Rare Diseases," to discuss complex issues in clinical trials for developing drug and biological products for rare diseases. In addition, FDA approved the first Humanitarian Device Exemption (HDE) for the CliniMACS CD34 Reagent System intended for use in a sub-population of patients with Acute Myeloid Leukemia who are in first remission undergoing myeloablative transplant (depletion of bone marrow cells) from a matched sibling donor.

Increase the Nation's Preparedness to Address Threats as a Result of Bioterrorism, Pandemic, and Emerging Infectious Diseases

FDA responds to the challenges of bioterrorism, pandemic and emerging infectious diseases by being proactive in preparing for and facilitating product development to protect the public against these threats and approving products that have been demonstrated to be safe and effective. To increase preparedness, the Biologics Program facilitates the development of both seasonal and pandemic influenza vaccines through expedited regulatory pathways. FDA also supports efforts to increase manufacturing capacity using both new and existing technologies and to develop faster methods for testing the potency of influenza vaccines. Accomplishments in increasing the Nation's preparedness to bioterrorism, pandemic and emerging infectious disease threats include the following items.

The Biologics Program prepared potency reagents and provided them to vaccine manufacturers and other global partners, for the U.S. federal public health response to the appearance of H7N9, a novel avian influenza virus with pandemic potential. The Biologics Program collaborated with NIH to develop a protocol for the conduct of human clinical trials to obtain preliminary safety and immunogenicity data which will inform use of the vaccine in populations.

To date, FDA has approved 15 seasonal influenza vaccines for the United States, including Flucelvax and Flublok, two vaccines that do not use egg-based technology in their manufacturing, which offer the potential for faster start-up of the vaccine manufacturing process in the event of a pandemic. Three new Quadrivalent vaccines were approved, bringing the total licensed to four that increase the likelihood of adequate protection against circulating influenza B strains.

The Biologics Program approved the first adjuvanted vaccine for the prevention of H5N1 influenza, commonly known as avian or bird flu. This vaccine could be used in the event that the H5N1 avian influenza virus develops the capability to spread efficiently from human-to-human, resulting in the rapid

spread of disease across the globe and will be included within the National Stockpile for distribution by public health officials if needed.

FDA initiated a study, in collaboration with CMS and the Center for Disease Control, to compare the effectiveness of Fluzone High-Dose vaccine and the standard dose among the elderly in the United States.

FDA collaborates and provides technical assistance to the Biological Advanced Research and Development Authority and HHS on multiple medical countermeasure initiatives including using mass spectrometry for influenza vaccine potency testing, assessing the potential for the UK Anthrax Vaccine Precipitated production facility to supply vaccines for use in the United States, and establishing Centers for Innovation in Advanced Development and Manufacturing to increase medical countermeasures and pandemic influenza manufacturing capabilities in the United States.

The Biologics Program published promising research on vaccines in peer reviewed publications. One publication showed that baboons provide an excellent model of clinical pertussis; therefore allowing researchers to investigate how Bordetella pertussis bacteria cause disease, how it is spread in a population, how it is prevented by existing vaccines and how those vaccines and their evaluation may be improved in the future. In follow-up to this study, the Biologics Program conducted additional important research that helps provide an understanding of the rising rates of pertussis disease and response to vaccination. In addition, FDA Co-authored two landmark studies related to H1N1 influenza vaccination that provide critical new evidence on the safety of existing vaccines and promising approaches to the development of a universal vaccine to protect against both H1N1 and H5N1 viruses.

In March 2013, FDA approved Botulism Antitoxin Heptavalent for treating patients with symptomatic botulism following exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G. A few hundred cases of symptomatic botulism occur each year due to ingestion of bacterial spores or as a result of improperly canned foods. Botulinum is also a highly potent toxin that can be aerosolized as a bioterrorism agent and is the first biological product to be approved under the "animal rule" since human efficacy studies were not feasible or ethical.

Improve Global Public Health through International Collaboration, Including Research and Information Sharing

As a part of improving public health through international collaboration, the Biologics Program promotes research and information-sharing globally to address diseases and emerging threats impacting human populations; facilitates global access to vaccines and biological products that address critical health needs; harmonizes existing regulatory standards, where feasible to promote global public health; and participates in international scientific efforts to establish and maintain reference materials and standards for biologics. Accomplishments in improving global health include the following items.

FDA conducts regulatory science research and shares results with other WHO Collaborating Centers and the global community to advance product development. FDA contributes to the development of international standards for Dengue Viruses and West Nile Virus, a consensus statement supporting the inclusion of whole blood and red blood cells on the WHO Model List of Essential Medicines, and a consensus position statement on blood donor deferral for men who have had sex with other men.

The Biologics Program worked with WHO Collaborating Centers and other national regulatory authorities to evaluate and select candidate materials that are used as reference standards for hematologic proteins such as Factor VIII and IX, and in the development of international reference preparations for hematological products and blood safety related In Vitro Diagnostics.

FDA developed data requirements for influenza virus vaccines to expedite importation. These requirements were implemented in May 2013 and letters were issued to manufacturers in July 2013 specifying data needed on entry documents to expedite vaccine imports into the United States.

Biologics Program staff members served as chair for two international working groups on gene therapy, the Regulators Forum Cell Therapy Group (RFCTG) and the Regulators Forum Gene Therapy Discussion Group, under the International Pharmaceutical Regulators Forum, including meeting with regulatory authorities of nine countries.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$302,020,000	$211,790,000	$90,230,000
FY 2012 Actual	$308,620,000	$212,298,000	$96,322,000
FY 2013 Actual	$ 296,866,000	$ 194,638,000	$ 102,228,000
FY 2014 Enacted	$ 337,543,000	$ 210,928,000	$ 126,615,000
FY 2015 Budget Request	$ 342,639,000	$ 209,754,000	$ 132,885,000

BUDGET REQUEST

The FY 2015 Budget for the Biologics Program is $342,639,000, of which $209,754,000 is budget authority and $132,885,000 is user fees. This is $5,096,000 above the FY 2014 Enacted level. The Center portion is $297,773,000 and the Field portion is $44,866,000.

FDA is committed to advancing public health through innovative regulation that promotes the safety, effectiveness, and timely delivery of biological products to patients.

In FY 2015, the Biologics Program will address threats as a result of bioterrorism, pandemic, and emerging infectious diseases, including facilitating development, evaluation, and availability of high-priority medical products and countermeasures. FDA will develop reagents, evaluate new methods, implement policies, engage with industry on emerging scientific and regulatory issues, and develop models to better understand disease pathogenesis and response.

The Biologics Program will improve global public health through international collaboration by facilitating global access to vaccines and biological products that address critical health needs, including promoting research and sharing information to address global diseases and emerging threats impacting human populations.

FDA is strategizing to harmonize existing regulatory standards and cooperate with international scientific efforts to establish and maintain reference materials and standards for biologics.

The Biologics Program will advance science and technology to bring products to market by developing and issuing guidance and regulations to communicate scientific and regulatory requirements, provide recommendations and frameworks for product development, develop policy and take appropriate regulatory actions on premarket product submissions. In addition, FDA will advance regulatory research to facilitate product review, including development of animal models, genomics, proteomics, high-sensitivity gene sequencing, biomarkers to improve the evaluation of effectiveness of products in clinical trials, and other cutting-edge scientific technologies.

FDA is striving to ensure safety of biological products by conducting a robust postmarket program after products are approved and evaluate the results of clinical studies, including use of healthcare data to move to active surveillance, enhance statistical data analysis and mathematical models for improved epidemiological and risk assessment of regulated products.

Medical Product Safety

Pharmacy Compounding: Inspections and Enforcement and Policy Development Coordination (+$454,000)

The Pharmacy Compounding Initiative component of the Biologics Program is part of a multi-program initiative to provide more appropriate and effective oversight of pharmacy compounding through investments in inspections and enforcement, policy development, and state coordination. This initiative will support inspections and enforcement of high-risk pharmacy compounding facilities regulated by the Biologics Program. Also, the Biologics Program will participate in policy development activities with the Human Drugs Program with emphasis on cases and policies that affect biological products regulated by the Biologics Program. Further details on this initiative as well as the other organizations involved in this initiative appear in the Overview of the Budget Request narrative, Human Drugs Program narrative, Animal Drugs and Feeds Program narrative, Office of Regulatory Affairs narrative, and FDA Headquarters narrative.

PERFORMANCE

The Biologics Program's performance measures focus on biological product review, manufacturing diversity and capacity for influenza vaccine production and postmarket inspections for ensuring the safety, purity, potency, and effectiveness of biological products, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
233207: Review and act on standard New Molecular Entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the 60 day filing date. (Output)	NA New Goal	90%	90%	maintain
233208: Review and act on priority NME NDA and original BLA submissions within 6 months of the 60 day filing date. (Output)	NA New Goal	90%	90%	maintain
233209: Review and act on standard non-NME original NDA submissions within 10 months of receipt. (Output)	NA New Goal	90%	90%	maintain
233210: Review and act on priority non-NME original NDA submissions within 6 months of receipt. (Output)	NA New Goal	90%	90%	maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (Output)	FY 2012: 100% Target: 90% (Target Exceeded)	90%	90%	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (Output)	FY 2012: 100% Target: 90% (Target Exceeded)	90%	90%	maintain
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (Output)	FY 2012: 99% Target: 90% (Target Exceeded)	90%	90%	maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2013: Developed and evaluated new methods to produce high-yield influenza vaccine reference strains.(Target Met)	Continue evaluation of new methods to produce high-yield influenza vaccine reference strains.	Continue evaluation of new methods to produce high-yield influenza vaccine reference strains.	maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. (Output)	FY 2013: 1,031 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
234203: Number of human foreign and domestic tissue establishment inspections. (Output)	FY 2013: 669 Target: 533 (Target Exceeded)	570	570	maintain

The following selected items highlight notable results and trends detailed in the performance table.

Review Goals

FDA continues to exceed the standard PDUFA efficacy supplements and blood bank and source plasma review goals. Review Goals 233207, 233208, 233209 and 233210 were added in FY 2013 to align with the new PDUFA V performance commitments. Performance results will not be available until November 2014, when the review of the applications for the FY 2013 Cohort is complete. In October 2013, CBER approved its first product under PDUFA V. CBER approved Novoeight, Antihemophilic Factor (Recombinant), for use in adults and children with hemophilia A for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. No material of human or animal origin is used in the establishment of the production cell line, cell culture, purification, or formulation of Novoeight.

Influenza Goal

This performance goal supports the Department's national preparedness efforts in combating the seasonal influenza outbreak, by increasing manufacturing diversity and capacity for influenza vaccine production. Further information on this goal can be found in the Department's Online Performance Appendix.

In FY 2013, FDA met the target to develop and evaluate new methods to produce high-yield influenza vaccine reference strains. Activities to meet this target include the following examples.

FDA evaluated multiple assays to determine the best methods for assessing vaccine reference strain yield. The results indicated that a single method was insufficient for an accurate assessment of a candidate vaccine's potential for vaccine manufacturing and that multiple methods should be utilized.

FDA approved further modifications to previously developed influenza vaccine reference strains for the 2009 H1N1 pandemic strain, increasing hemagglutinin (HA) yield. HA yield is important to produce the needed quantity of vaccine and helps to ensure rapid availability of vaccines.

One new influenza reference strain was developed as a possible vaccine candidate for the H7N9 influenza virus that emerged in China during 2013. This reference strain has been shared with the WHO collaborating centers.

PROGRAM ACTIVITY DATA

Biologics Program Activity Data (PAD)[1]

Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Original Biologics License Applications (BLA)			
Workload /2	25	25	25
Total Decisions /3	60	60	60
Approved	32	32	32
BLA Efficacy Supplements			
Workload /2	16	16	16
Total Decisions /3	15	15	15
Approved	11	11	11
BLA Manufacturing Supplements			
Workload /2	1,201	1,201	1,201
Total Decisions /3	1,470	1,470	1,470
Approved	1,129	1,129	1,129
BLA Labeling Supplements			
Workload /2	208	208	208
Total Decisions /3	245	245	245
Approved	221	221	221
Original New Drug Application (NDA)			
Workload /2	0	0	0
Total Decisions /3	2	2	2
Approved	2	2	2
NDA Efficacy Supplements			
Workload /2	2	2	2
Total Decisions /3	1	1	1
Approved	1	1	1
NDA Manufacturing Supplements			
Workload /2	49	49	49
Total Decisions /3	87	87	87
Approved	15	15	15
NDA Labeling Supplements			
Workload /2	13	13	13
Total Decisions /3	12	12	12
Approved	5	5	5
Original Abbreviated New Drug Application (ANDA)			
Workload /2	0	0	0
Total Decisions /3	1	1	1
Approved	0	0	0
ANDA Efficacy Supplements			
Workload /2	0	0	0
Total Decisions /3	0	0	0
Approved	0	0	0
ANDA Manufacturing Supplements			
Workload /2	2	2	2
Total Decisions /3	6	6	6
Approved	1	1	1
ANDA Labeling Supplements			
Workload /2	1	1	1
Total Decisions /3	2	2	2
Approved	1	1	1
Device 510Ks			
Workload /2	59	59	59
Total Decisions /3	56	56	56
Final Decision - SE	43	43	43

Biologics Program Activity Data (PAD)[1]

Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Device Premarket Applications (PMA)			
Workload [/2]	1	1	1
Total Decisions [/3]	2	2	2
Approved	2	2	2
Device Premarket Applications (PMA) Supplements			
Workload [/2]	48	48	48
Total Decisions [/3]	50	50	50
Approved	24	24	24
Investigational New Drugs (IND)			
Receipts: IND (new)	424	424	424
Receipts: IND Amendments	8,821	8,821	8,821
Total Active IND [/4]	2,010	2,010	2,010
Investigational Device Exemptions (IDE)			
Receipts: IDE (new)	12	12	12
Receipts: IDE Amendments	296	296	296
Total Active IDE [/4]	117	117	117
Patient Safety			
Adverse Event Reports Received [/5]	42,786	43,000	43,000
Biological Deviation Reports Received	54,716	55,000	55,000
Sponsor Assistance Outreach			
Meetings	403	403	403
Final Guidance Documents [/6]	37	30	30
Admin/Management Support			
Advisory Committee Meetings Held	16	17	17
FOI Requests Processed	335	350	350

[1/] Please note that the PAD presentation changed from the FY 2014 Congressional Budget Submission to be consistent with the format of other medical product program PAD presentations.

[2/] Workload includes applications received and filed.

[3/] Total Decisions include approved, denied, withdrawn, approvable, approvable pending inspection, not approvable, exempt, major deficiency, substantially equivalent (SE), not substantially equivalent (NSE), de novo and complete response (CR).

[4/] Total Active includes investigational applications received and existing applications for which CBER has received at least one amendment (IND) or supplement (IDE) during the FY being reported.

[5/] Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports or Medical Device Reports for CBER-regulated medical devices.

[6/] Includes all FDA final guidances issued by CBER and other FDA centers that pertain to biological products.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,004***	***2,047***	***2,047***
Bioresearch Monitoring Program Inspections	89	100	100
Blood Bank Inspections	758	1,000	1,060
Source Plasma Inspections	186	194	194
Pre-License, Pre-Market Inspections	14	7	7
GMP Inspections	35	28	28
GMP (Device) Inspections	6	7	7
Human Tissue Inspections	669	661	661
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***74***	***47***	***47***
Bioresearch Monitoring Program Inspections	24	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	8	8	8
Pre-License, Pre-market Inspections	8	2	2
GMP Inspections (Biologics & Device)	30	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***2,078***	***2,094***	***2,094***
IMPORTS			
Import Field Exams/Tests	37	45	45
Import Line Decisions	74,402	97,198	97,198
Percent of Import Lines Physically Examined	0.05%	0.05%	0.05%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,078***	***2,094***	***2,094***

ANIMAL DRUGS AND FEEDS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Animal Drugs and Feed	154,656	147,774	173,207	189,536	16,329
Budget Authority	*125,962*	*125,841*	*141,566*	*144,577*	*3,011*
User Fees	*28,694*	*21,933*	*31,641*	*44,959*	*13,318*
Center	102,272	98,726	115,461	119,339	3,878
Budget Authority	77,242	77,242	87,846	90,505	2,659
User Fees	25,030	21,484	27,615	28,834	1,219
Animal Drug (ADUFA)	*19,685*	*16,917*	*20,768*	*19,814*	*-954*
Animal Generic Drug (AGDUFA)	*4,827*	*4,567*	*6,302*	*5,995*	*-307*
Food and Feed Recall	*518*	---	*545*	---	*-545*
Food Facility Registration and Inspection	---	---	---	*1,557*	*1,557*
Food Import	---	---	---	*1,468*	*1,468*
Field	52,384	49,048	57,746	70,197	12,451
Budget Authority	48,720	48,599	53,720	54,072	352
User Fees	3,664	449	4,026	16,125	12,099
Animal Drug (ADUFA)	*339*	*291*	*472*	*404*	*-68*
Animal Generic Drug (AGDUFA)	*156*	*158*	*220*	*186*	*-34*
Food and Feed Recall	*635*	---	*668*	---	*-668*
Food Reinspection	*2,534*	---	*2,666*	*807*	*-1,859*
Food Facility Registration and Inspection	---	---	---	*1,038*	*1,038*
Food Import	---	---	---	*13,690*	*13,690*
Medical Products Reinspection	---	---	---	---	--
FTE	773		844	871	27

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act (42 U.S.C. 201, *et seq.*); 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; FDA Export Reform and Enhancement Act of 1996; 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; 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; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendment Act of 2007; Animal Drug User Fee Amendments of 2008 (P.L. 110-316); Animal Generic Drug User Fee Act of 2008 (P.L. 110-316); Patient Protection and Affordable Care Act; FDA Food Safety Modernization Act (P.L. 111-353); FDA Safety and Innovation Act (P.L. 112-144); Animal Drug User Fee Reauthorization Act of 2013 (P.L. 113-14); Animal Generic Drug User Fee Reauthorization Act of 2013 (P.L. 113-14); Drug Quality and Security Act (2013)

Allocation Methods: Competitive grant; Contract; Direct Federal/intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Animal Drugs and Feeds Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The mission of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety of the American food supply, as well as the safety of animal feed and the safety and effectiveness of animal drugs and devices. The FVM Program is comprised of the Animal Drugs and Feeds and the Foods Programs, and related field-based activities managed by the Office of Regulatory Affairs (ORA). The Animal Drugs and Feeds and the Foods Programs are administered by the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Nutrition (CFSAN) respectively. The Office of Foods and Veterinary Medicine provides leadership and strategic direction to the FVM Program, including direct oversight of all activities of CVM and CFSAN, and manages the crosscutting outbreak response and evaluation team.

The Animal Drugs and Feeds and the Foods Programs are administered by the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Nutrition (CFSAN) respectively, both in collaboration with the Office of Regulatory Affairs (ORA). CVM is responsible for ensuring the safety and effectiveness of animal drugs as well as ensuring the safety of animal feed. CFSAN is charged with

ensuring the safety of the human food supply, dietary supplements, and cosmetics as well as ensuring proper labeling of foods and cosmetics.

The Animal Drugs and Feeds Program began in 1968 with the amendment of the Federal Food, Drug, and Cosmetic (FD&C) Act to include new authorities for regulating animal drugs, devices, and additives used in animal feed. The Animal Drugs and Feeds Program supports FDA's mission by approving safe and effective products for animals and by enforcing applicable provisions of the FD&C Act and other authorities. Safe and effective animal drugs and feed additives play an important role in protecting animal health and the safety of America's food supply.

Congress recognized the unique challenges FDA faces in the area of food safety in the 21st Century and gave FDA a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act of 2011 (FSMA). FSMA directs FDA to build a food and feed safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA Foods and Veterinary Medicine Program (FVM) Strategic Plan[15] provides a framework for the implementation of FSMA, places high priority on the prevention of foodborne illness of unknown origins and illness that can be specifically attributed to known sources, as well as regulating the safety and effectiveness of animal drugs. In support of this endeavor, the Animal Drugs and Feeds Program is aligned with the Foods and Veterinary Medicine Strategic Plan goals of standards setting, compliance, risk assessment and regulatory science, nutrition and food labeling, response, and animal drug safety.

In order to achieve the goals of the FVM Strategic Plan, the Animal Drugs and Feeds Program focuses on providing timely premarket review of new animal drugs, ensuring that approved drugs are being used appropriately, providing scientific research solutions that ensure safety of the animal derived food and health products, putting measures in place to minimize the illegal sale of compounded and unapproved drugs and preventing marketing of unsafe products. The Animal Drugs and Feeds Program also ensures that animal drugs and feeds used in the care of food producing animals do not result in unsafe residues in food products that are harvested or produced (for example, milk) from these animals. Further, the Animal Drugs and Feeds Program protects the health of companion animals and addresses zoonotic diseases – animal diseases that can be transmitted to humans. These efforts contribute to a food supply that is safe for both humans and animals, and protects billions of poultry, cattle, swine, horses and minor animal species, as well as more than 150 million companion animals in the United States.

A combination of appropriations and user fee programs fund the regulatory process to assure product safety and effectiveness. User fees are authorized under the Animal Drug User Fee Act (ADUFA), the Animal Generic Drug User Fee Act (AGDUFA), and the FDA Export Reform and Enhancement Act (Export Certification program). The ADUFA and AGDUFA user fee programs supplement the appropriated portion of the new animal drug review program to continue improving the quality and timeliness of the pioneer animal drug and generic new animal drug review processes. The Export Certification user fee program promotes the export of products made in the United States and facilitates international trade.

The Animal Drugs and Feeds Program had many recent major accomplishments. These accomplishments include the reauthorization of the Animal Drug User Fee Act and Animal Generic Drug User Fee Act in June 2013, the finalization of Guidance for Industry #213 implementing a plan to help phase out the use of medically important antimicrobials in animals for food production purposes in December 2013, and the use of grant funds to bolster efforts to validate testing methods as part of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) in FY 2013.

[15] The strategic plan can be found on the FDA website.

The following, selected accomplishments demonstrate the Animal Drugs and Feeds Program's delivery of its regulatory and public health responsibilities within the context of current priorities.[16]

Standard Setting

The Animal Drugs and Feeds Program supports the use of preventive control standards to prevent all food and feeds from becoming contaminated. Prevention is the cornerstone of an effective and proactive food safety strategy. FDA is able to protect consumers and animal populations with the use of scientific and analytical tools to better identify food safety risks, effective control measures and food safety standards.

Preventive Controls for Animal Food

The Animal Drugs and Feeds Program drafted the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" proposed rule for animal food. The proposed rule was posted for comment in the Federal Register in October 2013. The purpose of the regulation is to establish requirements for current good manufacturing practice and preventive controls for the manufacturing, processing, packing, and holding of food for animals. This rule will provide FDA with the ability to implement the modern prevention-focused food safety mandate granted to FDA under FSMA.

Compliance

The Animal Drugs and Feeds Program utilizes appropriate enforcement strategies and regulatory decisions, such as inspections, to maximize prevention efforts and ensure higher rates of compliance with prevention-based and risk-based food and feed safety standards. Working with FDA's state counterparts, the Animal Drugs and Feeds Program conducts targeted, risk-based interventions with emphasis on the points of manufacture and distribution in order to prevent contaminated food and feed from entering the food supply.

Safety Standards

The Animal Drugs and Feeds Program evaluates industry compliance with safety standards throughout the production and handling stages of the global food and feed supply chain. Under FSMA, FDA received authorization to suspend a facility's registration if FDA is determines that food and feed manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Training grants have been awarded to ensure consistent implementation and application of the Integrated Food Safety System (IFSS) and FSMA training requirements as they relate to setting standards and administering training and education programs to State, local, territorial, and tribal food safety officials. For example, a course unit in animal production from the medicated feed and food safety viewpoint was created to address proper use of medicated feeds and avoidance of cross contamination in feed mills. Also, several manuals were developed regarding production animal management and nutrition for beef and dairy cattle and swine.

Enforcement Strategies

The Animal Drugs and Feeds Program protects human and animal health by developing and implementing appropriate enforcement strategies, such as inspections, to ensure the compliance of marketed products. Through the establishment of a High Risk Working Group (HRWG) in FY 2012, FDA identified and addressed policy and process changes required for the implementation of a high risk (HR) inspection program for food and feeds. This information will be used to better target inspections in FY 2013 and beyond.

[16] Please visit FDA.gov for additional program information and detailed news items.

When firms violate the FDA requirements of the FD&C Act, FDA takes regulatory action and assists the firms in reaching full compliance while ensuring that products of concern do not reach U.S. consumers. When firms refuse to comply with FDA regulations, FDA takes further enforcement action to ensure unsafe products do not reach U.S. consumers and requests the firms potential shut down of operations. FDA issued 113 warning letters in FY 2013 as a result of ORA recommendations for regulatory action based on violative inspection findings. In FY 2013, there were 2 injunctions for illegal tissue residues. FDA also monitors recalls of veterinary products and feed and ensures the effectiveness of the firm's recall to remove the defective product from commerce. Additionally, FDA classified 31 Class I (most serious), 18 Class II, and 14 Class III recalls of regulated animal products.

Risk Assessment and Regulatory Science

The Animal Drugs and Feeds Program invests in advanced science and technologies to more efficiently address issues threatening animal drugs, food, and feed. These investments help evaluate risk, surveillance of effectiveness of the food and feed safety system and regulatory science to inform risk evaluation and standard setting activities across the farm-to-table continuum.

Research Studies related to Antibiotic Resistance and Salmonella
FDA provides scientific research solutions that ensure safety of human and animal health. In FY 2013, FDA completed several research studies to assess the safety of distillers grains, which are a by-product of ethanol production and are frequently used in animal feed. When implemented, the residue analytical methods and microbiological techniques developed will allow FDA to determine if the residues of antibiotics used in the fermentation process are at a concentration that can lead to the development of antibiotic resistance. Furthermore, several studies have been conducted to develop more sensitive and specific methods for detecting *Salmonella* in various food and feed samples. Upon further validation, these rapid methods should be valuable tools in routine testing and quantification of *Salmonella* in regulatory samples. FDA released a new Compliance Policy Guide (CPG) for its field staff on actions they intend to take when finding *Salmonella* contamination in food for animals. Under this new CPG, FDA targets its resources more effectively to protect the health of both animals and humans.

PREDICT
Since FDA's completion of the full national rollout of Entry Review and the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to all 16 import Districts, FDA has improved the rules that support a risk-based approach to import screening. PREDICT allows FDA to make efficient and accurate admissibility decisions and allows FDA field office staff to target the examination of higher risk imported products. In FY 2013, FDA refused 115 lines of animal feed and drug products. In FY 2013, FDA has performed 89,000 prior notice risk assessment reviews submitted for imported food and feed shipments and has refused 115 lines of animal feed and drug products.

Nutrition and Food Labeling

The Animal Drugs and Feeds Program protects and enhances animal health by improving the way nutritional and ingredient information for pet foods is communicated to the public. Pet foods, like human foods, must be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled.

Pet Food Safety Standards
Current legislation requires FDA to establish the following pet food standards by regulation:

- ingredient standards and definitions with respect to pet food
- processing standards for pet food
- updated standards for the labeling of pet food that include nutritional and ingredient information.

The Animal Drugs and Feeds Program is working on this legislative mandate. Under the proposed rule for the Preventive Controls for Food for Animals, facilities that manufacture, process, pack, or hold food

for animals, including pet food, would be required to adhere to current good manufacturing practices and implement hazard analysis and risk-based preventive controls. As evidence based approaches for informative labeling in food and feed products are developed, consumers will be able to make healthier choices about the pet food products they select that can support improved health and well-being in animals.

Response

The Animal Drugs and Feeds Program responds to outbreaks and contamination incidents, while enhancing prevention of future food and feed safety issues. Early detection of illnesses associated with food, tracing the source of the outbreak, and removing the contaminated product from the market are critical to containing potential risks to the public.

Vet-LIRN
The Animal Drugs and Feeds Program announced in FY 2013 the availability of grant funds to bolster efforts to validate testing methods as part of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Vet-LIRN is a network of state and university laboratories that receive funding from FDA to increase testing capabilities and assist the agency in its investigations into potential problems with animal feeds (including pet foods) and animal drugs.

Pet Jerky Treats
In FY 2014, FDA continues its investigation of pet illnesses, which may be linked to the consumption of pet jerky treats. Inspections and samples collections have been performed; however, no contaminants have been identified linking the illnesses to the pet food products. FDA continues its investigations of pet jerky treat complaints, conducting over 1000 tests on pet jerky treat products. During 2013 FDA worked closely with veterinary laboratories through Vet-LIRN to conduct over 150 in depth clinical evaluations and test diagnostic samples from ill or deceased animals. FDA continues to conduct consumer complaint follow-ups, inspections, and sample collections and analyses.

Animal Drug Safety

The Animal Drugs and Feeds Program protects human and animal health by conducting pre-market review and approval, and post-market surveillance and compliance oversight of animal drugs, devices and additives used in animal feed. Timely review for safety and effectiveness of new animal drug products is critical to bringing innovative, high quality and safe medical products to market.

Animal Drug Review
The Animal Drugs and Feeds Program increases the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, and do not compromise human health. The animal drug user fee acts require that FDA meet specified timeframes for review and action on 90 percent of applications received during a fiscal year to successfully meet the goals established by the Acts. FDA exceeded both performance goals and completed the review and action on 99.6 percent of original New Animal Drug Applications (NADAs) and other ADUFA sentinel submissions within timeframes specified by ADUFA for applications reviewed in FY 2012. FDA also completed the review and action on 100 percent of original Abbreviated New Animal Drugs and Reactivations and other AGDUFA sentinel submissions as required and within the timeframes in FY 2012. Additionally, FDA championed industry's adoption and use of the CVM Electronic Submission Tool for premarket review launched in FY 2011; as a result electronic submissions rose from 17 percent to 63 percent by the end of FY 2013. Because all paper submissions from the industry are scanned, FDA now has 100 percent use of electronic submissions, reviews, and responses.

Animal Drug Inspections
FDA’s field force conducts preapproval inspections to support the review of premarket applications for pioneer and generic animal drugs. The field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. Also, FDA performs

inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices have been followed. Accurate data is essential to the review and approval of new animal drugs and helps to ensure that the rights and welfare of animals are protected.

Animal Drug User Fees Reauthorization
Both ADUFA II and AGDUFA I expired on October 1, 2013. FDA successfully negotiated the reauthorization of the ADUFA and AGDUFA programs, signed into law in June 2013, ensuring FDA highly productive and effective review program continues to be sufficiently resourced to carry on its valuable public health role: getting critical medical products to the market place and thereby improving human and animal health.

Minor User Minor Species
FDA reviews conditional drug approvals and index and designation requests to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species. Further, FDA administers a grant program to support the development of new animal drugs intended for minor species or minor uses in major species. As of December 2013, FDA granted 122 drug designations, mostly related to aquaculture, and added four new animal drugs to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

Compounded and Unapproved Animal Drug Products
In addition to focusing on providing timely premarket review of new animal drugs, FDA is leading the effort to aggressively combat the growing problem of compounded and unapproved animal drug products being marketed and sold. FDA has initiated the regulatory framework that will bring substandard and illegally marketed drugs into the regulatory fold, and significantly reduce the risk of harm to animal health.

Antimicrobial Resistance
As part of its overall responsibility for ensuring the safety of animal drugs, the Animal Drugs and Feeds Program continues to address public health safety concerns associated with antimicrobial drug use in animals and the related development of antimicrobial resistant bacteria. These efforts are focused on the use of antimicrobial drugs in food-producing animals and the impact of such use on antimicrobial resistance in foodborne bacterial pathogens. During FY 2012, the Animal Drugs and Feeds Program developed strategies to address antimicrobial resistance concerns. These strategies included limiting the use of antimicrobial drugs in food-producing animals and enhancing the quality and accuracy of data on antimicrobial drug sales and distribution. In December 2013, FDA released final Guidance for Industry #213 on removing production claims for medically important antimicrobials and bringing remaining therapeutic claims for these products under veterinary oversight, as well as a proposed rule revising the Veterinary Feed Directive. FDA held five public meetings to seek input on the potential impacts of FDA's plan to require veterinary oversight of certain antibiotics in April through June 2013 to help inform the final guidance and directive.

To develop enhancements to FDA's annual summary of data reported under Section 105 of the Animal Drug User Fee Act, FDA published a Federal Register Notice (78 FR 59308) in September 2013 seeking public input on proposed additional tables to include in its annual summary report on antimicrobials sold or distributed for use in food-producing animals. These additional tables included categorization of active ingredient sold by medical importance, dosage form, marketing status, and indication. The comment period for this Federal Register Notice closed in November 2013 and FDA is analyzing comments and is planning on incorporating the proposed tables into its next report on the 2012 sales and distribution data.

The Animal Drugs and Feeds Program advances the protection of human and animal health through the integrated monitoring of antimicrobial resistance among enteric bacteria with new collaborative approaches for the National Antimicrobial Resistance Monitoring System (NARMS), that are statistically representative, scientifically sound, and support FDA regulatory activities. NARMS data have played key roles in recent regulatory activities (2012 cephalosporin extra-label use prohibition) resulting in a need to

critically re-evaluate the sampling approach to assure that the data being generated can withstand scrutiny from both a scientific and regulatory perspective. Through an interagency agreement with FDA, USDA-Food Safety Inspection Service (FSIS) implemented a greatly improved food animal sampling scheme for federally-inspected slaughter houses that is designed to generate a more representative data set for the purposes of NARMS. In addition, FDA worked with USDA -Agriculture Research Service (ARS) to develop a new consortium of ARS research centers and select universities to collect and test samples on farm for the first time. In addition, the Animal Drugs and Feeds Program is implementing whole genome sequencing technology and supportive bioinformatics to provide definitive information on the nature, origin and spread of resistant bacteria in foods.

Adverse Drug Review
The Animal Drugs and Feeds Program reviews 86,000 Adverse Drug Experience (ADE) reports annually. It is the largest animal drug ADE database in the world, with over 500,000 entries. Over the past two years, the Animal Drugs and Feeds Program significantly reduced the paper submission backlog, and made substantial improvements to the electronic portal allowing for over 95% of reports to be submitted electronically. This database provides the Animal Drugs and Feeds Program with the ability to data mine for use in both pre and post market approval animal drug work. The efforts to increase the functionality and utilization of the Pharmacovigilance database have improved animal drug safety.

International Activities
The U.S.-Canada Regulatory Cooperation Council (RCC) is mandated to promote economic growth and job creation and provide benefits to consumers and industry through increased regulatory transparency and coordination. The Veterinary Drug Initiative (VDI) encourages the U.S. and Canada to seek greater alignment in regulatory approaches to remove duplicative requirements, reduce costs, and work towards more time access to products. The cornerstone of the RCC action plan to advance regulatory cooperation was the simultaneous review by regulators in FDA and Canada's Veterinary Drug Directorate (VDD) of Elanco's veterinary drug product, Comfortis completed in FY 2013. Since the approval of Comfortis, continued and steady progress has been achieved by both the U.S. and Canada. With the onset of the FSMA, deliberative efforts were made to expand the class of medicines to include both food and non-food animals. This expansion coupled with FDA's enhanced international communication strategies, as part of the One Health and Globalization Initiatives, has bolstered outreach efforts with other industries and agencies to promote the RCC VDI.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$158,771,000	$139,025,000	$19,746,000
FY 2012 Actual	$156,909,000	$137,964,000	$18,945,000
FY 2013 Actual	$147,774,000	$125,841,000	$21,933,000
FY 2014 Enacted	$173,207,000	$141,566,000	$31,641,000
FY 2015 Budget Request	$189,536,000	$144,577,000	$44,959,000

BUDGET REQUEST

The FY 2015 Budget for the Animal Drugs and Feeds Program is $189,536,000, of which $144,577,000 is budget authority and $44,959,000 is user fees. This is $16,329,000 more than the FY 2014 Enacted level. The Center portion is $119,339,000 and the Field portion is $70,197,000. This increase will allow the Animal Drugs and Feeds Program to meet its mission to protect human and animal health by increasing the availability and diversity of safe and effective products that relieve animal pain and

suffering, sustain their health, improve food-producing animal productivity, and not compromise human health.

The Animal Drugs and Feeds Program will support the evaluation, approval, and post-approval monitoring of animal drugs, devices and additives used in animal feed. In addition, the funding will satisfy the trigger requirements for user fee collections under the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). These user fees supplement the appropriated portion of the new animal drug review program while enabling the Animal Drugs and Feeds Program to retain user fee supported staff. With these user fees, the Animal Drugs and Feeds Program will continue to improve the quality and timeliness of the pioneer animal drug and generic new animal drug review processes.

The initiatives proposed under the FY 2015 President's Budget request support mission critical program activities and Presidential, HHS and FDA public health priorities such as the Food Safety Modernization initiative, which aims to protect consumers by implementing the Food Safety Modernization Act (FSMA) and the Pharmacy Compounding initiative, which aims to provide more effective oversight of pharmacy compounding facilities.

The Animal Drugs and Feeds Program has prioritized the activities of greatest public health importance in order to best protect the American people. FDA will maintain support for the FDA priorities to Advance the Safety and Effectiveness of Medical Products and Advance Food Safety and Nutrition as well as the goals outlined in the FVM Strategic Plan.

The Animal Drugs and Feeds Program will continue to develop guidance and conduct limited education, training, and outreach to support implementation of the preventive control safety standards of FSMA. FDA will continue to develop new risk assessment methodology, expand existing risk tools, and collect data to enhance and refine existing and ongoing models as well as conduct risk prioritization and comparative risk assessment to better target use of FDA resources. Additionally, the funding level will allow FDA to partner with state and local public health agencies to assess and develop strategies that promote risk assessment activities at those agencies.

At the funding level, the Animal Drugs and Feeds Program will be able to improve compliance and inspection programs to incorporate FSMA final rules for preventive controls for animal food. The Animal Drugs and Feeds Program will execute integrated food safety strategies in partnership with states, establish oversight of the third party audit program, continue to support foreign inspection planning and related enforcement cases, and expedite the integration of risk-based decision-making. Additionally, the Animal Drugs and Feeds Program will continue to sustain a network of veterinary laboratories to conduct investigations and run diagnostic tests to help FDA respond to high priority chemical and microbial feed or drug contamination events.

In addition, at this funding level, FDA can closely monitor the progress of its strategy for the voluntary adoption of the changes outlined in Guidance for Industry (GFI) #213 calling for the elimination of the use of medically important antimicrobial drugs for growth promotion purposes. FDA believes such veterinary oversight is critically important for ensuring that these drugs are used judiciously, and will help ensure that use for disease prevention is judicious and appropriate. FDA will also continue to address the source and magnitude of antimicrobial resistance in the food supply by making the necessary enhancements to NARMS. Enhancements include analytical tools, risk analysis, and real-time monitoring of food safety signals necessary to harness all relevant and available information to make rigorous, data-driven decisions necessary to protect public health.

Medical Product Safety

Pharmacy Compounding: Inspections and Enforcement, Policy Development, and State Collaboration and Coordination (+$2,034,000)

The Pharmacy Compounding Initiative component of the Animal Drugs and Feeds Program is part of a multi-program initiative to provide more appropriate and effective oversight of pharmacy compounding through investments in inspections and enforcement, policy development, and state coordination. Further details on this initiative as well as the other organizations involved in this initiative appear in the Performance Budget Overview, the Human Drugs Program narrative, the Biologics Program narrative, the Office of Regulatory Affairs narrative, and the FDA Headquarters narrative.

FDA will develop and implement a surveillance program involving sampling and analysis of purchased compounded products to identify animal drug compounders for inspection based on risk assessment. FDA will develop a draft guidance that sets out its enforcement priorities with respect to animal drug compounding with bulk chemicals and implement an educational program regarding the revised policies.

FDA will support case management for inspections including writing the inspection assignments, handling issues that arise during the inspections such as the need to obtain an administrative warrant to access records, assessing the inspection results, and developing and executing any necessary regulatory or enforcement actions against illegal compounding firms. FDA will also support policy development and state collaboration and coordination.

Additional funding will be used to support FDA's initiative related to the investigation of high-risk pharmacy compounding facilities producing animal drugs.

Food Safety

Food Safety Modernization: Antimicrobial Resistance (+$977,000)

The Animal Drugs and Feeds Program is part of a multi-program initiative to create a modern, prevention-focused, science and risk-based food safety system and implement the requirements of FSMA. Further details on this initiative as well as the other organizations involved in this initiative appear in the Overview of the Budget Request narrative, Foods Program narrative, Office of Regulatory Affairs narrative, and FDA Headquarters narrative.

With this funding increase, FDA will acquire data needed to better understand antimicrobial drug use practices in animals and the impacts of such use on bacteria of public health concern. Planned efforts include enhancing methods for characterizing bacteria, conducting studies to better understand drug effects on bacteria, and developing approaches to monitor and assess drug use and antimicrobial resistance trends.

Proposed Food Import User Fee (+$15,158,000)

The proposed Food Import user fee request is part of a multi-program initiative to support implementation of FSMA by improving FDA's import process. With this funding increase, FDA will establish new systems to prevent the import of unsafe feeds earlier in the process rather than detaining a product at the border. FDA will establish an accreditation system for third party certifiers that will review and assess the feed safety systems in other countries. Furthermore, FDA will conduct outreach with international public health agencies to help establish international cooperation to ensure a safe feed supply. These resources will improve consumer protection by allowing FDA to make better informed decisions about the admissibility of imported food and feed products to ensure they are safe for U.S. consumers.

With this investment FDA will provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process. FDA will implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the

import review process. This investment will allow FDA to establish a national call center to provide timely responses to inquiries concerning the import process or the status of imports. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. It will also support increased port and border coverage with increased staff and longer hours of operation, thus providing improved screening for food safety while also speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be made to acquire additional space at various border locations to support this effort, resulting in increased efficiency, improved industry/FDA communication, reduced time to resolve problems, and improved movement of trade. With this IT investment, FDA will improve information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives.

FDA will utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. Expedited review, examination, and sampling of products will decrease the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities FDA physically examines. This outlay will support the implementation of the Foreign Supplier Verification Program (FSVP), a comprehensive prevention-focused import food and feed safety program that relies heavily on those in the food supply chain, food and feed manufacturers, processors, packers, distributors, and importers, to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. The prevention-focused food and feed safety system allows FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program.

Proposed Food Facility Registration and Inspection User Fee (+$2,595,000)

The proposed Food Facility Registration and Inspection User Fee request is part of a multi-program initiative to support implementation of FSMA by modernizing FDA's inspection system. With this increase, FDA will develop and administrate preventive control-based inspection training to FDA and other Federal, State, Local, Tribal, and Territorial regulatory and public health partners as well as conduct education activities for industry on new preventive control standards that are intended to prevent the contamination of animal food and feed to help ensure that feed products are safe for U.S. consumers. FDA will also collect, analyze, and manage risk data from a variety of sources, build the necessary decision tools, and outline the internal processes for systems-based approach enabling data-driven, evidence-based decision making. These funds will allow FDA to rank and prioritize food and feed safety concerns and identify how to apply limited FDA resources to achieve the best possible public health outcomes. In addition, FDA will modernize compliance programs and inspection practices to improve inspection efficiency by using the safety risk models to identify high risk firms and to prioritize firms for inspections and also the frequency of inspections. Furthermore, FDA will conduct microbiological surveillance in strains and monitor high priority commodities whose public health risk has yet to be ascertained, such as imported seafood, and animal feeds.

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. These investments will allow FDA to implement and enforce preventive controls in feed processing facilities and continue to train more than 215 inspection personnel consisting of FDA inspection personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners in preventive controls inspections and enforcement methods. FDA will continue assisting the states in their

implementation of Animal Feed Regulatory Program Standards (AFRPS), as well as providing support and coordinating with the states as FDA moves to national standards for laboratories.

PERFORMANCE

The Animal Drugs and Feeds Program's performance measures focus on premarket animal drug application review, high risk inspections including BSE, warning letter review, lab coordination for detection and response, and judicious use of medically important antimicrobials, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2012: 99.6% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2012: 100% w/in 380 days Target: 90%w/in 380 days (Target Exceeded)	90% w/in 270 days	90% w/in 270 days	maintain
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2013: 275 Target: 250 (Target Exceeded)	250	250	maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2013: 540 Target: 500 (Target Exceeded)	500	500	maintain
244204: Complete review and action on warning letters received within 15 working days to better safeguard the food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2013: 58% w/in 15 working days Target: 60% w/in 15 working days (Target Not Met)	60% w/in 15 working days	60% w/in 15 working days	maintain
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed including pet food contamination events. *(Outcome)*	FY 2013: 26 Target: 26 (Target Met)	26	28	+2

The following selected items highlight notable results and trends detailed in the performance table.

New Animal Drug Application Review

FY 2012 was the fourth year in ADUFA II, and during that time CVM met review-time goals for almost all (180 of 181) FY 2012 submissions. A key improvement implemented for ADUFA II was the "end-review amendment" (ERA) process that allowed reviewers to work with drug sponsors to amend certain pending submissions. The ERA process allowed us to decrease the number of review cycles, ultimately leading to a shorter time to approval. Improved communication early in the process had the greatest impact to reduced review cycles. ADUFA was recently reauthorized again extending from FY 2014 through FY 2018 resulting in ADUFA III.

Warning Letter Review

Due to the increase in volume, CVM missed the review and action on warning letters received within 15 working days target by 2 percent. In FY 2013, CVM received 45 more warning letters from the districts which was a 63 percent increase over the number of warning letters received in FY 2012. This increase in warning letters can partially be attributed to a 45 percent increase in the number of illegal drug residue inspections performed by the districts in FY 2013. While the workload of reviewing warning letters increased within CVM, the number of staff assigned to review these letters has remained the same.

Domestic and Foreign High-Risk Inspections

One critically important step toward enhanced consumer protection is FDA's development of a risk-based model to establish consistent, FDA-wide priorities when developing annual domestic and foreign field activities. Important features of the risk-based model 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; including both inherent risk (outbreaks, Class I recalls, adverse events, etc.) and compliance history. FDA continues to enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk firms enter the market, or the definition of high risk evolves based on new information on 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 or sample results. FDA has made inspecting high-risk domestic and foreign firms a priority, and has set multiple performance goals for these high-risk facilities. As a result of these efforts, in FY 2013 FDA met or exceeded inspection targets for animal drugs and feeds facilities.

PROGRAM ACTIVITY DATA

Animal Drugs & Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
New Animal Drug Applications (NADAs) [1]			
Received	4	14	14
Completed	6	13	13
Approved	6	13	13
Pending [2]	0	1	2
New Animal Drug Application Supplements [1, 3]			
Received	409	560	560
Completed	410	565	545
Approved	334	375	350
Pending [2]	99	94	109
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	38	29	29
Completed	46	27	25
Approved	24	7	6
Pending [2]	21	23	27
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	193	195	195
Completed	162	200	185
Approved	127	125	120
Pending [2]	112	107	117
Investigational New Animal Drug (INAD) Files [4]			
Received	3,560	2,995	2,995
Completed	3,538	2,987	2,913
Pending [2]	402	410	492
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	498	258	258
Completed	489	260	247
Pending [2]	66	64	75
Food (Animal) Additive Petitions Completed	40	65	65
Investigational Food Additive Petitions Completed	144	115	175
Adverse Drug Event (ADE) [5]			
ADE Reports Received	86,444	73,000	73,000
Post-Approval ADE Data Reviews	147	70	70

[1] Includes originals applications and reactivations. If the application is not approvable, the sponsor may submit

[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

[4] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased

[5] This measure tracks the number of "Post-approval ADE data reviews" completed each fiscal year. A Post-approval ADE Data Review is a comprehensive report by product of multiple ADE reports (in some cases this could be hundreds or thousands of individual reports).

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2013 Actual			FY 2014 Estimate			FY 2015 Estimate		
	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,131***	***300***	***1,865***	***1,792***	***299***	***1,524***	***1,792***	***299***	***1,524***
Pre-Approval /BIMO Inspections	65	65	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	220	220	0	222	222	0	222	222	0
BSE Inspections	1,570	0	1,570	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	28	0	28	25	0	25	25	0	25
Illegal Residue Program Inspections	491	0	491	473	0	473	473	0	473
Feed Manufacturing Program Inspections	185	0	185	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,746	7	1,739	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***71*** [1]	***59***	***12***	***76***	***69***	***6***	***76***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	20	20	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	48	48	0	33	33	0	33	33	0
Foreign Feed Inspections	10	0	10	7	0	7	7	0	7
BSE Inspections	5	0	5	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,202***	***359***	***1,877***	***1,868***	***368***	***1,530***	***1,868***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	4,325	140	4,185	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	657	3	654	750	2	748	750	2	748
Import Physical Exam Subtotal	**4,982**	**143**	**4,839**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	368,447			448,604			448,604		
Percent of Import Lines Physically Examined	1.35%			0.97%			0.97%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***5,087***	***0***	***5,087***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***32***	***0***	***32***	***0*** [2]	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***443***	***0***	***443***	***600***	***0***	***600***	***600***	***0***	***600***
State Contract Inspections: BSE	4,623	0	4,623	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	436	0	436	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	264	0	264	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	32	0	32	23	0	23	23	0	23
State Cooperative Agreement BSE Inspections	443	0	443	600	0	600	600	0	600
State Contract Animal Drugs/Feeds Funding	$2,825,340	$0	$2,825,340	2,782,770	0	$2,782,770	2,782,770	0	$2,782,770
BSE Cooperative Agreement Funding	$2,540,623	$0	$2,540,623	2,572,920	0	$2,572,920	2,572,920	0	$2,572,920
State Contract Tissue Residue Funding	$545,331	$0	$545,331	686,440	0	$686,440	686,440	0	$686,440
Total State Funding	**$5,911,294**	**$0**	**$5,911,294**	**$6,042,130**	**$0**	**$6,042,130**	**$6,042,130**	**$0**	**$6,042,130**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,321***	***359***	***6,996***	***6,913***	***368***	***6,575***	***6,913***	***368***	***6,575***

[1] The FY 2013 actual unique count of foreign inspections includes 1 OIP inspection (1 Animal Feeds inspection in China).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

DEVICES AND RADIOLOGICAL HEALTH

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Devices and Radiological Health	384,427	379,752	427,998	440,874	12,876
Budget Authority	*296,240*	*296,393*	*320,825*	*317,937*	*-2,888*
User Fees	*88,187*	*83,359*	*107,173*	*122,937*	*15,764*
Center	295,854	294,156	332,528	342,241	9,713
Budget Authority	221,880	221,880	240,345	238,308	-2,037
User Fees	73,974	72,276	92,183	103,933	11,750
Medical Device (MDUFA)	*68,267*	*67,230*	*86,180*	*97,810*	*11,630*
Mammography Quality Standards Act (MQSA)	*5,707*	*5,046*	*6,003*	*6,123*	*120*
Field	88,573	85,596	95,470	98,633	3,163
Budget Authority	74,360	74,513	80,480	79,629	-851
User Fees	14,213	11,083	14,990	19,004	4,014
Medical Device (MDUFA)	*1,782*	*1,722*	*1,913*	*1,913*	*--*
Mammography Quality Standards Act (MQSA)	*12,431*	*9,361*	*13,077*	*13,339*	*262*
Medical Products Reinspection	---	---	---	---	*--*
International Courier	---	---	---	*3,752*	*3,752*
FTE	2,041	2,077	2,167	2,234	67

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health & Safety Act (21 U.S.C. 360hh-360ss); Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Mammography Quality Standards Act of 1992 (42 U.S.C. 263b); Medical Device Amendments of 1992; Food and Drug Administration Modernization Act; Medical Device User Fee and Modernization 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 (FDAAA); Patient Protection and Affordable Care Act, 2010; FDA Safety and Innovation Act (FDASIA), 2012

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Devices and Radiological Health Program (the Devices Program) began in 1976 with the passage of the Medical Device Amendments to the Food, Drug, and Cosmetic Act (the Act). The program operates with appropriations and user fees and is comprised of the Center for Devices and Radiological Health and the Office of Regulatory Affairs.

The Devices Program is responsible for the national regulation of all medical devices, from simple articles such as tongue depressors to complex robotic equipment for surgery and cutting-edge diagnostic products such as implantable defibrillators. To protect the public from unnecessary exposure to radiation, the Devices Program also regulates radiation-emitting products that include microwave ovens, X-ray equipment, and medical ultrasound and MRI machines. In addition, the Devices Program monitors mammography facilities to make sure the equipment is safe and properly run.

The mission of the Devices Program is to protect and promote the public health. FDA assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. FDA provides consumers, patients, their caregivers, and providers with understandable and accessible science- based information about the products it oversees. FDA facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and by assuring consumer confidence in devices marketed in the United States.

The vision of the Devices Program is that patients in the United States have access to high-quality, safe, and effective medical devices of public health importance first in the world. The United States is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the United States and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and

providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

The following strategic priorities describe the most important areas that FDA will focus on to reach this vision. These priorities are to:

- strengthen the clinical trials enterprise
- balance between premarket and postmarket data collection
- provide excellent customer service.

By addressing these priorities, FDA aims to help medical device developers choose the United States as the country of first choice for their innovative new technologies – a key contributor to early patient access to high quality, safe and effective devices. Providing excellent customer service will also improve interactions with stakeholders and colleagues, both internal and external, support better regulatory outcomes, and improve patient health.

Recent accomplishments of the Devices Program include the following:

- met or on track to meet all FY 2013 MDUFA performance goals, as indicated by preliminary data that includes completed and pending premarket reviews as of September 30, 2013
- published the Unique Device Identification (UDI) System final rule on September 24, 2013, a landmark step in improving patient safety and modernizing the postmarket surveillance system for medical devices
- increased the percentage of IDE submissions that received an approval decision authorizing study initiation, within two IDE cycles, by almost one third since 2011, while reducing by over half the median time to full study approval.

The following, selected accomplishments demonstrate the Devices Program's delivery of its regulatory and public health responsibilities within the context of current priorities.[17]

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

FDA is committed to a premarket review system that gives American patients timely access to safe and effective medical devices and facilitates innovation in the device industry. Each year, the Devices Program evaluates the safety and effectiveness of new devices and approves or clears thousands of products for market. As a result, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health. Recent first of a kind device approvals and clearances include:

- an implanted device to replace the function of degenerated eye cells, improving the visual ability of patients with a rare genetic eye condition
- an externally worn system that delivers insulin and continuously measures glucose levels, automatically stopping insulin delivery at a level set by the user
- a test system cleared for marketing that can sequence a patient's genome and may be used by doctors to determine the causes and right treatment of disease.

Plan of Action for 510(k) and Science

In 2011, FDA announced a Plan of Action for 510(k) and Science to modernize and improve its premarket review of medical devices, with some corrective action starting in 2010. The plan was designed to increase the predictability, consistency, transparency, efficiency, and timeliness of device premarket reviews. Indicators that the program is steadily improving from 2010 levels by:

[17] Please visit http://www.fda.gov/MedicalDevices for additional program information and detailed news items.

- reducing the number of backlogs of 510(k) submissions and PMA applications are each down by about one-third
- reducing by over one third the average total time to decision of PMA applications
- increasing the percentage of submitted 510(k)s that are cleared and PMAs that are approved with PMA approvals back to levels not reached in about a decade.

The turnaround in the length of premarket reviews and the decrease in backlogs will help industry bring safe and effective devices to market more quickly and at lower cost, providing better healthcare for American patients. Improvements in Device Review, a detailed report informing constituents of many actions FDA is undertaking, is available online.[18]

Innovation Pathway 2.0

Bringing breakthrough medical devices to patients quickly, safely and effectively improves lives and health care. To help this process, FDA created the Innovation Pathway 2.0 – a priority program for device technologies that address unmet medical needs in disease treatment, diagnosis, and health care delivery. By engaging with innovators in earlier stages of product development, more collaboratively, and in new ways, FDA intends to reduce the time and cost of the entire process of bringing safe and effective devices to patients. The Innovation Pathway 2.0 was developed in close collaboration with FDA's Entrepreneurs in Residence (EIR) program. The EIR program is part of the Strategy for American Innovation, a White House priority.

To test the new tools in Innovation Pathway 2.0, FDA announced the Innovation Challenge – a pilot program for innovative devices that address end-stage renal disease (ESRD). Three innovative devices for treatment of ESRD were chosen for an interactive Collaboration Phase, which produced a roadmap outlining the necessary regulatory and scientific issues to address prior to each device receiving a FDA premarket approval or clearance. These devices include an implantable artificial kidney, a wearable artificial kidney, and an implantable vascular access device for ESRD treatment. The Innovation Pathway 2.0 process is expected to result in significant savings in time and cost of bringing these breakthrough products to market. More information is available on FDA's website.[19]

Mobile Medical Applications

On September 25, 2013, FDA published final guidance on mobile medical applications – mobile medical apps – to provide clarity and predictability regarding which mobile medical apps are the focus of FDA oversight and which are not. Mobile medical apps are software programs that run on smartphones and other mobile communication devices and perform the same functions as traditional medical devices, such as remote blood pressure monitors and smartphone-based glucose monitors. Like traditional medical devices, mobile medical apps may in some cases present significant health risks to patients if they do not work as intended.

FDA seeks to strike the right balance by providing a risk-based, focused approach to the oversight of a small subset of mobile apps that present risks to patients if they do not work as intended. As explained in the final medical mobile apps guidance, FDA intends to exercise enforcement discretion for the majority of mobile apps that are devices as they pose minimal risk to consumers and will not regulate the sale or general consumer use of smartphones or tablets. FDA has already cleared more than 100 such mobile apps since the late 1990s, with over 40 cleared since FY 2011.

[18] Available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm329008.htm
[19] Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/InnovationPathway/default.htm

FDA Safety and Innovation Act
While moving forward with ongoing program improvements, FDA is also in the process of implementing several new authorities from the FDA Safety and Innovation Act (FDASIA), which was signed into law on July 9, 2012. FDASIA includes a third authorization of the Medical Device User Fee Act, or MDUFA III. Reauthorization of the medical device user fee program has helped speed innovative products to market without compromising safety and effectiveness by establishing new policies, procedures, performance goals and boosting review capacity. More FDASIA information is available on FDA's website.[20]

De Novo Pathway
FDASIA included provisions to streamline the de novo classification pathway for novel devices of low-to-moderate risk. Sponsors of these devices may now submit a de novo request for classification without being required to first submit a 510(k) premarket notification and receiving a "not substantially equivalent" determination. As a result of this new authority and FDA process improvements, the number of de novo requests has more than doubled.

Class III Pre-Amendments Devices
FDASIA changed the process for reclassifying devices and requiring premarket approval for Class III pre-amendments devices from rulemaking to an administrative order process. Using this new authority, FDA has issued proposed orders to finalize classification of 13 Class III pre-amendments device types. As of FY 2013, FDA has either issued a proposed order, or finished classifying the device type through the rulemaking process, for all but six Class III pre-amendments device types. More information is available on FDA's website.[21]

Humanitarian Device Exemptions (HDE)
FDASIA broadened the circumstances under which a sponsor of an HDE-approved device could make a profit to encourage the development of devices for rare diseases and conditions. On January 9, 2014, FDA issued a final rule amending the regulations on premarket approval of medical devices and Humanitarian Device Exemptions to include requirements relating to the submission of data on pediatric patients. In FY 2014, FDA plans to use this data to determine unmet pediatric needs and facilitate device development and proper labeling of existing medical devices for pediatric use.

Quality Management Framework
As part of MDUFA III, FDA committed to conduct an independent assessment of the premarket review process and implement appropriate recommendations from the assessment. In FY 2014, FDA announced the Quality Management (QM) framework that directly addresses the report's recommendation. In FY 2014, FDA will focus on outreach and education to share a common understanding of quality, improve the development, management, and tracking of process documentation, and take steps to establish a feedback program that includes corrective action and preventive action processes. These actions will help FDA continue to make sound choices concerning quality, measure progress in meeting quality objectives, and identify and bring issues to a satisfactory resolution to improve performance.

Clinical Trials Enterprise
FDA has taken a number of actions to expedite the safe initiation of clinical trials in the United States. These actions include starting a pilot program to facilitate early clinical evaluations and issuing final guidance on October 1, 2013 entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies." This final guidance outlines more flexible options for clinical study approvals that allow studies to begin sooner while assuring

[20] Available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/default.htm
[21] Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm

patient protections. FDA also implemented process changes to its IDE program, consistent with FDASIA. The June 14, 2013, draft guidance entitled "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations" proposed additional program modifications to allow earlier and more efficient clinical study enrollment.

FDA has already seen a substantial improvement as a result of actions taken to streamline the IDE process. Specifically, the percentage of IDE submissions that received an approval decision authorizing study initiation, within two IDE cycles, increased from 46 percent in FY 2011 to 77 percent in FY 2013, while the median time to full study approval was reduced from 435 days to 174 days. FDA is committed to improving U.S. patient access to new devices by strengthening and streamlining the clinical trial enterprise so that medical device clinical trials are conducted in the United States in an efficient and cost-effective manner, while maintaining appropriate patient protections.

United States is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

The Devices Program's regulatory science activities help bridge the gap between important discoveries and opportunities in science and the real world medical devices and treatments Americans need. This activity includes:

- researching how new devices interact with the body
- developing test methods for new technologies
- testing products to identify root causes of failure
- developing epidemiological methods to help conduct postmarket studies of devices.

These activities foster a robust U.S. medical device industry. These activities create high-tech manufacturing jobs and reduce the time and resources needed to develop and assess new products and expedite the rate that advanced medical technologies reach U.S. patients.

Regulatory science advances open scientifically sound pathways for safe and effective medical devices to improve public health. For instance, magnetic resonance imaging (MRI) is an important and widely-used diagnostic tool but can heat or move certain types of implantable devices. To facilitate the development of innovative MRI-compatible implanted devices, FDA developed, validated, and provided industry with novel evaluation methods that test how well implantable devices, such as hip and knee implants, are compatible with MRI diagnostics. As a result of these novel methods, MRI-compatible implantable devices are on the U.S. market today.

Other emerging technologies such as Additive Manufacturing, better known as 3-D printing, can help revolutionize the development of medical devices by allowing the creation of three-dimensional solid objects from digital models. In support of President Obama's call to spark a Renaissance in American Manufacturing, FDA is identifying medical device 3-D printing standardized terminology, regulatory concerns, and developing quality control tests. FDA has already identified how 3-D printing techniques and processes affect the strength and durability of materials used in medical devices. By February 2013, FDA was able clear for marketing a 3-D printed medical device – a plate used in a surgical repair of the skull that is built specifically for the individual patient.

Medical Device Innovation Consortium

In FY 2013 the Medical Device Innovation Consortium (MDIC) was launched in partnership with the largest state-based life sciences trade association in the United States, Minnesota's LifeScience Alley. MDIC is the first public-private partnership with the sole objective of advancing medical device regulatory science through leveraging the expertise, projects, and breakthroughs of industry, government, and non-profits. In FY 2014, a Cooperative Research and Development Agreements (CRADA) was established with MDIC that has the potential to improve the efficiency of the clinical study process and in turn, lead to earlier U.S. patient access to beneficial innovative technologies. MDIC already has over 30 member organizations and will expand FDA's capacity for device-related regulatory science by creating a safe space for facile, creative, and ambitious medical device collaborations.

Medical Device Development Tools
On November 14, 2013, FDA issued a draft guidance titled "Medical Device Development Tools: Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff." This draft guidance describes the framework and process for voluntary qualification of MDDT including evaluation criteria, qualification threshold and the three types of MDDT used to measure relevant parameters. Through the MDDT qualification process, FDA aims to expedite the development of publicly available scientific tools that can be used across multiple device development programs and reduce the time and resources needed to develop and assess new products. More information is available on FDA's website.[22]

Women's Health
In FY 2013, FDA launched the Health of Women (HoW) program to ensure the unique health needs of women are considered in medical device research and innovation. The three main goals of HoW are to:

- improve the availability, consistency and communication of information to patients and providers that is specific to women's needs
- address identified gaps and unmet needs through targeted resources
- foster the development of innovative strategies, technology, and clinical study models.

With these efforts, FDA strengthens the focus of government, industry and the clinical community on developing medical devices designed to meet the unique clinical needs of women.

Radiological Health Program
FDA monitors radiation doses and industry's compliance with performance standards to reduce the incidence and severity of radiation injury. FDA conducts inspections of establishments that manufacture radiation emitting electronic products and devices to determine compliance with the law, which are documented in Establishment Inspection Reports (EIRs). In FY 2013, 75 percent of field establishment inspection reports (EIRs) were reviewed within 60 days, with average review time for a single EIR reduced to less than 50 days. This performance permits more timely communication and rapid correction of deficiencies in radiation emitting electronic products and devices.

Mammography Quality Standards Act Program
As part of the Mammography Quality Standards Act (MQSA) Program, FDA and its state contract partners, annually inspect over 8,000 certified mammography facilities in the United States to ensure compliance with national quality standards for mammography. MQSA certified facilities provide over 38,000,000 mammography procedures annually in the United States. As a result of the MQSA program, over 85 percent of facilities are free of violations at the time of inspection, and less than one percent of facilities are cited with the most serious Level I violations.

The MQSA program promotes the strengthening and upgrading of mammography facilities to improve the quality of healthcare for Americans. In FY 2013, FDA required the accreditation bodies to implement full-field digital mammography (FFDM) softcopy image review as a condition for approval, a requirement which each accreditation body met. These efforts help to provide high-quality mammography for early breast cancer detection, leading to a range of early treatment options and a decline in breast cancer morbidity and mortality in the United States.

U.S. postmarket surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.

The Devices Program's postmarket safety activities focus on monitoring medical device and radiological product performance – including adverse events – once the products reach market. FDA analyzes safety signals with potential clinical impact, and when an issue surfaces, it strives to respond quickly to identify

[22] MMDT draft guidance available at the following FDA website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm374427.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

and limit potential public health problems. These efforts are critical to ensuring that devices and radiological products remain safe and effective for patients and consumers.

National Medical Device Postmarket Surveillance Plan
FDA is committed to strengthening its postmarket surveillance efforts to collect, analyze, and act on medical device postmarket performance information. In April 2013, FDA published an update to the report entitled, "Strengthening our National System for Medical Device Postmarket Surveillance" that describes the next steps FDA plans to take to establish a more integrated national medical device postmarket surveillance system. FDA intends to pursue the following actions as part of its postmarket strategy:

- establish a multi-stakeholder Device Postmarket Surveillance Planning Board
- establish a unique device identification (UDI) system and promote its incorporation into electronic health information
- promote the development of national and international device registries
- modernize adverse event reporting and analysis
- develop and use new methods for evidence generation, synthesis, and appraisal.

The National Medical Device Postmarket Surveillance System quickly identifies new safety concerns and better characterizes real-world performance of medical devices by complementing existing programs that capture adverse event and postmarket problems, including the Medical Device Reporting (MDR) program and the Medical Product Safety Network (MedSun). More information is available on FDA's website.[23]

Medical Device Reporting
Under the Medical Device Reporting (MDR) program, FDA receives more than 1,000,000 individual medical device reports annually from manufacturers, importers, distributors, user facilities, and voluntary reporters. Incidents in which a device may have caused or contributed to a death or serious injury, or experienced a malfunction must be reported. Applying the least burdensome principle, FDA has implemented a paperless electronic Medical Device Reporting (eMDR) system to reduce the reporting burden of adverse events. As of FY 2013, FDA has successfully enrolled the top 15 MDR reporters into the eMDR program, helping to reduce document control costs for more than three-quarters of all MDR reports received.

MedSun
MedSun is an "active" adverse event reporting program that allows FDA to work collaboratively with the clinical community to identify, understand, and solve problems associated with the use of medical devices. MedSun provides a better understanding of how certain devices are used in the clinical environment, how regulatory actions against manufacturers will affect patient care in hospitals and if manufacturer recalls and other actions successfully solved the reported device problems. To enhance analysis of real-world device performance data, approximately one-third of MedSun reports received annually are marked manufacturer follow up. In FY 2013, there were 37 recalls and 54 manufacturer actions directly influenced by MedSun reports.

Unique Device Identification
On September 24, 2013, FDA published the Unique Device Identification (UDI) final rule, a landmark step in improving patient safety and modernizing FDA's postmarket surveillance system for medical devices. The final rule requires the label of every medical device and every device package to include a UDI, except where the rule provides for alternative placement of the UDI or provides an exception for a particular device or type of device. At the same time, a Global Unique Device Identification Database (GUDID) has been made available to serve as a reference for every device with an identifier, empowering stakeholders with access to non-confidential device information.

[23] Available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm

The incorporation of UDI into FDA's National Medical Device Postmarket Surveillance System will have many benefits for patients, the health care system, and the device industry. UDI will enhance FDA's ability to quickly and efficiently identify recalled marketed devices, improve the accuracy of adverse event reports, and provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems that can help promote a faster, more innovative and less costly device development process.

Medical Device Epidemiology Network
Through the Medical Device Epidemiology Network (MDEpiNet) Initiative, FDA collaborates with key domestic and international partners to build novel approaches to enhance postmarket surveillance. In FY 2013, MDEpiNet efforts lead to the development of the International Consortium of Orthopedic Registries (ICOR), a mechanism for sharing data on medical devices used in orthopedic procedures from over 20 countries. Building on the successes of international consortia in the field of orthopedics, FDA spearheaded the development of the International Consortium of Cardiovascular Registries (ICCR) that involves six international Transcatheter Aortic Valve Replacement (TAVR) Registries. MDEpiNet collaborations help CDRH modernize the national system for medical device post-market surveillance at a reduced cost to American taxpayers.

Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Ensuring manufacturer compliance with laws and regulations helps assure the safety and efficacy of devices and protects consumer confidence in U.S. medical products worldwide. The Devices Program quickly identifies major violations and takes prompt, clear, and appropriate actions to resolve issues before they have widespread negative impacts on public health.

Recall Process Improvements
Key efforts include the Recall Process Improvement project, which advanced the clarity and timeliness of actions involving medical device firms whose products violate the FD&C Act. As a result of the project, the proportion of recalls classified on time increased from 45 percent in FY 2010 to over 90 percent in FY 2013 – an over twofold performance improvement. By streamlining the recall classification process, FDA is able to better protect American patients and consumers from defective products while helping to avoid unnecessary negative impacts on US consumer confidence.

Case for Quality Initiative
Through the Case for Quality Initiative, FDA is engaging stakeholders to identify and share important quality practices to foster medical device quality. In FY 2014, FDA plans to publicize systemic practices that are linked to device quality outcomes that may help reduce quality-related costs of medical device manufacturing in the United States. As part of the Case for Quality Initiative, FDA is also working to determine specific operations, design considerations, and controls to improve the quality of implantable devices that use batteries. Through the Case for Quality Initiative, FDA aims to reduce the risk of patient harm by helping manufacturers to identify and deploy quality-related design and production practices while improving the quality of and confidence in U.S. manufactured medical products. More information is available on FDA's website.[24]

Voluntary Compliance Improvement Pilot Program
In FY 2014, FDA launched the Voluntary Compliance Improvement Pilot (VCIP) program as part of its ongoing commitment to use smart regulation to achieve a higher return in service for American patients. The VCIP program aims to improve medical device quality by promoting voluntary compliance of firms that have self-identified compliance deficiencies. Instead of an FDA inspection and the regulatory

[24] Available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm

consequences that follow, participating manufacturers are afforded the opportunity to voluntarily correct identified deficiencies if they meet VCIP program criteria. FDA is limiting the pilot to manufacturers of class II devices that are non-life saving and non-life sustaining. These approaches may help decrease the number of inspections necessary overtime while permitting FDA to focus on manufacturers with higher risk issues. More information is available on FDA's website.[25]

Medical Device Single Audit Program

The Medical Device Single Audit Program (MDSAP) is an international coalition of trusted regulatory authorities working together to eliminate the need for multiple medical device manufacture audits and inspections. In FY 2014, FDA will begin piloting the MDSAP with manufacturers that satisfies the requirements of regulatory authorities participating in the program including Australia, Brazil, Canada, and the United States. These actions include beginning to accept MDSAP audit reports as a substitute for routine Agency inspections. Single and shared audits help lower costs to industry and taxpayers by eliminating duplicate audits and inspections of medical device manufacturing facilities. More information is available on FDA's website.[26]

Inspections and Enforcement

FDA conducts risk-based domestic and foreign postmarket inspections, field exams, and sampling of medical device manufacturers to assess compliance with the Quality Systems regulations. In FY 2013, FDA:

- performed field label exams and sample collections on 24,393 entry lines of medical devices and 1,265 entry lines of radiological health products, refusing entry of 4,290 lines of violative products
- filed one injunction against a device manufacturer
- classified and issued 69 Class I, 1010 Class II, and 67 Class III device recall events
- issued warning letters to, 217 companies
- placed 118 firms were placed on import alert (detention without physical examination)
- made 37 device related arrests and secured 15 device related convictions.

Through these field activities, the Device Program is able to enhance public health by maximizing compliance of medical devices and radiological products while minimizing risk to patients and consumers.

FDA is identifying effective approaches that can target high-risk products so resources can be concentrated on devices that pose the greatest risk to public health. These efforts include re-assessment and possible re-vamping of field exams, expanding the methodology base to address more complicated drug issues, collaborating with external partners to expand capability.

Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

FDA is committed to providing excellent customer service, including timely and meaningful information on medical devices and radiological products to promote public health. In FY 2013, FDA responded to over 50,000 inquiries about its services, regulated products, and public health issues. At the same time, Learn and Device Advice web pages were visited approximately 500,000 times. These efforts help the public make smarter choices about the medical devices they rely upon daily, help entrepreneurs and innovators choose the United States first when bringing new medical products to market, and help stimulate investment in and the development of promising new medical technologies.

[25] Available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378183.htm

[26] Available at http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

Device Labeling Improvements
Patients and caregivers need immediate and easily accessible information on medical devices used in the home. At the same time, health care professionals need easy access to labeling information that may not always accompany a medical device. To directly address this public health need, FDA is working with manufacturers to develop a medical device labeling repository for all devices, beginning with those intended for home use. In FY 2014, FDA plans to publish a proposed rule to establish a publically available device labeling repository, helping to improve the consistency, usefulness, and accessibility of device labeling for home use.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$378,509,000	$322,182,000	$56,327,000
FY 2012 Actual	$390,954,000	$322,636,000	$68,318,000
FY 2013 Actual	$384,427,000	$296,240,000	$88,187,000
FY 2014 Enacted	$427,998,000	$320,825,000	$107,173,000
FY 2015 Budget Request	$440,874,000	$317,937,000	$122,937,000

BUDGET REQUEST

The FY 2015 Budget for the Devices and Radiological Health Program is $440,874,000, of which $317,937,000 is budget authority and $122,937,000 is user fees. This amount is $12,876,000 more than the FY 2014 Enacted level, due to a user fee increase of $15,764,000 and a budget authority decrease of $2,888,000. The FY 2015 Budget enables the Devices Program to continue to ensure the safety and effectiveness of medical devices that U.S. patients rely on every day, while facilitating scientific innovations that extend and improve lives.

The FY 2015 Budget includes an MQSA user fee inflationary increase of $382,000 to cover inflationary cost needed to ensure high quality mammography for early breast cancer detection. The request also includes an International Courier user fee of $3,752,000 to address the growing volume of medical device imports and prevent unsafe products from reaching American patients.

The FY 2015 Budget increases the Devices Program MDUFA III user fees by $11,630,000. This increase allows the Devices Program to continue to establish a solid reviewer base to meet the increasingly rigorous MDUFA III performance goals, as approved by Congress under FDASIA. Preliminary data indicates that the Devices Program has met or has the potential to meet all established MDUFA III performance goals, which demonstrates FDA's continued commitment to increase the efficiency with which medical devices are developed and made available to American patients.

This request includes base funding that permits the Devices Program to continue to meet its core mission to protect and promote public health. The Devices Program's mission – geared toward a system of smart regulation – results in better, safer, more effective treatments and world-wide confidence in, and adoption of, the devices that U.S. industry produces. This work is essential to the protection and growth of the nation's medical device industry and the jobs it creates, including:

- 400,000 American jobs[27]
- 12,000 U.S. manufacturing establishments[28]

[27] Medical device industry employment estimated using 2011 - 2012 data from the U.S. Bureau of Census and Dunn & Bradstreet (D & B) Inc.
[28] Medical device industry establishments estimated using 2011 - 2012 data from CDRH Registration and Listing and U.S. Bureau of Census.

- three percent of total annual spending by U.S. consumers[29]
- $53 billion in U.S. exports and growing, positive trade surplus.[30]

The FY 2015 Total Program Funding Level enables the Devices Program to continue to make historic leaps forward toward achieving the vision of ensuring patients in the United States have access to high-quality, safe, and effective medical devices of public health importance – first in the world. The Plan for Action to improve the premarket review of medical devices has successfully increased the efficiency and predictability of the Devices Program, creating a foundation for innovation and the acceleration of lifesaving devices and treatments for the American people. Adequate and stable funding of the Devices Program allows the evidence-based, proven improvements to continue to support a smarter, more innovative and efficient government for the American people.

PERFORMANCE

The Devices Program's performance measures focus on premarket device review, postmarket safety, compliance, regulatory science, and Mammography Quality Standards activities assuring the safety and effectiveness of medical devices and radiological products marketed in the United States, as detailed in the following table:

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon. *(Outcome)*	FY 2012: 79% in 180 days and 97% in 295 days Target: 60% in 180 days and 90% in 295 days (Target Exceeded)	80% in 180 days	80% in 180 days	maintain
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. *(Outcome)*	FY 2011: 95% in 180 days and 100% in 210 days Target: 85% in 180 days and 95% in 210 days (Target Exceeded)	90% in 180 days	90% in 180 days	maintain
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. *(Outcome)*	FY 2012: 96% in 90 days and 100% in 150 days Target: 90% in 90 days and 98% in 150 days (Target Exceeded)	93% in 90 days	95% in 90 days	+2% in 90 days
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2013: 333 Target: 300 (Target Exceeded)	300	300	maintain

[29] Annual consumer spending estimated using 2012 data from Dunn & Bradstreet, including sales from primary and secondary medical device manufacturers.
[30] Export estimated using 2012 data from the U.S. Department of Commerce and the U.S. International Trade Commission. The value of in-vitro diagnostic product exports is not included in this statistic as it is not tracked by the U.S. Department of Commerce.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
252203: Percent of total received Code Blue MDRs reviewed within 72 hours during the year. *(Output)*	FY 2013: 92% Target: 90% (Target Exceeded)	90%	90%	maintain
254202: Percentage of time CDRH meets the targeted deadline of 45 working days to review GMP information and issue Device Warning Letters. *(Output)*	FY 2013: 71% Target: 60% (Target Exceeded)	60%	60%	maintain
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (*Output)*	FY 2013: 92% (Historical Actual)	80%	85%	+ 5%
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2013: 2,048 Target: 1,515 (Target Exceeded)	1,600	1,600	maintain
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2013: 279 Target: 131 (Target Exceeded)	125	125	maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2013: 1,774 Target: 1,300 (Target Exceeded)	1,435	1,435	maintain
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. *(Outcome)*	FY 2013: 99.3% Target: 97% (Target Exceeded)	97%	97%	maintain

The following selected items highlight notable results and trends detailed in the performance table.

Premarket Device Review

FDA is committed to protecting and promoting public health by providing timely access to safe and effective medical devices by providing reasonable assurance of the safety and effectiveness of medical devices. In FY 2013, FDA met or exceeded all of its MDUFA III performance goals, as indicated by preliminary data. FDA expects to continue to see decreases in average total time to decision for all applications. Premarket performance data reflects action through January 29, 2014, for complete goal and target information, refer to the MDUFA performance report.

"Code Blue" Medical Device Reports

Code Blue Medical Device Reports (MDRs) are defined as high priority MDR reports based on criteria including but not limited to pediatric deaths, multiple deaths and serious injuries, device explosions, and electrocutions. Timely review of code blue MDRs can minimize widespread failure of the device, thereby limiting the loss of life due to similar events as the one submitted. This goal replaces the former eMDR goal.

Mammography Quality Standards Act (MQSA)

MQSA certified facilities provide over 38,000,000 mammography procedures annually in the United States. As a result of the MQSA program, over 85 percent of facilities are free of violations at the time of inspection, and less than one percent of facilities are cited with the most serious Level I violations.

PROGRAM ACTIVITY DATA

CDRH Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1/]	31	30	30
Total Decisions [2/]	34	30	30
Approved [3/]	22	14	14
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	9	10	10
Total Decisions [2/]	5	10	10
Approved	4	6	6
Modular PMAs			
Workload	58	65	65
Actions [4/]	60	60	60
180-day PMA Supplements			
Workload	181	170	170
Total Decisions [5/]	221	170	170
Approved	189	120	120
Real Time PMA Supplements			
Workload	306	300	300
Total Decisions [6/]	306	300	300
Approved	266	270	270
510(k) Premarket Notifications			
Workload	4,019	4,000	4,000
Total Decisions [7/] (SE & NSE)	3,163	3,300	3,300
Cleared [9/] (SE)	3,016	3,100	3,100
Humanitarian Device Exemptions (HDE)			
Workload	6	6	6
Total Decisions [2/]	4	5	5
Approved	1	3	3
Investigational Device Exemptions (IDE)			
Workload	287	270	270
Total Decisions [8/]	266	260	260
Approved	205	205	205
Investigational Device Exemption Supplements			
Workload	3,429	1,700	1,700
Closures [10/]	3,489	1,700	1,700
Pre-Submissions			
Workload	1,781	1,800	1,800
Closures [11/]	1,728	1,850	1,800
Standards			
Total Standards Recognized for Application Review	1,125	1,200	1,250
Medical Device Reports (MDRs) [12/]			
Reports Received	1,019,505	1,584,000	1,900,800
Analysis Consults [13/]	1,364	1,500	1,650

[1/] 'Workload' includes applications received and filed. (Receipt Cohort)

[2/] 'Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial - regardless of the fiscal year received. (Decision Cohort)

[3/] 'Approved' includes applications approved regardless of the fiscal year received. (Decision Cohort)

[4/] 'Actions' include accepting the module, request for additional information, receipt of the PMA, and withdrawal of the module. (Decision Cohort)

[5/] 'Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable. (Decision Cohort)

[6/] 'Total Decisions' include approval, approvable, and not approvable. (Decision Cohort)

[7/] 'Total Decisions' include substantially equivalent (SE) or not substantially equivalent (NSE). (Decision Cohort)

[8/] 'Total Decisions' include approval, approval with conditions, disapproved, acknowledge, incomplete, withdrawal, or other. (Decision Cohort)

[9/] 'Cleared' includes substantially equivalent decisions (SE). (Decision Cohort)

[10/] 'Closures' include approval, approval with conditions, disapproved, acknowledge, incomplete, no response necessary, withdrawal, or other.

[11/] 'Closures' include a meeting with Industry, deficiency, or other. (Decision Cohort)

[12/] 'MDRs' include individual and summary Medical Device Reports.

[13/] 'Analysis Consults' include analysis of individual and summary Medical Device Reports (analyzing trends and signals in MDR data).

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	*2,887*	*2,864*	*2,864*
Bioresearch Monitoring Program Inspections	313	300	300
Pre-Market Inspections	43	67	67
Post-Market Audit Inspections	66	34	34
GMP Inspections	1,787	1,592 [3]	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	658	723	723
Inspections (MQSA) FDA Domestic (VHA)	45	43	43
Domestic Radiological Health Inspections	96	205	205
Domestic Field Exams/Tests	72	215	215
Domestic Laboratory Samples Analyzed	167	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	*535* [1]	*603*	*603*
Foreign Bioresearch Monitoring Inspections	21	25	25
Foreign Pre-Market Inspections	27	31	31
Foreign Post-Market Audit Inspections	29	19	19
Foreign GMP Inspections	473	519	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	43	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	*3,422*	*3,467*	*3,467*
IMPORTS			
Import Field Exams/Tests	23,342	18,821	18,821
Import Laboratory Samples Analyzed	1,042	1,123	1,123
Import Physical Exam Subtotal	**24,384**	**19,944**	**19,944**
Import Line Decisions	14,320,961	27,698,496	27,698,496
Percent of Import Lines Physically Examined	0.17%	0.07%	0.07%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	*7,811*	*7,929*	*7,929*
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	*0* [2]	*0*	*0*
Inspections (MQSA) by State Contract	6,687	6,800	6,800
Inspections (MQSA) by State non-Contract	1,105	1,110	1,110
GMP Inspections by State Contract	19	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$81,685	$81,685	$81,685
State Contract Mammography Funding	$8,761,192	$9,089,659	$9,089,659
Total State Funding	**$8,842,877**	**$9,171,344**	**$9,171,344**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	*11,233*	*11,396*	*11,396*

[1] The FY 2013 actual unique count of foreign inspections includes 10 OIP inspections (6 for China and 4 for India).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.

[3] The FY 2014 planned mix of domestic vs. foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2013 Actuals, but the overall coverage is not changing. This is being done to acheive greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
National Center for Toxicological Research (BA Only)	54,965	54,965	62,494	58,998	-3,496
FTE	246	255	281	282	1

Authorizing Legislation: 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; FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The National Center for Toxicological Research (NCTR) was established in 1971. As a national scientific resource, NCTR conducts peer-reviewed research to advance scientific approaches and tools required to support public health and to improve FDA's ability to assess the safety of regulated products. NCTR has an outstanding scientific reputation worldwide. NCTR supports FDA's strategic priorities to:

- advance regulatory science to promote product safety, efficacy, quality, and innovation
- enhance medical product safety, efficacy, quality, and innovation
- enhance food safety.

NCTR enhances FDA's basis for sound, science-based regulatory decisions and strengthens public-health assurance by:

- accelerating FDA's capability to manage, analyze, and interpret research data generated from new technologies using bioinformatics
- understanding the risks and benefits to the American public of nanoscale materials being used in FDA-regulated products
- expanding imaging capabilities to reduce the need for costly and dangerous surgical procedures and to prevent recurring illness
- providing improved understanding of a contaminant's toxicity so FDA can issue improved safety guidelines
- identifying adverse effects earlier in product development
- identifying individualized therapies using biomarkers – to lower costs for industry and consumers
- developing new methods for rapid-detection of contaminants in FDA-regulated compounds
- providing strategies to reduce pathogens and identify contamination sources in the food supply in support of the Food Safety Modernization Act (FSMA)
- imparting research knowledge, technical advice, and research training through global collaborations like the Global Summits on Regulatory Science.

NCTR's top three accomplishments support Advancing Regulatory Science (ARS) accomplishments, including two that support the ARS Strategic Plan goal to Improve Product Development and Patient Outcomes. The third accomplishment supports the ARS goal to Promote Global Interactions.

The following, selected accomplishments demonstrate NCTR's delivery of its regulatory and public health responsibilities within the context of current ARS Strategic Plan priorities.[31]

[31] Please visit FDA.gov for additional program information and detailed news items.

Improve Product Development and Patient Outcomes

Bioinformatics is an interdisciplinary field that uses software tools to develop and improve methods for storing, retrieving, organizing, and analyzing large quantities of biological data. FDA uses bioinformatics to increase understanding of biological processes by extracting results from large amounts of raw data. FDA can then use this data to improve product development and patient outcomes.

NCTR develops, provides training for, and makes available new bioinformatics tools to FDA and the international research community. With increasing amounts of data being generated by new technologies, FDA must have the software and database tools to manage the large amount of scientific data required for safety assessments and risk analysis. Some examples of NCTR's uses of bioinformatics follow.

ArrayTrack™ – FDA's Bioinformatics Infrastructure
The foundation of NCTR's bioinformatics infrastructure is ArrayTrack™, an NCTR-developed database and data-analysis tool. ArrayTrack™ includes tools openly available to scientists, such as:

- SNPTrack – measures the impact of genetic variation on drug treatment and personalized medicine
- Endocrine Disruptor Knowledge Base (EDKB) – a database of roughly 8,000 chemicals with endocrine disruptor activity data
- Estrogenic Activity Database (EADB) – assembles data from a variety of data sources and contains 18,114 estrogenic-activity data points collected for 8,212 chemicals tested in 11 different species.

FDALabel Database – Analyzing Drug Labels
FDASIA requires "inclusion of demographic subgroups in clinical trials and data analysis." NCTR scientists are refining FDALabel, an application that allows FDA to manage and analyze drug-label information. Using the set of approximately 50,000 FDA-approved drug labels, FDALabel enhances drug-safety assessments for demographic subgroups. These subgroups allow for personalization of treatment in the clinical setting.

Approximately 400-500 new or updated drug-labels with information about product indications, target populations, and adverse drug reactions are added weekly to an FDA product-labeling database. This rapid growth poses a challenge for FDA staff members who routinely review labeling for safety and effectiveness data by demographic subgroups. FDALabel addresses this challenge. In fact, user statistics show that the number of active users for FDALabel has tripled in the last two years.

In 2013, NCTR scientists refined FDALabel by collaborating with CDER and CBER to integrate FDALabel with the Medical Dictionary for Regulatory Activities (MedDRA). Additionally, NCTR compared the results of manually extracted MedDRA terms with those that were extracted using computer programs. The results validated the performance of the automated MedDRA-term extraction feature. This integration allows rich resources of adverse drug-reaction information in FDALabel to be accessed and used in drug reviews and research.

Drugs and Adverse Events
Also in support of FDASIA, NCTR scientists and CDER have developed an algorithm to identify the similarities and differences among drugs and adverse events in the FDA Adverse Events Reporting System database. The algorithm identifies associations between subsets of drugs and adverse events which analysts can then investigate to identify unrecognized adverse-event associations. In FY 2013, the analysis results of a sample dataset consisting of 193 cardiovascular drugs with 8,543 adverse events were published in the Journal of Biopharmaceutical Statistics (2013, 23:146-160) as an illustration.

NCTR and scientists from Germany's Hannover Medical School used the algorithm to analyze 164 FDA-approved oral medications and showed an association of high daily doses with significant risk for drug-

induced liver injury (DILI), known as a "rule of two." This "rule of two" can be used to estimate risk for DILI better than by dose alone.

NCTR is developing other mathematical models to predict how effective a regulated drug will be or if serious adverse drug reactions can be anticipated based on a patient's genetic make-up. These models can be implemented in an online knowledge base to alert reviewers, physicians, and patients of the potential for a drug to cause a serious adverse drug reaction in individuals with particular genetics before the drug is prescribed to the patient. With this information, FDA can offer patients and their health providers valuable information as to whether to use a particular drug.

Also, instead of withdrawing a drug that may have adverse reactions in certain patients, FDA can require the manufacturer to include appropriate warnings and to specify patient-marker criteria for prescribing it.

Identifying and Developing Biomarkers

Another tool for predicting FDA-regulated product toxicity is biomarker development. A biomarker indicates a biological state or condition that is measurable in human tissues, cells, or fluids. Biomarkers can be an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention. NCTR scientists continue research to identify new biomarkers to identify toxicity of FDA-regulated products sooner and to provide personalized medicine solutions.

NCTR is conducting research to identify more sensitive and specific biomarkers of chemical-driven liver damage. This research identifies compounds not typically identified as being toxic to the liver. A finding from this work is that urinary microRNA, found in all cells, may be useful to health providers as a biomarker of overall liver injury and by FDA for the classification of specific toxicants. In fact, the NCTR publication titled "Identification of Urinary microRNA Profiles in Rats That May Diagnose Hepatotoxicity" (*Toxicological Sciences*, 2012, 125: 335-344) received Honorable Mention for the 2013 Best Paper Award by the Society of Toxicology (SOT) Board of Publications. The article reported the identification of a number of microRNAs (miRNAs) with elevated levels in the urine in the liver of animals treated with liver-toxic compounds.

NCTR scientists have also demonstrated that exposure to chemical carcinogens results in altered gene expression which may be used as a biomarker for cancer-risk assessment, and that treatment of a lung epithelial-cell line with cigarette smoke condensates resulted in changes in a number of critical genes shown to be involved in lung-cancer development. These results suggest that gene changes could serve as early biomarkers of harm due to cigarette smoke exposure.

Molecular biomarkers are being developed to identify drug-induced heart damage. These molecular biomarkers can be used to predict harmful effects of drugs during safety evaluations, to reduce or reverse cardiac injury, and to improve therapeutic patient treatment. Additionally, NCTR has been running parallel studies in zebrafish and nonhuman primates to identify critical biomarkers for studying pediatric products. While conducting a zebrafish study, NCTR scientists found that some compounds with little inherent toxicity, like L-carnitine, can have remarkable protective effects against the toxicities induced by general-anesthetic agents.

Enhance Product Safety

Using scientific tools like mathematical models and bio-imaging, NCTR provides FDA with data to enhance the safety of its regulated products. Both tools are noninvasive. Bio-imaging, for example, is a noninvasive technique, where you can visualize biological processes in "real time" with as little interference as possible with life processes.

Bisphenol A (BPA)

Several published studies have raised concern about the potential toxicity of certain substances at sensitive developmental stages in humans. BPA is an example of a substance that has aroused concerns recently. To provide FDA unbiased information, NCTR scientists developed a mathematical model in FY

2013 to predict BPA's age-dependent effects and has shown that BPA exposures in very young rats over-predicts the effect on human infants. Results of this study were published in July 2013, in Toxicology and Applied Pharmacology (Vol. 270–1, July 2013, 45-59).

NCTR scientists will continue to develop data on BPA in fetal, neonatal, and adult rodent and nonhuman primate models. They will then combine data from these animal models with human data for predictive modeling of tissue exposures to BPA from food-contact materials, medical devices, and other sources.

Pediatric Anesthetics
The effect of pediatric anesthetics on children is an important area of research at NCTR. Advancements at NCTR's bio-imaging facility using NCTR-developed bio-imaging tools allows FDA to gather information not previously obtainable to help the medical community understand the relationship between the amount, type, duration, and frequency of pediatric-anesthetic use and its adverse effects on children. NCTR scientists have extended their original findings with pediatric anesthetics ketamine, isoflurane, and nitrous oxide to include propofol and sevoflurane. During the studies, scientists repeatedly find that acetyl-L-carnitine provides neuroprotective properties when given prior to and during pediatric anesthesia. This protective effect occurs in a variety of species. FDA will use this data to establish guidelines to reduce anesthetic-induced neurological toxicity.

Magnetic Resonance Imaging (MRI)
Additionally, NCTR is developing methods to validate MRI scans. These methods may help distinguish between an adverse event, such as a tumor, and a normal event, such as scar tissue, without invasive surgery and may lead to the development of new noninvasive biomarkers that offer the possibility of better diagnosis with less risk and cost to the patient.

Protect the Food Supply

Patient cost for treatment of foodborne illnesses is a heavy burden on the U.S. economy. NCTR supports FSMA by identifying food-related health hazards and defending the food system, thus decreasing the frequency and severity of food- and feed-borne illness outbreaks and diminishing the negative economic effect.

Antimicrobial Resistance
Supporting FSMA, NCTR – in collaboration with the Marshfield Clinic Research Foundation and China Agricultural University – characterized antimicrobial genes from *Salmonella enterica*, a foodborne pathogen. Researchers found that multiple genes were resistant to the same antimicrobial and that a high number of genes were able to transfer resistance to other genes for at least six antimicrobials. This finding shows that antimicrobial resistance can be transferred from resistant organisms to those that were not previously resistant, leading to an increased public-health concern. The results of these studies were published in PLoS One (7(12): e51160, doi:10.137/journal.pone.0051160) and Foodborne Pathogens and Diseases (doi: 10.1089/pd.2012.1455). Additionally, DNA sequences from these studies were deposited in the GenBank database as a resource for other researchers.

Bioterrorism
NCTR and the Illinois Institute of Technology, have shown that the thermal stability of ricin – a lethal protein toxin and potential bioterror agent – was greater in yogurt and yogurt-containing fruit drinks compared to other foods tested, such as milk, infant formulas, and fruit juices. Although the toxins in ricin may be inactivated using heat, these research results show that the pH level of the ricin-containing product influences the effectiveness of the heating process to detoxify the ricin. The results of this study were published in August 2013, in *Food and Chemical Toxicology* (Vol. 58, Aug 2013, 116-123).

Evaluate Innovative Emerging Technologies

Nanotechnology is science, engineering, and technology conducted at the nano scale. This emerging trend of using extremely small materials has the potential to be used in a broad array of FDA-regulated products.

New nanotechnology information becomes available every day and must be proactively assessed to protect the American public. Right now NCTR is conducting nanotechnology research. The NCTR-ORA Nanotechnology Core Facility generates data used by FDA reviewers to assess the safety and responsible development of products using nanomaterials and aids the development of guidelines for the safe and effective use of these materials in drug products, devices, foods, cosmetics, and dietary components.

Nanosilver
NCTR scientists are studying various routes of exposure to nanomaterials and the effects on the body. This information provides a better understanding of nanomaterials, which can then be used to inform regulatory decisions.

Exposure to nanoparticles – nanosilver especially, because of its antimicrobial use – from food or food packaging is the greatest nano-related risk to consumers. Scientists are studying nanosilver ingested by rodents for hazard identification and developing methods to measure nanosilver migration, providing data for regulatory decisions. In FY 2013, NCTR scientists found that some nanomaterials such as nanosilver interact with blood-brain-barrier cells and generate an adverse reaction.

Promote Global Interactions

Global Summit on Regulatory Science
Because of the importance for international regulators, policy makers, and scientists to exchange views on how to develop, apply, and implement innovative methodologies into regulatory assessments, NCTR established an annual Global Summit on Regulatory Science, now in its third year. NCTR hosted the two day third annual Global Summit in September, 2013 with international participants with a focus on nanotechnology, providing an opportunity for government, industry, and academic-research scientists to objectively assess the utility of emerging technologies, such as nanotechnology, imaging, and omics for translational science and personalized medicine, and how to translate these technologies into real-world applications.

To engage the global community and harmonize strategy via global collaboration, the Summit is held in a different location each year. The Summit prompted the development of a Global Coalition for Regulatory Science Research with scientific experts and Federal executives from around the world who collaborate to build knowledge of and promote regulatory science, define research needs, and strengthen product safety worldwide.

Bioinformatics Collaborations
NCTR and the Arkansas State University system are working together to establish a virtual Arkansas Bioinformatics Center to build bioinformatics capabilities. In FY 2013, there have been three planning meetings between NCTR, representatives from Arkansas colleges, and the Arkansas Research Alliance.

Nanotechnology Collaborations
Supported by a Memorandum of Understanding with FDA and the State of Arkansas, NCTR is collaborating with five Arkansas research universities on a virtual center for nanotechnology and nanotoxicology. In FY 2013, these partners held a consortium to discuss studies to synthesize the carbon-based nanomaterial, graphene, similar to the compound anticipated to be found in FDA-regulated products.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$60,563,000	$60,563,000	$0
FY 2012 Actual	$60,039,000	$60,039,000	$0
FY 2013 Actual	$54,965,000	$54,965,000	$0
FY 2014 Enacted	$62,494,000	$62,494,000	$0
FY 2015 Budget Request	$58,998,000	$58,998,000	$0

BUDGET REQUEST

The FY 2015 Budget is $58,998,000, which is all budget authority. This amount is $3,496,000 less than the FY 2014 Enacted level. This reduction in budget authority will delay the progress or start of critical research projects, delaying advances in science.

With this budget request NCTR will:

- conduct innovative research
- develop new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated products
- integrate comprehensive toxicology safety assessments maximizing existing and emerging technologies
- keep pace with the changing landscape of regulatory science
- provide valuable research data on products using new technologies
- conduct studies and create tools to help FDA better understand data submissions by product sponsors that are generated using new technologies.

The FY 2015 Budget allows NCTR to continue its ground-breaking research to support the ARS priorities of Evaluating Emerging Technologies, such as nanotechnology, bio-imaging, bioinformatics, and biostatistics. In each of these areas, investments have been made in recent years to build the capabilities and expertise for the benefit of FDA and ultimately, the American public. These funds will allow such efforts to continue and will give the programs and associated projects the opportunity to mature. Additionally, the advances made by NCTR in the area of biomarker identification can continue in support of the ARS Priority to Improve Product Development and Patient Outcomes by tailoring medical products to provide more personalized medicine.

PERFORMANCE

NCTR's performance measures focus on research to advance the safety of FDA-regulated products, on developing a strong FDA science base for emerging technologies, and on providing personalized medicine solutions in order to protect and improve the health of the American public as detailed in the following table.

Measure	Most Recent Result / Target for Recent Result	FY 2014 Target	FY 2015 Target
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates *(Output)*	FY2013: 1) Findings on prolonged exposure to certain anesthetic agents have been published and presented at several scientific conferences	1) Complete a simulation protocol to help reduce the uncertainty in the risk-assessment of BPA 2) Evaluate the effects of methylphenidate, a	1) Complete research that will provide information on toxicity of nanoscale silver 2) Present findings on

Measure	Most Recent Result / Target for Recent Result	FY 2014 Target	FY 2015 Target
	(Target Met) 2) Identified specific genetic factors that may lead to varying vulnerability seen with a progressive form of liver disease (Target Met) 3) Characterized the virulence and antimicrobial resistance of *Salmonella Enteritidis* and Heidelberg isolates (Target Met)	drug for the treatment of Attention-Deficit Hyperactivity Disorder, using bioimaging techniques	research aimed at identifying biomarkers(biological indicators) to predict the effects of cancer drugs on the heart
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies *(Output)*	FY2013: 1)14 novel biomarkers were identified when using a combination of next generation sequencing, microarray, and bioinformatics (Target Met) 2) Showed that divergent strains of coronavirus circulate in regions of Arkansas (Target Met) 3) Developed an FDA-related nanoparticle for study (Target Met)	1) Define the miRNA biomarker genes that are associated with carcinogen exposure 2) Determine if biomarkers can be found to improve the detection of drugs and chemicals that cause liver injury	Outline and initiate research to find practical imaging approaches for studying developmental neurotoxicity produced by exposure to general anesthetics
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize therapeutic care *(Output)*	FY2013: Published results that found potential for new breast cancer therapy using epigenetic approach (Target Met)	Determine if some drugs cause a higher incidence of liver toxicity in women than men	1) Complete pilot project that will promote women's health by facilitating the development of personalized approaches to treat breast cancer 2) Evaluate serum metabolic biomarkers to determine whether they are correlated to acute kidney illness diagnosis and prognosis
264101: Develop risk assessment methods and build biological dose-response models in support of food protection *(Output)*	FY2013: Initial results of new method for rapid detection of pathogens indicate potential detection in smaller particles(Target Met)	Identify an assay to detect infectious norovirus in contaminated foods	Initial results issued on research to find a robust and convenient method to verify the potency of potential bioterrorism agents in food supply

Measure	Most Recent Result / Target for Recent Result	FY 2014 Target	FY 2015 Target
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates *(Output)*	FY2013: 1) Developed a centralized system of both data and predictive models useful for research and regulation concerning drug-induced liver injury (Target Met) 2) Algorithm developed that characterizes similarities and differences among drugs in an FDA adverse event database (Target Met)	Determine if miRNA(found in easily-obtained body fluids) exhibit superior biomarker properties that can be used for indicating drug induced liver injury	Use a new approach—antibody microarray analysis—to identify proteomic changes that may precede neurotoxicity
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products *(Output)*	FY2013: 1) Published review on performance of major next generation sequencing systems and analyses related to cancer 2) Developed suite of pharmacogenetic software tools	Find new uses for existing and abandoned drugs	Establish a modeling tool that can be used to predict drug-repurposing opportunities

The following selected items highlight notable results and trends detailed in the performance table.

Advance the Safety of FDA-Regulated Products

Findings on prolonged exposure to certain anesthetic agents have been published and presented at several national and international scientific conferences including two FDA advisory panel meetings and are enabling clinical studies by supplying exposure, endpoint, and prevention approaches to improve the safe use of anesthetics in children. Research in the field of children's anesthetics is ongoing at NCTR and continued evaluation of the neurotoxicity of sevoflurane and propofol is a goal for 2014.

Develop Science Base for New and Emerging Technologies

A combination of next-generation sequencing, microarray, and bioinformatics techniques was used to identify 14 novel biomarkers in an animal model. The research adds to the growing knowledge of using miRNA - found in easily-obtained body fluids - as biomarkers for the early detection of diseases and adverse drug events. In 2014, NCTR will conduct research to define the miRNA biomarker genes that are associated with carcinogen exposure.

Personalized Medicine

Investigators at NCTR conducted experiments that highlighted the potential for a new epigenetic approach in improving breast-cancer therapy by targeting cancer genes using miRNA. The method shows promise as a noninvasive breast cancer therapy. These findings were published in the *Journal of Carcinogenesis* in July 2013. Future plans for research in the area of personalized medicine include determining whether some drugs cause a higher incidence of liver toxicity in women than men and completing research that promotes women's health with personalized approaches to breast cancer.

PROGRAM ACTIVITY DATA

National Center for Toxicological Research Program Activity Data (PAD)

Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Research Outputs			
Research Publications	146	180	185
Research Presentations	149	158	152
Patents (Industry)	5	5	6
Leveraged Research			
Federal Agencies (Interagency Agreements)	3	6	5
Nongovernmental Organizations	13	16	16
Active Research Projects	154	166	155

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OFFICE OF REGULATORY AFFAIRS – FIELD ACTIVITIES

(dollars in thousands)	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Office of Regulatory Affairs	**937,745**	**874,601**	**1,038,317**	**1,218,425**	**180,108**
Budget Authority	***830,222***	***830,219***	***917,329***	***929,139***	***11,810***
User Fees	***107,523***	***44,382***	***120,988***	***289,286***	***168,298***
Prescription Drug (PDUFA)	*13,932*	*9,170*	*15,489*	*16,263*	*774*
Medical Device (MDUFA)	*1,961*	*2,179*	*2,105*	*2,105*	*---*
Animal Drug (ADUFA)	*339*	*291*	*472*	*404*	*-68*
Animal Generic Drug (AGDUFA)	*156*	*158*	*220*	*186*	*-34*
Family Smoking Prevention and Tobacco Control Act	*8,936*	*13,717*	*14,989*	*15,887*	*898*
Mammography Quality Standards Act (MQSA)	*12,431*	*9,361*	*13,077*	*13,339*	*262*
Voluntary Qualified Importer Program	*---*	*---*	*---*	*4,320*	*4,320*
Food and Feed Recall	*9,973*	*---*	*10,491*	*1,000*	*-9,491*
Food Reinspection	*9,316*	*---*	*9,800*	*5,382*	*-4,418*
Generic Drug (GDUFA)	*49,253*	*9,506*	*53,023*	*54,083*	*1,060*
Biosimilars (BsUFA)	*1,226*	*---*	*1,322*	*1,348*	*26*
Food Facility Registration and Inspection	*---*	*---*	*---*	*28,414*	*28,414*
Food Import	*---*	*---*	*---*	*137,056*	*137,056*
International Courier	*---*	*---*	*---*	*5,003*	*5,003*
Cosmetics	*---*	*---*	*---*	*4,496*	*4,496*
FTE	**4,562**		**4,970**	**5,250**	**280**

Authorizing Legislation: Filled Milk Act (21 U.S.C. §§ 61-63); Federal Meat Inspection Act (21 U.S.C. § 679(b)); Federal Import Milk Act (21 U.S.C. § 141, et seq.); Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.); The Office of Criminal Investigations (OCI) of ORA conducts criminal investigations and executes search warrants as permitted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372), the Public Health Service Act (42 U.S.C. 262) and the Federal Anti-Tampering Act (18 U.S.C. 1365); Poultry Products Inspection Act (21 U.S.C. § 467f(b)); Small Business Act (15 U.S.C. § 638); The Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.); Executive Order 11490, § 1103; Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241); Controlled Substances Act (21 U.S.C. § 801, et seq.); Lead-Based Paint Poisoning Prevention Act (42 U.S.C. § 4831(a)); Federal Advisory Committee Act (5 U.S.C. Appx. 2); Federal Caustic Poison Act (44 Stat. 1406); Egg Products Inspection Act (21 U.S.C. § 1031, et seq.); Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. § 3701, et seq.) and Executive Order 12591; Equal Access to Justice Act (5 U.S.C. § 504); Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. §§ 10007 and 10008); Patent Term Extension (35 U.S.C. § 156); Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. §§ 1401-1403); Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. §138a); Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104-180); Best Pharmaceuticals for Children Act (Public Law 107-108), as amended by Pediatric Research Equity Act of 2003 (Section 3(b)(2) of Public Law 108-155); and Drug Quality and Security Act of 2013.

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Office of Regulatory Affairs (ORA) is the lead office for all FDA Field activities and provides leadership on imports, inspections, investigations, execution of compliance and enforcement policy, and regulatory science.

ORA has personnel throughout the United States stationed in:

- five regional offices
- 20 district offices
- 13 laboratories
- 171 resident posts and border stations
- FDA Headquarter offices.

ORA's Office of Criminal Investigation (OCI) personnel are located in 46 field, resident, and domicile offices throughout the United States. ORA collaborates with state, local, tribal, and territory counterparts to further FDA's mission. ORA funds contracts, grants, and cooperative agreements to enable states to perform inspections and provide technical assistance in such areas as milk, food, and shellfish safety. State inspection staff members attend and participate in ORA sponsored training courses.

Foods

ORA contributes to the establishment of a fully integrated food safety system to prevent foodborne illness through the Manufactured Food Regulatory Program Standards, Voluntary Retail Program Standards, other appropriate program standards, and cooperative training grants. ORA advances public health by protecting consumers through:

- preventive controls
- outreach coordination
- technical assistance to industry
- training and collaborating with external stakeholders.

ORA explores and adopts innovative technologies and processes to detect and investigate outbreaks and contamination incidents, strengthen food defense and safety, surveillance, and risk analysis. ORA creates efficiencies through the utilization of mobile laboratories, handheld analytical tools, and nanotechnology capabilities. ORA leverages data sharing and outreach partnerships including:

- Food Emergency Response Network laboratories
- Rapid Response Teams
- Partnership for Food Protection
- Food Protection Task Force grants
- state contracts
- 50 State meetings
- working with U.S. Customs Border Protection (CBP).

ORA targets high risk food shipments that may cause death or serious injury to humans or animals. As the number of import entry lines into the United States continues to increase, this strategic application of import activities is critical for directing ORA resources such as:

- prior notice reviews
- entry reviews
- field exams
- label examinations
- broker and filer evaluations
- sample collections
- laboratory analyses.

ORA assists in the development and implementation of rules to support a risk-based approach to screen and make admissibility decisions of imported shipments using various IT applications, which include:

- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)
- Import Trade Auxiliary Communications System (ITACS)
- Entry Review.

ORA uses risk factors to target firms to inspect and focus the onsite inspections in the most critical areas of regulated domestic and foreign food establishments. ORA initiates enforcement actions to address violations of public health laws and regulations.

Food inspection contracts provide funding to states and territories to conduct domestic inspections. Internationally, ORA district-based investigators, foreign inspection cadre, and inspection staff located at ORA's foreign offices, cover the foreign establishment inventory. ORA conducts inspections and performs sample analyses on foreign products in order to prevent unsafe food and cosmetic products from reaching U.S. consumers.

During FY 2013, ORA:

- filed ten injunctions and consent decrees signed against food and dietary supplement firms
- executed five seizures at various firms against various articles of food and dietary supplements
- classified 309 Class I, 241 Class II, and 66 Class III food and cosmetic related recall events
- issued 1,006 import alert notices – detentions without physical examination – encompassing numerous food products and food manufacturers determined to be manufacturing or shipping non-compliant products
- maintained seven cooperative agreement training grants – entering their third year – that directly link to the work of the Partnership for Food Protection and assist in the implementation of the Integrated Food Safety System and the Food Modernization Act training requirements
- made 14 foods related arrests and 16 foods related convictions; resulting in $18 million in fines or restitutions

Human Drugs

ORA is responsible for conducting oversight of the drug industry with the public health objective of ensuring the safety of pharmaceuticals and preventing consumers from being exposed to unsafe, illegal, fraudulent, substandard, or improperly labeled products.

Adverse Event Reporting and Risk Evaluation Mitigation Strategies (REMS) were mandated by the Food and Drug Administration Amendments Act (FDAAA). The purpose of REMS is to provide drug safety information to the public, to improve transparency and communication. The manufacturer is required to disseminate information to ensure patients are aware of both the benefits and risks of drugs. ORA reviews this data to further assess manufacturing and quality issues in addition to any under reporting of adverse events.

The Bioresearch Monitoring Program (BIMO) conducts inspections of scientific studies to support the safety and effectiveness of investigational drugs. Physicians and other qualified experts, such as clinical investigators who conduct these studies, are required to comply with applicable statutes and regulations. These statutes and regulations help ensure the integrity of clinical data on which product approvals are based, and to help protect human rights, safety, and welfare by ensuring the integrity of investigations involving human subjects.

In FY 2013, ORA launched a pilot program enabling manufacturers to electronically submit Field Alert Reporting (FARs) to improve the speed and efficiency of reporting quality issues relating to the manufacture of FDA approved drug products. This new electronic reporting system for use by regulated industry provides simultaneous reporting to FDA to act quickly in determining when firms are implementing corrective actions, recalling products, or when inspections are required.

During FY 2013, ORA:

- conducted field and label examinations on 22,775 import entry lines of human drug product
- collected samples collections on 355 import entry lines
- refused over 16,035 import entry lines of violative products
- screened 264 dietary supplement products and found 225 positive for the presence of Sibutramine, an active pharmaceutical ingredient or sibutramine analogs
- conducted more than 30 inspections of firms processing sterile drug products
- conducted 443 domestic and 365 foreign high risk human drug inspections

- issued 43 warning letters to foreign firms
- issued 183 import alert notices – detentions without physical examination – related to human drug products
- filed five injunctions or consent decrees against drug firms; one seizure at a drug firm was executed against (an) article(s) of drug
- made 303 human drug related arrests and 273 human drugs related convictions resulting in over $235,000,000 in fine and restitutions
- classified 46 Class I, 192 Class II, and 101 Class III drug recall events
- conducted 1,851 domestic and 827 foreign inspections for human drugs
- ORA and CDER collaborated with Health Canada through the Regulatory Cooperation Counsel's Good Manufacturing Practice (GMP) Work Group, to develop routine exchange of information and initiated an observed inspection program; 4 observed inspections were completed.

Biologics

ORA supports the Biologics Program in ensuring the safety, purity, potency and effectiveness blood and blood products, for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries and helps to defend the public against the threats of emerging infectious diseases and bioterrorism.

ORA assesses industry compliance with current Good Manufacturing Practice (cGMP) and other applicable FDA regulations and recommends regulatory actions to the Biologics Program.

ORA performs the following Biologics Program related activities:

- conducts inspections both domestically and internationally
- conducts entry review and verification for imported products
- investigates and supports voluntary compliance and enforcement cases when violations of regulations are identified
- monitors recalls.

ORA investigators conduct surveillance inspections of foreign and domestic biologic manufacturers, including blood and tissue establishments, vaccine and allergenic facilities, biologic device manufacturers, gene and cell therapy facilities, and plasma fractionators. Inspections include documenting cGMP violations and assessing the overall compliance with regulations. These efforts ensure that the biologics industry continuously reviews the quality standards of their manufacturing operations to ensure the safety of biologics products on the U.S. market.

During FY 2013, ORA:

- conducted 669 inspections of high risk tissue establishments and 976 inspections of high risk blood banks, and 55 inspections of biologics manufacturing establishments
- issued an Order to Cease Manufacturing to a fertility clinic in March 2013
- made one biologic product related arrest and five biologic product related convictions; resulting in $442,552 in fines and restitutions
- classified four Class I, 1103 Class II, and 426 Class III biologic related recall events.

Animal Drugs and Feeds

ORA focuses on prevention as a top field priority through:

- outreach coordination
- technical assistance
- training internal and external stakeholders.

ORA raises awareness and understanding of current policies and guidance and provides insight and information on pending and new requirements. ORA collaborates with the programs and states to develop standards for an integrated food safety system.

ORA takes a proactive and evidence based approach to resolving regulatory issues through:

- sample collection and analysis
- product testing
- methods development and validation
- data analysis
- data reporting.

Two IT systems which assist in providing evidence based information to take into consideration when making regulatory decisions are PREDICT and ITACS. PREDICT allows ORA to make more efficient and accurate admissibility decisions and allows FDA to target the examination of higher-risk imported products. ITACS allows the import community to provide information electronically and improve communication with FDA. By adopting risk-based approaches in conducting domestic and foreign inspections, ORA strategically utilizes resources and maximizes the public health benefit by ensuring higher rates of compliance.

ORA provides funding to state, local, tribal, and territorial partners to support capacity building in the areas of recalls and inspections in support of Food Safety Modernization Act (FSMA). When firms are found to be in violation of FDA requirements, ORA takes regulatory action to assist the firms to comply. When firms refuse to comply with FDA regulations, ORA takes further enforcement action to ensure unsafe products do not reach U.S. consumers and requests the firms potential shut down.

During FY 2013, ORA:

- made six arrests and three convictions; resulting in $45,000 in fines and restitutions related to animal drugs and feeds
- filed two tissue residue injunctions and consent decrees signed
- classified 31 Class I, 18 Class II, and 14 Class III animal drug and feed related recall events.

Devices and Radiological Health

ORA laboratories develop new and innovative test methods for analyzing a variety of medical devices and radiation emitting products to ensure that products meet FDA quality standards:

- x-ray units
- infusion pumps
- ventilators
- lasers.

ORA oversees state conducted mammography inspections and conducts foreign inspections to ensure the safety of mammography services conducted in military facilities in foreign countries.

During FY 2013, ORA:

- conducted 2,887 domestic and 535 foreign inspections of Medical Device and Radiological Health facilities
- issued 118 import alert notices – detentions without physical examination – encompassing numerous medical device and radiation emitting products and manufacturers determined to be manufacturing or shipping non-compliant products
- issued one injunction against a device manufacturer
- made 37 device related arrests and secured 15 device related convictions resulting in assessing $1,745,689 in fines and restitutions

- classified and issued 69 Class I, 1010 Class II, and 67 Class III device related recalls events.

ORA continues to collaborate with the Devices and Radiological Health Program to develop a pilot program intended to provide FDA with the capability of receiving third party audit reports on medical device manufacturers. The objective of the pilot is to provide FDA with additional information related to the compliance status of manufacturers, thus expanding FDA's knowledge of regulated industry when identifying manufacturers for routine surveillance inspections. In implementing and assessing this pilot, FDA aims to have increased information to perform its risk-based work planning, allow for greater efficiency in FDA's use of resources, and provide broader understanding of regulated industry. This program will lead to greater regulatory and consumer confidence in the medical device supply chain and allow for safe and effective medical device products for the U.S. market.

Tobacco

ORA conducts inspections of registered tobacco product manufacturers to determine their compliance with applicable FDA laws and regulations, including registration, product and ingredient listing, packaging, labeling and advertising requirements, and marketing authorization for new or modified risk tobacco products.

ORA issued two import alerts related to the restrictions on the terms "low," "mild," and "light" to describe tobacco products and for prohibited candy or fruit flavored cigarettes to identify, detain, and refuse these products being offered for import. This effort creates a mechanism for detention without physical examination of imported tobacco products found to be adulterated or which otherwise do not conform to the same regulatory requirements as domestically-manufactured tobacco products. To ensure compliance with current regulations, a total of 6,052 warning letters were issued in FY 2013 related to Center of Tobacco issues.

ORA is establishing tobacco flavor methods, so that the ban on characterizing flavors under the Tobacco Control Act can be enforced through special testing assignments. In addition, ORA is developing analytical methods to support product standards testing that will commence in the near future as companies start submitting pre-market approvals for new tobacco products.

During FY 2013, ORA:

- completed approximately 110,000 compliance check inspections of tobacco retailers
- conducted 50 inspections of registered tobacco manufactures
- conducted six site visits to tobacco product managers to gain knowledge of manufacturing process and regulations
- made seven tobacco related arrests, secured 14 tobacco related convictions, and assessed $1,600 in fines and restitutions.

One representative case involves a foreign-based distributor of counterfeit tobacco products. In February 2013, a Chinese national was found guilty in Providence, Rhode Island, for selling and importing counterfeit tobacco products into the United States from China. The removal of counterfeit cigarettes from the marketplace is vital in that counterfeit cigarettes typically do not contain fire standard compliant technology and have been shown to contain high levels of heavy metals and other harmful constituents.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$912,120,000	$890,474,000	$21,646,000
FY 2012 Actual	$931,778,000	$906,768,000	$25,010,000
FY 2013 Actual	$874,601,000	$830,219,000	$44,382,000
FY 2014 Enacted	$1,038,317,000	$917,329,000	$120,988,000
FY 2015 Budget Request	$1,218,425,000	$929,139,000	$289,286,000

BUDGET REQUEST

The FY 2015 Budget is $1,218,425,000, of which $929,139,000 is budget authority and $289,286,000 is user fees. This amount is $180,108,000 more than the FY 2014 Enacted level. The FY 2015 Budget includes initiatives for food safety and pharmacy compounding. This increase will allow ORA to meet its mission of ensuring that food, feed and medical products available to the American public are safe and effective.

The FY 2015 Budget will allow FDA to accomplish its mission by managing a network of investigators and lab analysts that will conduct all of FDA's field inspections, investigations, exams, sample collection, lab analysis, and enforcement. These activities, in coordination with the efforts of the six Product Centers, ensure the adherence of laws that protect and advance public health. The continued support equips ORA to meet the challenges posed by the increasing globalization of the U.S. food supply and FSMA requirements. The increase in budget authority will allow FDA to make improvements to several systems that have been implemented to support its numerous initiatives such as PREDICT, ITACS, and MACS ER. In addition, FDA will increase the number of inspections and other related functions. The initiatives proposed under the FY 2015 budget request support HHS, FDA, and Presidential public health priorities and mission critical activities.

Medical Product Safety

Pharmacy Compounding Initiative: Inspections and Enforcement and Policy Development (+$7,397,000)

Human Drugs (+$6,943,000)

The FY 2015 budget request will allow ORA field offices to protect public health through the ongoing investigation and inspection of human drug products from both domestic and foreign production facilities. Through field sampling, facility inspections, laboratory analysis and entry examinations, the ORA field offices ensure human drugs are compliant with all Federal safety laws and pursue those who are negligent in their compliance.

ORA has requested increased funding to conduct additional inspections of high-risk human drug compounding pharmacies including sterile compounding facilities that seek to qualify for the exemptions under section 503A and facilities that register as outsourcing facilities under section 503B. This funding will provide for additional proactive and follow-up inspections of compounding pharmacies and outsourcing facilities.

Biologics (+$102,000)

Additional funding will be used to support FDA's initiative related to the investigation of high-risk pharmacy compounding facilities producing compounded biologics.

Animal Drugs and Feeds (+$352,000)

Additional funding will be used to support FDA's initiative related to the investigation of high-risk pharmacy compounding facilities producing compounded animal drugs.

Proposed International Courier User Fee (+$4,253,000)

Human Drugs (+$501,000)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. Current FDA staffing does not match the growth in import volume. Couriers expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee. The user fee resources will support increased import surveillance of FDA-regulated products at express courier hubs

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

This user fee supports patient safety and reduces health care costs by keeping unapproved and counterfeit products out of U.S. commerce.

Devices and Radiological Health (+$3,752,000)

Millions of shipments of FDA regulated commodities, predominantly medical products, enter the United States through express courier facilities. These shipments are often destined for individual consumers or for illegal distribution. The number of shipments continues to grow, and current FDA staffing does not match the growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

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

Food Safety

Food Safety Modernization: Training and Federal-State Integration (+$7.0 million)

FDA will increase training to certify personnel among federal, state, local, tribal, territorial, and international stakeholders by creating, administering, and maintaining a system that provides an opportunity for the personnel to demonstrate their competency as food safety regulatory officials. The budget request supports collaborative agreements, such as the Manufactured Food Regulatory Program Standards, which allows for the development of a risk-informed food safety program that establishes a uniform basis for measuring and improving the performance of state manufactured food regulatory program standards. The Budget also ensures that the Integrated Food Safety System cooperative training grants are continued.

Proposed Food Import User Fee (+137,056,000)

Foods (+$123,366,000)

This investment will support the implementation of the Foreign Supplier Verification Program, which is a comprehensive prevention-focused import food program that relies heavily on those in the food supply chain – food manufacturers, processors, packers, distributors, and importers – to provide assurances that the food imported to the United States are safe and meet regulatory requirements. FDA will implement

foreign establishment registration verification of foreign firms by conducting a foreign supplier verification program.

FDA will provide outreach and education on FSMA import provisions, including outreach to the import community and other federal agencies involved in the import process. FDA will implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process. The national call center initiative will improve responsiveness to inquiries concerning the import process or the status of imports. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems.

The implementation of expanded port and border hours will increase port and border coverage by adding staff and expanding hours of operation, thus providing improved screening for food safety while speeding up the overall entry admissibility process for safe products. Moreover, capital investments will be directed to acquire additional space at various border locations to support this effort. This additional space will increase efficiency, improve industry and FDA communication, reduce time to resolve problems, and improve movement of trade.

Improving the import review process will allow FDA to improve information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives. FDA also plans to utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation.

In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities FDA physically examined. FDA will research, test, validate, and purchase analytical tools for rapid screening of products at the border. The tools will allow for improved risk analytics by permitting the targeting of products with the highest probability of being violative and the rapid release of all others into U.S. commerce. This investment will also allow for the development of FDA's fee collection system that supports the design, testing, and implementation of a system to administer the import user fee program.

Animal Drugs and Feeds (+$13,690,000)

With this investment FDA will provide outreach and education on FSMA import provisions, including outreach to the import community and other Federal agencies involved in the import process. FDA will implement a quality management system and quality control measures for the import review process at all locations and provide dedicated quality management measures to assess and assure the consistency of the import review process. This investment will allow FDA to provide timely responses to inquiries concerning the import process or the status of imports by establishing a national call center. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. Along with support to increase port and border coverage with increased staff and longer hours of operation, thus providing improved screening for food safety while also speeding up the overall entry admissibility process for safe products.

Moreover, FDA will make capital investment to acquire additional space at various border locations to support this effort. This investment will result in increased efficiency, improved industry and FDA communication, reduced time to resolve problems, and improved movement of trade. FDA will improve

information technology to enhance risk information and thus risk-based decision making for import personnel. IT tools, systems, and infrastructure allow FDA to improve and expedite the identification of threats to the public health, and ultimately reduce the incidence of foodborne illness outbreaks. With these resources, FDA will implement systems and IT changes to improve the consistency, predictability, and speed of the import review process, by working with industry to enhance the quality of data FDA receives.

FDA will utilize Remote Access Devices to allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities FDA physically examined. This funding will support the implementation of the Foreign Supplier Verification Program (FSVP), which is a comprehensive prevention-focused import food and feed safety program that relies heavily on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. Thus, allowing FDA to implement registration verification of foreign firms by conducting a foreign supplier verification program.

Proposed Food Facility Registration and Inspection User Fee (+$28,414,000)

Foods (+$27,376,000)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will provide funding to Federal, State, local, territorial, and tribal regulatory and public health partners in the form of at least 20 grants or cooperative agreements, contracts, or inter-agency agreements between federal agencies. A minimum of 16 of the state grants, contract, cooperative agreements, or inter-agency agreements between federal agencies would be funded with budget authority and four State contracts would be funded with user fees. ORA also plans to improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations. The resources allocated to planning and response will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts. This funding will support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new trace-back tools and new systems that unify information received from FDA regulatory partners and private industry. ORA will develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard. Additional resources will be provided to ensure programmatic objectives and implementations of the Integrated Food Safety System are coordinated and provide support for the governance structure. ORA will also serve as field State liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards. ORA will develop and validate certification testing instruments, serve as Official Establishment Inventory (OEI) Coordinators for the field and support the States as FDA moves to national standards for laboratories. FDA will implement and enforce preventive controls in food processing facilities, and begin training more than 3,400 (1,100 FDA and 2,300 State) ORA inspections personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct

sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Animal Drugs and Feeds (+$1,038,000)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. Investments will allow FDA to implement preventive controls in feed processing facilities. Through the support the implementation and enforcement of preventive controls in feed processing facilities; and continue to train more than 215 inspection personnel consisting of ORA inspection personnel, as well as a portion of FDA's State, tribal, and territorial regulatory partners in preventive controls inspections and enforcement methods. ORA will continue to assist the States implementation of Animal Feed Regulatory Program Standards (AFRPS), as well as provide support and coordinate with the States as FDA moves to national standards for laboratories.

Proposed Cosmetics User Fee (+$4,496,000)

Foods (+$4,496,000)

FDA is proposing new legislative authority to require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and list their products with FDA as well as pay an annual fee on a sliding scale for certain small businesses. Registration will provide both FDA and industry with a better understanding of the cosmetic products being marketed. The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used by consumers.

Without this initiative, FDA will continue to lack vital information necessary to provide domestic regulatory oversight and leadership, as well as leadership in international harmonization efforts. Moreover, without knowledge of the full range of cosmetic products and ingredients marketed in the United States and the facilities that are involved in providing such products to American consumers, including foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe products.

Proposed International Courier User Fee (+$750,000)

Foods (+$750,000)

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

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

With this new user fee, FDA will:

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

PERFORMANCE

ORA's performance measures focus on import screening activities, laboratory capacity, and domestic and foreign inspections in order to ensure that food, feed and medical products available to the American public are safe and effective, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
214201: Number of prior notice import security reviews. *(Output)*	FY 2013: 81,199 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2013: 187,819 Target: 160,158 (Target Exceeded)	160,000	160,000	maintain
214203: Number of Filer Evaluations. (Output)	FY 2013: 1,300 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2013: 10,405 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2013: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	maintain
214209: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 19,500 firms) every three years. *(Output)*	FY 2013: 100% Target: 100% of approximate inventory every three years based on 22,000 firms (Target Met)	33%	67%	+33%
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2013: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	maintain
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2013: 808 Target: 750 (Target Exceeded)	750	750	maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2013: 1,031 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2013: 669 Target: 533 (Target Exceeded)	570	570	maintain
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2013: 275 Target: 250 (Target Exceeded)	250	250	maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2013: 540 Target: 500 (Target Exceeded)	500	500	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2013: 333 Target: 300 (Target Exceeded)	300	300	maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2013: 2,048 Target: 1,515 (Target Exceeded)	1,600	1,600	maintain

The following selected items highlight notable results and trends detailed in the performance table.

FSMA High Risk Domestic Inspection Coverage

FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world. ORA plays a critical role in the implementation of FSMA; and the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting 100 percent of the high-risk domestic inventory every three years. The FY 2014 target represents the first year of a three-year cycle. This goal serves to cumulatively track the progress over the three year period as the coverage of inventory approaches the FSMA requirement of 100 percent. At the time of enactment, the legislation permitted a five-year cycle to meet the level of inspection coverage; and 100 percent of coverage to be met in three-year cycles thereafter. The close of FY 2013 marked a milestone in which ORA met the five year high-risk goal in three years.

Increase Laboratory Surge Capacity

A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of sample of potentially contaminated foods for the presence of contaminants. 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.

Domestic and Foreign High Risk Inspections

One critically important step toward enhanced consumer protection is the Agency's development of a risk-based model to establish consistent, agency-wide priorities when developing annual domestic and foreign field activities. Important features of the risk-based model 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; including both inherent risk (outbreaks, Class I recalls, adverse events) and compliance history. FDA continues to enhance its risk-based compliance and enforcement activities by increasing inspections of registered manufacturers, which are essential for meeting national public health objectives. These products involve complex manufacturing processes and are in limited supply in some cases. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk firms enter the market, or the definition of high risk evolves based on new information on 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 or sample results. FDA has made inspecting high-risk domestic and foreign firms a priority, and has set multiple performance goals for these high-risk facilities. As a result of these efforts, in FY 2013 FDA met or exceeded inspection targets for human drugs and foods, as well as animal drugs and feeds facilities.

PROGRAM ACTIVITY DATA

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,658***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,403	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	210		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	232		
Domestic Fish & Fishery Products (HACCP) Inspections	1,012		
Import (Seafood Program Including HACCP) Inspections	135		
Juice HACCP Inspection Program (HACCP)	146		
Interstate Travel Sanitation (ITS) Inspections	904		
Domestic Field Exams/Tests	2,272	3,945	3,945
Domestic Laboratory Samples Analyzed	10,466	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,403*** [1]	***1,200***	***1,200***
All Foreign Inspections	1,403	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,061***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	187,819	160,200	160,200
Import Laboratory Samples Analyzed	29,810	35,300	35,300
Import Physical Exam Subtotal	**217,629**	**195,500**	**195,500**
Import Line Decisions	11,502,065	12,201,809	12,201,809
Percent of Import Lines Physically Examined	1.89%	1.60%	1.60%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	81,199	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,355***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***269***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,137	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	967	1,104	1,104
State Contract Juice HACCP	89	103	103
State Contract LACF	75	68	68
State Partnership Inspections	269	273	273
State Contract Foods Funding	$13,741,087	$13,076,000	$13,076,000
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$18,455,000	$18,455,000	$18,455,000
Total State & Annual FERN Funding	**$32,196,087**	**$31,531,000**	**$31,531,000**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,685***	***20,496***	***20,496***

[1] The FY 2013 actual unique count of foreign inspections includes 65 OIP inspections (45 for China and 20 for India).

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**100**	**100**	**100**
Domestic Inspections	125	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**0**	**0**	**0**
Foreign Inspections	5	0	0
IMPORTS			
Import Field Exams/Tests	2,925	1,600	1,600
Import Laboratory Samples Analyzed	461	540	540
Import Physical Exam Subtotal	**3,386**	**2,140**	**2,140**
Import Line Decisions	2,433,747	2,883,187	2,883,187
Percent of Import Lines Physically Examined	0.14%	0.07%	0.07%
GRAND TOTAL COSMETICS ESTABLISHMENT	**130**	**100**	**100**

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,851***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	112	171	171
Pre-Approval Inspections (ANDA)	117	216	216
Bioresearch Monitoring Program Inspections	526	563	563
Drug Processing (GMP) Program Inspections	967	591 [2]	591 [4]
Compressed Medical Gas Manufacturers Inspections	173	295	295
Adverse Drug Events Project Inspections	89	120	120
OTC Monograph Project and Health Fraud Project Inspections	59	79	79
Domestic Laboratory Samples Analyzed	1,840	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***827*** [1]	***999***	***999***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	163	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	141	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	190	255	255
Foreign Drug Processing (GMP) Program Inspections	604	843	843
Foreign Adverse Drug Events Project Inspections	6	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,678***	***2,855***	***2,855***
IMPORTS			
Import Field Exams/Tests	7,137	7,200	7,200
Import Laboratory Samples Analyzed	418	490	490
Import Physical Exam Subtotal	**7,555**	**7,690**	**7,690**
Import Line Decisions	590,079	911,465	911,465
Percent of Import Lines Physically Examined	1.28%	0.84%	0.84%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS.	***30***	***0*** [3]	***0***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	0	0	0
State Partnership Inspections: GMP Inspections	30	0	0
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,708***	***2,855***	***2,855***

[1] The FY 2013 actual unique count of foreign inspections includes 67 OIP inspections (17 for China and 50 for India).

[2] The FY 2014 planned mix of domestic versus foreign GMP inspections shifts quite a few more inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2013 actuals, but the overall coverage is not changing, This is being done to achieve greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

[3] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

[4] The pharmacy compounding inspections were not included in the Field Human Drugs Program Activity Data Table (PAD) table because these inspections are not directly accounted for under the categories currently tracked in the PAD. The Good Manufacturing Practices (GMP) inspections line may include some inspections that happened to be conducted at pharmacy compounding facilities, but this number would only account for a subset of the total number of pharmacy compounding inspections.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,004***	***2,047***	***2,047***
Bioresearch Monitoring Program Inspections	89	100	100
Blood Bank Inspections	758	1,000	1,060
Source Plasma Inspections	186	194	194
Pre-License, Pre-Market Inspections	14	7	7
GMP Inspections	35	28	28
GMP (Device) Inspections	6	7	7
Human Tissue Inspections	669	661	661
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***74***	***47***	***47***
Bioresearch Monitoring Program Inspections	24	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	8	8	8
Pre-License, Pre-market Inspections	8	2	2
GMP Inspections (Biologics & Device)	30	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***2,078***	***2,094***	***2,094***
IMPORTS			
Import Field Exams/Tests	37	45	45
Import Line Decisions	74,402	97,198	97,198
Percent of Import Lines Physically Examined	0.05%	0.05%	0.05%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***2,078***	***2,094***	***2,094***

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2013 Actual			FY 2014 Estimate			FY 2015 Estimate		
	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,131***	***300***	***1,865***	***1,792***	***299***	***1,524***	***1,792***	***299***	***1,524***
Pre-Approval /BIMO Inspections	65	65	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	220	220	0	222	222	0	222	222	0
BSE Inspections	1,570	0	1,570	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	28	0	28	25	0	25	25	0	25
Illegal Residue Program Inspections	491	0	491	473	0	473	473	0	473
Feed Manufacturing Program Inspections	185	0	185	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,746	7	1,739	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***71*** [1]	***59***	***12***	***76***	***69***	***6***	***76***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	20	20	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	48	48	0	33	33	0	33	33	0
Foreign Feed Inspections	10	0	10	7	0	7	7	0	7
BSE Inspections	5	0	5	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,202***	***359***	***1,877***	***1,868***	***368***	***1,530***	***1,868***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	4,325	140	4,185	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	657	3	654	750	2	748	750	2	748
Import Physical Exam Subtotal	**4,982**	**143**	**4,839**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	368,447			448,604			448,604		
Percent of Import Lines Physically Examined	1.35%			0.97%			0.97%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***5,087***	***0***	***5,087***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***32***	***0***	***32***	***0*** [2]	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***443***	***0***	***443***	***600***	***0***	***600***	***600***	***0***	***600***
State Contract Inspections: BSE	4,623	0	4,623	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	436	0	436	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	264	0	264	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	32	0	32	23	0	23	23	0	23
State Cooperative Agreement BSE Inspections	443	0	443	600	0	600	600	0	600
State Contract Animal Drugs/Feeds Funding	$2,825,340	$0	$2,825,340	2,782,770	0	$2,782,770	2,782,770	0	$2,782,770
BSE Cooperative Agreement Funding	$2,540,623	$0	$2,540,623	2,572,920	0	$2,572,920	2,572,920	0	$2,572,920
State Contract Tissue Residue Funding	$545,331	$0	$545,331	686,440	0	$686,440	686,440	0	$686,440
Total State Funding	**$5,911,294**	**$0**	**$5,911,294**	**$6,042,130**	**$0**	**$6,042,130**	**$6,042,130**	**$0**	**$6,042,130**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***7,321***	***359***	***6,996***	***6,913***	***368***	***6,575***	***6,913***	***368***	***6,575***

[1] The FY 2013 actual unique count of foreign inspections includes 1 OIP inspection (1 Animal Feeds inspection in China).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

Field Devices Program Activity Data (PAD)

Field Devices Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	*2,887*	*2,864*	*2,864*
Bioresearch Monitoring Program Inspections	313	300	300
Pre-Market Inspections	43	67	67
Post-Market Audit Inspections	66	34	34
GMP Inspections	1,787	1,592 [3]	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	658	723	723
Inspections (MQSA) FDA Domestic (VHA)	45	43	43
Domestic Radiological Health Inspections	96	205	205
Domestic Field Exams/Tests	72	215	215
Domestic Laboratory Samples Analyzed	167	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	*535* [1]	*603*	*603*
Foreign Bioresearch Monitoring Inspections	21	25	25
Foreign Pre-Market Inspections	27	31	31
Foreign Post-Market Audit Inspections	29	19	19
Foreign GMP Inspections	473	519	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	43	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	*3,422*	*3,467*	*3,467*
IMPORTS			
Import Field Exams/Tests	23,342	18,821	18,821
Import Laboratory Samples Analyzed	1,042	1,123	1,123
Import Physical Exam Subtotal	**24,384**	**19,944**	**19,944**
Import Line Decisions	14,320,961	27,698,496	27,698,496
Percent of Import Lines Physically Examined	0.17%	0.07%	0.07%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	*7,811*	*7,929*	*7,929*
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS	*0* [2]	*0*	*0*
Inspections (MQSA) by State Contract	6,687	6,800	6,800
Inspections (MQSA) by State non-Contract	1,105	1,110	1,110
GMP Inspections by State Contract	19	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$81,685	$81,685	$81,685
State Contract Mammography Funding	$8,761,192	$9,089,659	$9,089,659
Total State Funding	**$8,842,877**	**$9,171,344**	**$9,171,344**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	*11,233*	*11,396*	*11,396*

[1] The FY 2013 actual unique count of foreign inspections includes 10 OIP inspections (6 for China and 4 for India).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.

[3] The FY 2014 planned mix of domestic vs. foreign GMP inspections shifts quite a few rmore inspections into the foreign arena, with a corresponding decrease to domestic GMP inspections in comparison to the FY 2013 Actuals, but the overall coverage is not changing. This is being done to acheive greater parity of the foreign versus domestic inspections and thus level out the inspection coverage.

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TOBACCO CONTROL ACT

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Family Smoking Prevention and Tobacco Control Act	**458,580**	**848,807**	**501,476**	**531,527**	**30,051**
Center (UF Only)	449,644	835,090	486,487	515,640	29,153
Field (UF Only)	8,936	13,717	14,989	15,887	898
FTE		**496**	**640**	**773**	**133**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); Public Health Service Act of 1944 (42 U.S.C. 201); Federal Advisory Committee Act of 1972, as amended.

Allocation Methods: Competitive Grants; Contracts; Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Center for Tobacco Products oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA executes its regulatory and public health responsibilities in three program areas that support the following objectives:

- reducing initiation of tobacco product use
- decreasing the harms of tobacco products
- encouraging cessation among tobacco product users.

To achieve its goals, FDA relies on its statutory authorities to regulate the manufacturing, marketing, and distribution of tobacco products. Some of these authorities include:

- requiring tobacco product manufacturers, importers, and distributors to register with FDA
- requiring manufacturers and importers to provide a list of tobacco products they sell
- requiring industry to report harmful and potentially harmful constituents
- inspecting tobacco product manufacturing establishments and tobacco retailers to assure compliance with FDA laws and tobacco product regulations
- prohibiting tobacco product labeling or advertising or other marketing that is inaccurate, false, or misleading
- establishing tobacco product standards to protect the public health
- issuing regulations with respect to the marketing and advertising of tobacco products
- strengthening health warnings for cigarettes and smokeless tobacco products
- enforcing violations of the Tobacco Control Act.

The following selected accomplishments demonstrate FDA's delivery of its regulatory and public health responsibilities within the context of current priorities.

Reduce Initiation of Tobacco Product Use

FDA works to prevent youth from using FDA-regulated tobacco products, including cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and encourages young tobacco users to quit. These authorized activities involve planning, developing, producing, and delivering national multimedia public education campaigns in FY 2014, which are designed to reduce tobacco initiation and use among young people aged 12 to 17. More recently FDA launched its first ever national youth tobacco prevention campaign, "The Real Cost," launched on February 4, 2014.

These sustained, multi-media campaigns will enable FDA to educate the public, particularly vulnerable youth populations, about the harms and risks of regulated tobacco products in order to help prevent initiation. Specifically, these campaigns will equip the public with important facts about:

- the health risks of regulated tobacco products
- the addictiveness of regulated tobacco products
- harmful and potentially harmful constituents in regulated tobacco products
- the public health basis for marketing restrictions on regulated tobacco products, such as those on using the descriptors "light," "mild," or "low."

FDA is committed to a science-based approach that addresses the public health issues raised by menthol cigarettes. On July 23, 2013, FDA issued an advance notice of proposed rulemaking (ANPRM) seeking comments and data, research, and other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes. FDA also conducted a preliminary independent scientific evaluation of existing data and research on menthol cigarettes. The *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* addresses the association between menthol cigarettes and various outcomes, including initiation, addiction, and cessation. The preliminary scientific evaluation, along with other relevant scientific information on the topic of menthol, was included in the docket for the ANPRM.

The FDA tobacco compliance and enforcement program ensures that industry and retailers follow existing laws and regulations designed to reduce the health burden of tobacco use on the American public and protect America's youth. To ensure compliance with the law, FDA works to prevent youth access to tobacco products and the influence of marketing by reviewing print and online advertising, monitoring promotional activities, and inspecting tobacco retail establishments.

During FY 2013, FDA issued its 10,000th tobacco retailer warning letter. Although many retailers are actively trying to keep tobacco away from kids, some continue to violate the law. In order to help reduce these violations, FDA established the State Enforcement Program that awards contracts to States and Territories to assist with inspections of tobacco retail establishments. FDA awarded one new State contract in FY 2013 for a total of 45 States, territories, and the District of Columbia in the program.

To ensure compliance with the Tobacco Control Act, FDA conducts surveillance, investigations, inspections, sample collections, and detention and refusal of tobacco products.

In FY 2013, FDA conducted approximately 109,900 tobacco retailer inspections, resulting in about 6,000 Warning Letters being issued and over 530 Civil Monetary Penalties being imposed related to violations of the Tobacco Control Act.

FDA established and maintains a testing laboratory at FDA's Southeast Regional Laboratory (SRL) with expertise and capacity to analyze tobacco products. The SRL laboratory has been acquiring specific testing equipment, such as mass spectrometers and smoke machines and is working to develop multi-residue flavor analysis methods.

Decrease the Harms of Tobacco Products

FDA is dedicated to reducing tobacco harms by engaging in and supporting numerous research and scientific endeavors. Research results will expand the scientific evidence needed to implement several authorities specified in the Tobacco Control Act and will also help assess the impact of regulatory actions. This research is also consistent with the Department of Health and Human Services (HHS) Strategic Plan and the Secretary's strategic initiatives which seek to prevent and reduce tobacco use through accelerated research to expand the science base and monitor progress.

During FY 2013, FDA partnered with the National Institutes of Health (NIH) to create 14 Tobacco Centers of Regulatory Science (TCORS). The TCORS program brings together investigators from across the country to aid in the development and evaluation of tobacco product regulations. Each TCORS

application identified a targeted research goal. Taken together, the TCORS sites will increase knowledge across the full spectrum of basic and applied research on tobacco and addiction. The program also provides new investigators with training opportunities to ensure the development of the next generation of tobacco regulatory scientists.

Throughout FY 2013, FDA and NIH also collaborated to stimulate investigator-initiated research and to release targeted Funding Opportunity Announcements to study:

- the impact of marketing and communications on tobacco use behavior
- perceptions, knowledge, attitudes, and beliefs regarding tobacco products
- the toxicity, carcinogenicity, and health risks of tobacco products
- understanding the role of varying nicotine levels and other constituents on initiation, dependence, and quitting.

FDA also worked with the Centers for Disease Control and Prevention (CDC) on laboratory research of tobacco products, as well as national cross-sectional surveys. Data from these surveys will allow FDA to monitor awareness of, susceptibility to, and experimentation with the use of a wide range of tobacco products.

In FY 2014, FDA will award research contracts and expand funding for tobacco regulatory science research within FDA and in alliance with NIH and CDC.

FDA has developed systems and procedures for the review and evaluation of tobacco industry submissions. In June 2013, FDA began issuing substantially equivalent (SE) marketing orders and not substantially equivalent orders for new tobacco products. FDA has also started issuing Refusal to Accept letters for exemption from SE requests. As part of its ongoing SE review process, FDA has communicated with many manufacturers about the status of their product submissions.

FDA sent "Advice and Information Request" letters to many manufacturers whose SE reports were missing administrative and scientific information, requesting clarification or the submission of the missing information. FDA held three public workshops in 2013 to gather information regarding third-party governance of industry-sponsored tobacco product research, tobacco product analysis, and electronic submission of tobacco product applications and other information.

As of December 31, 2013, FDA authorized the marketing of 17 new tobacco products and denied the marketing of 13 others. In addition, the first cycle of scientific review was completed for over 400 regular SE reports and Scientific Advice, and Information letters were issued for all regular SE reports received as of November 2012. FDA also formally withdrew 84 regular SE Reports at the request of the applicants and refused to accept 22 SE exemption requests because the manufacturers did not meet the requirements for such an exemption.

Encourage Tobacco Product Cessation

FDA is promoting public health and encouraging tobacco product cessation by leading comprehensive, science-based efforts to educate the nation about the dangers of tobacco products. Consistent with the HHS Strategic Plan and High-Priority Performance Goals, FDA seeks to prevent and reduce tobacco use.

FDA will allocate significant resources to enforce statutory requirements of the Tobacco Control Act, such as health warnings and public education. FDA will review new submissions and supplements involving health warning plans for smokeless tobacco products.

To encourage compliance with the Tobacco Control Act, FDA continues to educate retailers about their responsibilities to protect the Nation's young people from the harms of tobacco product use. These efforts include outreach to small businesses and to those in minority communities.

In FY 2014, FDA will hold regular compliance education webinars, providing retailers with an opportunity to ask questions about FDA regulatory authorities and activities. FDA will conduct regular

compliance education webinars directed towards small manufacturers to provide information about the Tobacco Control Act, FDA regulations, and other activities, including what to expect during an FDA inspection of a manufacturing facility.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$135,708,000	$0	$135,708,000
FY 2012 Actual	$277,136,000	$0	$277,136,000
FY 2013 Actual	$848,807,000	$0	$848,807,000
FY 2014 Enacted	$501,476,000	$0	$501,476,000
FY 2015 Budget Request	$531,527,000	$0	$531,527,000

BUDGET REQUEST

The FY 2015 Budget for the Tobacco Control Act Program is $531,527,000, of which $515,640,000 is for the Center and $15,887,000 is for the Field. The amount is the same as the FY 2015 level authorized in the Tobacco Control Act less the amounts for GSA rent and FDA headquarters. This amount is an increase of $30,051,000 above the FY 2014 Enacted level. The source of funding for is tobacco user fees, which the Tobacco Control Act requires be used only for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

The FY 2015 Budget allows the Program to protect and promote public health by planning, managing, directing, and coordinating major tobacco program objectives to support the implementation of the Tobacco Control Act.

In FY 2015, FDA will continue to implement the Tobacco Retail Inspection Program. This work includes re-awarding contracts to States and territories that are already under contract with FDA to conduct compliance check inspections of retail establishments that sell regulated tobacco products. Efforts will be made to expand the program with additional States and territories to cover more retailer inspections. In addition, FDA will continue to keep the results of the retail inspections public by maintaining a dedicated webpage that publicizes warning letters and civil money penalties issued to violative tobacco retailers and lists all retail establishments that pass FDA inspections.

In FY 2015, the Tobacco Retail Inspection Program will also:

- increase the number of inspections of tobacco retailers within the States and territories
- conduct quality assessments of performance under the State contracts
- maintain effective internal controls that meet the objectives of the Federal Managers' Financial Integrity Act to ensure effective and efficient operations and compliance with laws and regulations
- issue Warning Letters and Civil Money Penalty actions, and other enforcement actions, against retailers that violate the law and regulations.

FDA will expand its tobacco-related promotion, advertising, and labeling enforcement activities. FDA will enforce warning label requirements, including the review of warning plans for smokeless tobacco products. FDA will evaluate false and misleading claims made in the labeling and advertising of regulated tobacco products to ensure the public does not receive deceptive information from tobacco manufactures and is equipped with accurate information to assist with cessation.

In FY 2015, FDA will expand its enforcement and manufacturing activities by monitoring compliance with registration and listing requirements and will coordinate the activities surrounding the development of Tobacco Product Manufacturing Practice requirements for regulated tobacco manufacturers.

FDA will provide training, educational webinars and other web-based training for small tobacco manufacturers and retailers and to provide information about the Tobacco Control Act and regulations through:

- the Compliance and Enforcement webpage
- compliance training webinars
- responding to inquiries.

FDA will also provide compliance training and outreach to other Federal, State, and local stakeholders involved in tobacco control.

In FY 2015, FDA will develop public health education campaigns and key messages, and support effective design, development, implementation, and evaluation of its public health education efforts.

FDA will regulate the manufacture, marketing, and distribution of tobacco products under its jurisdiction. FDA will expand research on modified-risk tobacco products that may be authorized to be sold or distributed for use to reduce harm or the risk of tobacco-related disease. Section 911 of the Federal Food, Drug, and Cosmetic (FD&C) Act may be valuable tools to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if companies substantially reduce or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both. FDA must consider the risks and benefits to the population as a whole when evaluating a modified-risk tobacco product application.

Consequently, FDA needs to evaluate these products not only in terms of the relative health risks to individuals, but at the population level. FDA must evaluate the increased or decreased likelihood that nonusers will start using the product, whether tobacco users who would otherwise stop using tobacco products will switch to the product, whether tobacco users will use the product in combination with one or more other tobacco products, and if former users will begin using the product.

FDA's major ongoing research for FY 2015 includes studies and surveys including the Population Assessment of Tobacco and Health Study, the National Youth Tobacco Survey and the Tobacco Centers of Regulatory Science Program (TCORS).

The Population Assessment of Tobacco and Health Study – an ongoing national, longitudinal, cohort study of users and non-users will provide data to increase understanding of what makes people susceptible to tobacco use, evaluate patterns of tobacco product use, and evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes and behaviors. This longitudinal study will also provide a valuable platform for additional scientific investigations to assess and focus FDA regulatory action.

The National Youth Tobacco Survey is a nationally representative cross-sectional survey assessing adolescents in grades 6 to 12 regarding tobacco-related beliefs, attitudes, behaviors, and exposure to pro- and anti- tobacco influences. This survey's yearly data collection will provide national estimates of tobacco use prevalence among youth, including the use of tobacco products newly introduced onto the market. Because it is an on-going survey, data collected allows FDA to monitor changes in use, knowledge, and attitudes over time.

The Tobacco Centers of Regulatory Science is a nation-wide program to aid in the development and evaluation of tobacco product regulations is comprised of scientists with expertise in fields including epidemiology, behavior, biology, medicine, economics, chemistry, toxicology, addictions, public health, communications, and marketing. This cohort is the centerpiece of FDA's collaboration with NIH to

foster research relevant to tobacco regulatory science. New research from TCORS will help inform and assess the impact of FDA's prior, ongoing and potential future tobacco regulatory activities.

Section 905 of the FD&C Act provides FDA with tools to better understand tobacco products since it requires tobacco product manufacturers to submit scientific data and information to FDA whenever they make a change to an existing product to support that the changes do not raise questions of public health. For new tobacco products that do not qualify for review under the substantial equivalence provision, Section 910 of the FD&C Act provides premarket review authority to evaluate whether the marketing of new tobacco products would be appropriate for the protection of public health. In order to inform the evaluation and review of tobacco product submissions, FDA will carry out research in a number of areas, including but not limited to chemistry, engineering, toxicology, and behavioral and social science.

Section 907 of FD&C Act also gives FDA authority to establish tobacco product standards that are appropriate for the protection of public health. These authorities include reducing or eliminating constituents – including smoke constituents – and provisions related to the construction, components, ingredients, additives, and properties of the tobacco product. Product standards could have a meaningful impact on reducing the harm caused by tobacco products. FDA will continue to investigate potential product standards in the areas of addiction, toxicity, and tobacco appeal.

FDA's Forensic Chemistry Center laboratory will provide support to Office of Criminal Investigations by identifying criminal violations in tobacco-related cases. FDA is expanding the capabilities of the SRL laboratory to better analyze tobacco products and regulatory samples to support enforcement actions. To this end, FDA works with internal and external stakeholders to share data, databases, and analytical expertise.

PERFORMANCE

The Tobacco Control Act Program's performance measures focus on activities in order to achieve public health goals, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2013:109,908 Target: 75,000 (Target Exceeded)	100,000	105,000	+5,000
280002: Develop a scientific base to understand and reduce harm from tobacco products by initiating a testing program to support tobacco product standards development, which will include a review of tobacco product ingredients. *(Output)*	FY 2013: Established a list of 93 harmful and potentially harmful constituents to health, publishing it in the Federal Register on April 3, 2012. (Target Met)	Develop regulation requiring testing and reporting of tobacco product constituents, ingredients and additives Continue to review substantial equivalence reports, pre-market tobacco product applications, and modified risk tobacco product applications	Continue to review substantial equivalence reports, pre-market tobacco product applications, and modified risk tobacco product applications. Establish Tobacco Centers of Regulatory Science addressing high priority research needs	NA

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
280004: Educate stakeholders and the general public about the new tobacco products regulations and the health effects of tobacco use. *(Output)*	FY 2013: Implemented and refined education program directed to retailers and the general public, especially youth. (Target Met)	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education in support of FDA's regulatory authorities.	Continue to implement and improve programs designed to educate the public and industry. Expand consumer health education in support of FDA's regulatory authorities.	Maintain

The following selected items highlight notable results and trends detailed in the performance table.

Compliance Check Inspections

A key element in enforcing the Tobacco Control Act involves contracts with U.S. States and Territories to conduct compliance checks. In FY 2013, under these state contracts, FDA conducted 109,908 compliance check inspections of retail establishments. Although this number was much higher than expected, it reflects the high level of variability inherent in this goal that requires estimating the number of compliance checks that each State will be able to conduct. In addition, some of the state contracts are expiring, and will need to be renewed in the next year to continue these efforts. Although most States are expected to renew their contracts, there are always outside factors that may prohibit them from doing so. The FY 2014 and FY 2015 targets consider these challenges, but have still been increased.

PROGRAM ACTIVITY DATA

Tobacco Products Performance Activity Data (PAD)

CTP Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Administrative/Management Support Workload			
Number of Advisory Committee Meetings	3	6	8
Percentage of Tobacco User Fees Collected	99%	99%	99%
Number of Tobacco Manufacture Inspections	50	60	60

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FDA HEADQUARTERS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
FDA Headquarters	251,408	220,035	275,439	294,814	19,375
Budget Authority:	*160,114*	*160,112*	*172,107*	*175,360*	*3,253*
User Fees	*91,294*	*59,923*	*103,332*	*119,454*	*16,122*
Prescription Drug (PDUFA)	*41,665*	*37,107*	*46,323*	*48,639*	*2,316*
Medical Device (MDUFA)	*5,582*	*5,527*	*6,485*	*6,733*	*248*
Animal Drug (ADUFA)	*893*	*700*	*944*	*898*	*-46*
Animal Generic Drug (AGDUFA)	*224*	*175*	*293*	*277*	*-16*
Family Smoking Prevention and Tobacco Control Act	*14,446*	*11,012*	*19,500*	*20,668*	*1,168*
Voluntary Qualified Importer Program	---	---	---	*277*	*277*
Food and Feed Recall	*657*	---	*691*	*75*	*-616*
Food Reinspection	*3,374*	---	*3,549*	*480*	*-3,069*
Generic Drug (GDUFA)	*23,001*	*5,127*	*23,988*	*24,205*	*217*
Biosimilars (BsUFA)	*1,226*	---	*1,321*	*1,321*	*--*
Mammography Quality Standards Act (MQSA)	*226*	*275*	*238*	*243*	*5*
Food Facility Registration and Inspection	---	---	---	*4,576*	*4,576*
Food Import	---	---	---	*9,464*	*9,464*
Medical Products Reinspection	---	---	---	---	*--*
International Courier	---	---	---	*301*	*301*
Cosmetics	---	---	---	*1,020*	*1,020*
Food Contact Substance Notification	---	---	---	*277*	*277*
FTE		1,041	1,307	1,388	81

Authorizing Legislation: The Federal Food Drug and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss); The Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Foods Additives Amendments of 1958; Color Additives Amendments of 1960; Animal Drug Amendments (21 U.S.C. 360b); Controlled Substances Act (21 U.S.C. 801-830); The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Federal Anti-Tampering Act (18 U.S.C. 1365); Medical Device Amendments of 1976; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Generic Animal Drug and Patent Term Restoration Act; Prescription Drug Marketing Act of 1987; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Prescription Drug Amendments of 1992; Safe Medical Device Amendments of 1992; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12); Project Bioshield Act of 2004 (21 U.S.C.360bbb-3); Minor Use and Minor Species Animal Health Act of 2004; Food Allergy Labeling and Consumer Protection Act of 2004 Medical Device User Fee Stabilization Act of 2005; Sanitary Food Transportation Act of 2005 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1); Food and Drug Administration Amendments Act of 2007; Protecting Patients and Affordable Care Act of 2010; The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011); The Food and Drug Administration Safety and Innovation Act (P.L. 112-144); and the Drug Quality and Security Act (2013)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA Headquarters (HQ) provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

The seven primary HQ components responsible for providing FDA level oversight and advice are: The Office of the Commissioner, Office of Chief Counsel, Office of the Chief Scientist, Office of Foods and Veterinary Medicine, Office of Medical Products and Tobacco, Office of Operations, and the Office of Global Regulatory Operations and Policy.

Office of the Commissioner (OC)

OC provides program direction, coordination and liaison, and expert advice to FDA leadership and programs in support of FDA's foods, medical products, and science-based work. OC provides advice and leadership in policy development and oversees FDA rulemaking. OC serves as the focal point for coordinating strategic, performance, and business-process planning and analysis.

The following selected accomplishments demonstrate OC's delivery of its regulatory and public health responsibilities within the context of current priorities:

- issued the Food and Drug Administration Safety and Innovation Act (FDASIA) Implementation Plan, according to the FYs 2013-2015 goals
- reauthorized the Animal Drug and Animal Generic Drug user fee programs and authorized the Drug Quality and Security Act (DQSA)
- established the FDA-GeoWeb, a web-based interactive mapping portal to geospatially assess the impact of emerging incidents on FDA regulated industry and provide access to spatial data and maps related to FDA's mission
- expanded outreach of FDA's public health and policy messages by creating and posting 134 FDA Voice blogs in FY 2013, 50 more than the previous year.

On-going high priorities in FY 2014 include:

- making additional pages of FDA.gov mobile friendly and improving the user-experience on FDA.gov
- developing FDA's first Social Media Policy governing the use of social media throughout FDA and implementing a social media strategy to maximize engagement with stakeholders
- creating Consumer Updates on food safety, nutrition, and supply chain security in a globalized marketplace
- increasing agency preparedness and response capabilities through intra and inter-agency exercises, plan development and update, standard operating procedures development, and improved incident management systems.

Office of the Chief Counsel (OCC)

OCC provides a broad range of critically important legal services to support FDA's public health mission. OCC provides legal advice and policy guidance on a wide range of highly visible national issues, and acts as a liaison to the Department of Justice during active litigation. OCC's goal is to support the strategic goals and initiatives of the Commissioner and FDA, by providing high quality legal services, including sound and timely legal advice and counsel.

The following selected accomplishments demonstrate OCC's delivery of its regulatory and public health responsibilities within the context of current priorities:

- conducted legal review of seven significant proposed regulations implementing the Food Safety Modernization Act (FSMA) and regulatory activities related to nutrition
- provided legal counsel and litigation support for implementation of the Tobacco Control Act
- delivered legal support for activities related to medical product regulation, including pharmaceutical compounding, scheduling and abuse of opioids, and drug shortages.

On-going high priorities in FY 2014 include:

- continuing legal counseling related to the implementation of FSMA, including enforcement activities
- providing legal advice, review, and enforcement support for implementation of the drug compounding and drug supply chain security provisions of the FY 2013 DQSA, and the Generic Drug User Fee Amendment (GDUFA)
- giving legal advice in support of activities across product areas related to antimicrobial resistance.

Office of the Chief Scientist (OCS)

OCS provides strategic leadership, coordination, planning and scientific training to support the applied research and scientific innovation and collaborations essential to FDA's public health mission. In addition, OCS represents FDA at the Department of Health and Human Services and the White House for the Medical Countermeasures Initiative (MCMi) of the Public Health and Emergency Countermeasures Enterprise (PHEMCE). OCS develops medical countermeasures critical to the Nation's preparedness for natural and man-made threats and disasters, including pandemics, and acts of terrorism.

The following selected accomplishments demonstrate OCS' delivery of its regulatory and public health responsibilities within the context of current priorities:

- approved medical countermeasures for anthrax, plague, botulism, and influenza
- issued Emergency Use Authorizations for diagnostic tests for the emerging infectious disease threats avian influenza (H7N9) and Middle East Respiratory Syndrome
- initiated 15 projects to enhance the quality of regulatory science across FDA programs under an Office of Chief Scientist Broad Agency Announcement mechanism
- advanced scientific training and staff recruitment and development through 55 training events for 3,511 attendees, with 271 staff receiving Continuing Medical Education and 207 receiving Continuing Nursing and Pharmacy Education
- established a regulatory science research program in minority health through FDA's Centers for Excellence in Regulatory Science and Innovation
- funded 14 new and 17 continuing research projects on women's health.

On-going high priorities in FY 2014 include:

- developing medical countermeasures for infectious disease and radiation threats and issue revised guidance for countermeasure development under the Animal Rule [32]
- extending CERSIs to include academic centers located beyond the metropolitan Washington, DC region and expand their portfolio of regulatory science activities and training
- increasing the number of participants in the FDA Commissioner's Fellowship Program.

Office of Foods and Veterinary Medicine (OFVM)

OFVM provides executive leadership and strategic direction to the FDA Foods and Veterinary Medicine (FVM) program to protect and promote the health of humans and animals. OFVM ensures the safety of the American food supply, food additives and dietary supplements, animal feed, and the safety and effectiveness of animal drugs.

[32] Under the Animal Rule, when human challenge studies would not be ethical and field trials after accidental or hostile exposure have not been feasible, FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans. Demonstration of the product's safety in humans is still necessary. (See 21 CFR 314.600 for drugs and 21 CFR 601.90 for biological products.)

The following selected accomplishments demonstrate OFVM's delivery of its regulatory and public health responsibilities within the context of current priorities:

- rapidly detected and responded to major food borne illness outbreaks, including but not limited to the Cyclospora outbreak from salads and cilantro (631 sick), and the Hepatitis A outbreak from frozen organic berries (162 sick)
- proposed seven new food safety rules under FSMA to modernize the food safety system and focus on proactively preventing food safety problems, establishing the broad preventive controls framework envisioned in FSMA
- conducted extensive dialogue with stakeholders to support the FSMA rulemaking process
- issued a final rule defining "gluten-free" for food labeling to enable consumers, especially those living with celiac disease, to be confident that items labeled "gluten-free" meet a defined standard for gluten content
- published the final Guidance for Industry #213 to remove growth-promoting antimicrobials that contribute to antimicrobial resistance from animal feed, an important step in preserving the effectiveness of antimicrobials in human medical therapy
  proposed a rule to add selenium to the list of required nutrients for infant formulas to enhance infant health.

On-going high priorities in FY 2014 include:

- continued and improved coordination of FDA's Coordinated Outbreak Response and Evaluation Network (CORE) program which is dedicated to detection, response, and prevention efforts related to FDA regulated food, feed, and cosmetic outbreaks in collaboration with our partners
- publishing the three remaining preventive controls proposed rules under FSMA and finalizing all seven foundational rules
- developing a FSMA operational plan that will guide the agency as it moves from the rule making phase to the operational phase of FSMA, including all operational aspects of the new FSMA programs, such as training, outreach, and IT
- improving nutrition labeling by finalizing Affordable Care Act rules requiring menus and vending machines to display calorie counts
- developing proposed rules to modernize nutrition and supplement facts labels, including providing consumers with nutrition information based on the amount of food that is customarily consumed in a single meal
- implementing Guidance for Industry #213 on antimicrobial resistance as described above.

Office of Medical Products and Tobacco (OMPT)

OMPT provides executive leadership and strategic direction to the Drugs, Biologics, Medical Devices, and Tobacco Products programs. The Office of Special Medical Programs (OSMP) within OMPT serves as the FDA focal point for health programs and initiatives that cut across the FDA Centers and Office of the Commissioner.

The following selected accomplishments demonstrate OMPT/OSMP's delivery of its regulatory and public health responsibilities within the context of current priorities:

- issued final rules on the current good manufacturing practice requirements for combination products, and on clarifying orphan drug designation requirements to promote the development of products for rare diseases
- issued final guidance documents on the Humanitarian Use Device designation process, on clinical investigator financial disclosures, on Institutional Review Board (IRB) responsibilities, and on the scientific information for a pen, jet, or related injector for use with drug or biological products

- published scientific articles on failed pediatric trials and a reference book on Pediatric Drug Development.

On-going high priorities in FY 2014 include the following:

- ensuring scientific and ethical integrity by developing regulations or guidance on human subject protection, post market safety reporting for combination products, IRB procedures, disqualification of an IRB, and safeguards for children in research
- advancing pediatric medical device and neonatal product development and produce the FDA's rare pediatric disease strategic plan
- developing guidance regarding the appearance of a conflict of interest for members of FDA advisory committees; implement recruitment strategies for advisory committee members.

Office of Operations (OO)

OO provides executive direction, leadership, coordination, and guidance for the overall day-to-day administrative and management operations of FDA. OO ensures timely and effective implementation and high-quality delivery of services across FDA in support of mission-critical programs.

The following selected accomplishments demonstrate OO's delivery of its regulatory and public health responsibilities within the context of current priorities:

- provided ongoing oversight, evaluation, and analysis of policies and programs
- institutionalized continual business process improvements
- continued to strengthen FDA-wide priority setting processes to ensure that FDA budget and IT submissions align to the Agency's strategic and policy priorities
- implemented an FDA-wide User Fee Council to strengthen enterprise user fee program governance.

On-going high priorities in FY 2014 include:

- addressing mission critical administrative operation issues through increased collaboration within the OO, among centers, government, and industry
- providing ongoing and expanded operational and logistical functions for 9,000 employees on the White Oak Campus, including the new Life Sciences-Biodefense Complex
- assessing training, experience, and certification of IT project and program managers.

Office of Global Regulatory Operations and Policy (OGROP)

OGROP serves as FDA's lead for providing strategic leadership, policy direction, and oversight to FDA's global collaborations, data-sharing, development and harmonization of standards, field operations, and risk-based compliance and enforcement activities. OGROP works with FDA leaders to enhance FDA's global efforts in transforming FDA from being a regulator of domestic products to one overseeing a worldwide enterprise of food and drug production and supply.

The following selected accomplishments demonstrate the Office of International Programs' (OIP) contribution to OGROP's delivery of its regulatory and public health responsibilities within the context of current priorities:

- deployed handheld rapid screening tools to minimize patient exposure to counterfeit and substandard medicines and dietary supplements
- developed training for rapid screening tools including the Counterfeit Detection Device (CD3) and X-ray Fluorescence
- enhanced inspectional capacity through the use of in-country investigators, allowing more rapid deployment to facilities
- cultivated investigators with country and region-specific knowledge and expertise.

On-going high priorities in FY 2014 include:

- deploy and evaluate innovative rapid counterfeit screening tools
- add FDA investigators in India and China to implement GDUFA
- advance multi-partner efforts to build global regulatory capacity
- implement the China Safety Initiative to analyze socio-economic, geographic, and political landscapes, trends, and drivers of regulated products produced or sourced internationally.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$186,665,000	$149,477,000	$37,188,000
FY 2012 Actual	$199,054,000	$153,519,000	$45,535,000
FY 2013 Actual	$220,035,000	$160,112,000	$59,923,000
FY 2014 Enacted	$275,439,000	$172,107,000	$103,332,000
FY 2015 Budget Request	$294,814,000	$175,360,000	$119,454,000

BUDGET REQUEST

The FY 2015 Budget for FDA HQ is $294,814,000, of which $175,360,000 is budget authority and $119,454,000 is user fees. This amount is $19,375,000 million above the FY 2014 Enacted level. The FY 2015 Budget includes initiatives for FSMA implementation and pharmacy compounding.

The FY 2015 Budget allows FDA HQ to continue providing program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA will also maintain support for FDA priorities, including medical countermeasures, medical products quality and safety, and food safety.

Medical Product Safety

Pharmacy Compounding: Inspections and Enforcement, Policy Development, and State Collaboration and Coordination (+$3.5 million)

The Pharmacy Compounding Initiative component of the FY 2015 FDA HQ budget is part of a multi-program initiative to provide more appropriate and effective oversight of pharmacy compounding through investments in inspections and enforcement, policy development, and state coordination. Further details on this initiative as well as the other organizations involved in this initiative appear in the Performance Budget Overview, the Human Drugs Program narrative, the Biologics Program narrative, the Animal Drugs and Feeds Narrative, and the Office of Regulatory Affairs narrative.

FDA HQ will support case management, policy development, enforcement actions, and review and clearance of all Agency documents related to pharmacy compounding. FDA will also enhance its intergovernmental relations activities to provide strategic oversight of activities involving interactions with the states including strengthening relationships with state officials at all levels of state government(e.g., governors' offices, Boards of Health and Pharmacy, state legislators), working with associations of state officials, and facilitating interactions with the FDA program offices with substantive program knowledge. FDA already has well-established relationships in the foods area, but little in the drugs area and FDA believes this function could be improved Agency-wide. Because of the urgent need in the compounding area, the additional resources will be necessary to support ongoing and future compounding activities.

Proposed International Courier User Fee (+$256,000)

FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Food Safety

Food Safety Modernization: Risk Analysis (+$3.0 million)

FDA HQ is part of a multi-program initiative to create a modern, prevention-focused, science- and risk-based food safety system and implement the FSMA requirements. Further details on this initiative appear in the Performance Budget Overview, the Foods Program narrative, the Animal Drugs and Feeds Program narrative, and the Office of Regulatory Affairs narrative.

FDA will increase data gathering and analytical capacity to support risk-based priority setting and resource allocation, including automating and expediting risk analysis and integration of risk information into decision-making tools. FDA will continue to adapt these tools for use by the public and industry, which will increase the precision of risk evaluation of FDA regulated commodities and associated hazards.

Proposed Food Safety User Fees (+14,040,000)

FDA is proposing two user fees for Food Import and Food Facility Registration and Inspection to support implementation of FSMA, including improving FDA's import process and modernizing FDA's inspection system.

Proposed Food Contact Substance Notification User Fee (+$277,000)

FDA is proposing a new user fee of to ensure that the Food Contact Substance Notification (FCN) program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations.

Proposed Cosmetics User Fee (+$1,020,000)

FDA is proposing a new user fee to support FDA cosmetic safety responsibilities. The proposed user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

Proposed International Courier User Fee (+$45,000)

FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Medical Countermeasures

FDA will continue to promote the development of medical countermeasures by establishing clear regulatory pathways for medical countermeasures, instituting effective regulatory policies and mechanisms to facilitate timely access to available medical countermeasures, and advancing medical countermeasures regulatory science. High priority medical countermeasure initiatives include developing draft guidance on the development of medical countermeasures for treatment of acute radiation syndrome, which would be expected to occur after a nuclear or radiological event, and draft guidance on the development of biodosimetry devices that would be needed in the event of a radiologic or nuclear attack to determine radiation dose. FDA will also continue to provide technical assistance and interactive review to the developers of the highest-priority medical countermeasures and related technologies.

PERFORMANCE

The Office of the Commissioner's performance measures focus on emergency response, women's health, science, global cooperation, premarket application review of orphan, pediatric and combination products, outreach, and organization efficiency, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	Implemented electronic notifications of Report-able Food Registry Reports to Federal and State Counterparts. In addition OCM conducted training for FDA staff on the implementation of the FDA Emergency Operations Plan and its incident specific annexes. Progress was made on enhancing interoperability of EON IMS, but delays in funding prevented us from fully expanding its interoperability to systems administered by other agencies. (Target Not Met)	Improve the efficiency of agency incident management by expanding responsibility for entering and maintaining incidents in the FDA Emergency Operations Network Incident Management System to include 60% of FDA Regional and 40% of District Offices. Expand access to the agency's Geographical Information System (GIS) through a web-based portal and provide basic spatial analysis tools agency-wide. International exercise to assess effectiveness of FDA and foreign agencies' plans in guiding international response to an intentional product contamination event.	Maintain 95% efficiency on response to calls to the FDA After Hours Call Center. Successfully coordinate 20 incidents involving FDA regulated products during the year. Participate in six exercises during the year. Conduct 12 tests per year of FDA's system for contacting agency officials nationwide after-hours in the event of an emergency.	NA
294201: Number of site visits of Office of Women's Health-funded investigators (multiple year recipients) conducting laboratory-based research. *(Output)*	FY 2012: 9 Target: 9 (Target Met)	10	5	- 5
291305: Number of electronic and print communications disseminated to women's health stakeholders. *(Output)*	FY 2012: 20 (Historical Actual)	25	25	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
293206: Promote innovation and predictability in the development of safe and effective nanotechnology- based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)*	FDA continued the CORES program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. (Target Met)	Maintain FDA Nanotechnology CORES Program	Maintain FDA Nanotechnology CORES Program and increase transparency of FDA's efforts with public summaries of the CORES Program, Laboratory Facilities, and Training Efforts	NA
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	FY 2013: 63% Target: 50% (Target Exceeded)	45%	40%	-5%
293205: Percentage of requests for combination product designations processed within the 60 day statutory requirement. *(Output)*	FY 2013: 100% Target: 95% (Target Exceeded)	95%	95%	maintain
293203: Number of pediatric scientific, ethical, product and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, Japan, Canada and with Australia as observers. *(Output)*	FY 2013: 166 Target: 36 (Target Exceeded)	40	40	maintain
293204: Number of medical products studied in children with labeling changes and safety reviews completed and presented to FDA's Pediatric Advisory Committee. *(Output)*	FY 2013: 30 Target: 30 (Target Met)	30	30	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	FY 2013: 5 Target: 4 (Target Exceeded)	4	4	maintain
291306: Number of collaborative actions taken based upon meaningful analyses of the global regulatory landscape. *(Output)*	FY 2013: 20 (Historical Actual)	25	25	maintain
291406: Increase the timeliness of managing accounts receivables (A/R). Percentage of invoices issued on time within predefined dates in the month. *(Output)*	FY 2013: 100% Target: 98% (Target Exceeded)	98%	98%	maintain
293207: Percentage of reviews of first-time and amended orphan drug designation applications completed in 90 days or less. *(Output)*	FY 2013: 91% (Historical Actual)	75%	75%	maintain
293208: Percentage of Humanitarian Use Device designation reviews completed in 45 days or less. *(Output)*	FY 2013: 100% (Historical Actual)	95%	95%	maintain

The following selected items highlight notable results and trends detailed in the performance table.

Nanotechnology Development

For the FDA, a science-based regulatory agency whose mission is to protect and promote public health, nanotechnology poses regulatory challenges that are inherent in emerging technologies. Like many emerging technologies, nanotechnology can potentially benefit food, medicine, and other FDA-regulated product areas, but the risks to human and animal health are not yet completely identified or understood. Establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions will promote innovation and predictability in the development of safe and effective nanotechnology-based products. Collaborative Opportunities for Research Excellence in Science (CORES) projects are designed to produce internal and external reports and testing methods that FDA staff can use to evaluate FDA regulated products that contain or use nanotechnology.

INFRASTRUCTURE

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
FDA White Oak Consolidation	**57,172**	**57,159**	**61,922**	**47,116**	**-14,806**
Budget Authority	***53,684***	***53,684***	***58,044***	***43,044***	***-15,000***
Prescription Drug (PDUFA)	***3,488***	***3,475***	***3,878***	***4,072***	***194***
Other Rent and Rent Related	**100,179**	**88,129**	**116,439**	**120,862**	**4,423**
Budget Authority	***64,058***	***64,058***	***74,674***	***73,296***	***-1,378***
User Fees	***36,121***	***24,071***	***41,765***	***47,566***	***5,801***
Prescription Drug (PDUFA)	*23,889*	*17,707*	*26,794*	*28,134*	*1,340*
Medical Device (MDUFA)	*2,802*	*2,208*	*3,546*	*4,027*	*481*
Animal Drug (ADUFA)	*276*	*62*	*236*	*225*	*-11*
Animal Generic Drug (AGDUFA)	*95*	*14*	*73*	*69*	*-4*
Family Smoking Prevention and Tobacco Control Act	*1,548*	*1,598*	*3,050*	*3,233*	*183*
Voluntary Qualified Importer Program	---	---	---	*170*	*170*
Food and Feed Recall	*246*	---	*259*	*43*	*-216*
Food Reinspection	*588*	---	*619*	*204*	*-415*
Generic Drug (GDUFA)	*6,129*	*2,482*	*6,598*	*6,730*	*132*
Biosimilars (BsUFA)	*548*	---	*590*	*602*	*12*
Food Facility Registration and Inspection	---	---	---	*827*	*827*
Food Import	---	---	---	*2,528*	*2,528*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*184*	*184*
Cosmetics	---	---	---	*524*	*524*
Food Contact Substance Notification	---	---	---	*66*	*66*
GSA Rental Payments	**198,645**	**190,151**	**219,907**	**236,076**	**16,169**
Budget Authority	***149,970***	***149,970***	***162,076***	***169,336***	***7,260***
User Fees	***48,675***	***40,181***	***57,831***	***66,740***	***8,909***
Prescription Drug (PDUFA)	*20,504*	*23,575*	*22,997*	*24,147*	*1,150*
Medical Device (MDUFA)	*4,915*	*4,460*	*6,216*	*7,058*	*842*
Animal Drug (ADUFA)	*1,479*	*630*	*1,180*	*1,123*	*-57*
Animal Generic Drug (AGDUFA)	*431*	*267*	*440*	*417*	*-23*
Family Smoking Prevention and Tobacco Control Act	*5,493*	*6,243*	*9,974*	*10,572*	*598*
Voluntary Qualified Importer Program	---	---	---	*290*	*290*
Food and Feed Recall	*432*	---	*454*	*73*	*-381*
Food Reinspection	*1,330*	---	*1,399*	*348*	*-1,051*
Generic Drug (GDUFA)	*13,133*	*5,006*	*14,138*	*14,421*	*283*
Biosimilars (BsUFA)	*958*	---	*1,033*	*1,054*	*21*
Food Facility Registration and Inspection	---	---	---	*1,467*	*1,467*
Food Import	---	---	---	*4,417*	*4,417*
Medical Products Reinspection	---	---	---	---	---
International Courier	---	---	---	*319*	*319*
Cosmetics	---	---	---	*918*	*918*
Food Contact Substance Notification	---	---	---	*116*	*116*

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Treasury, Postal Service and General Government Appropriations Act (5 U.S.C.); The Federal Property and Administrative Services Act of 1949 (40 USC 486[d] and [e]); 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 Food and Drug Administration Revitalization Act (21 U.S.C. 379b); Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492); Omnibus Appropriations Act of 2009 (P.L. 111-8, 123 Stat. 524)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Infrastructure Program supports FDA's mission of protecting the public health by providing secure and cost-effective office and laboratory space to perform mission-critical work. The Infrastructure Program consists of:

- General Services Administration (GSA) Rental Payments
- Other Rent and Rent-Related Activities
- FDA White Oak Consolidation.

GSA Rental Payments

The GSA Rental account includes FDA rental payments to cover FDA's office and laboratory facilities. FDA occupies six million square feet of GSA owned or GSA leased office, laboratory, and warehouse space. More than two-thirds of the GSA rent charges for GSA owned or GSA leased space are for facilities in the Washington, D. C. area. FDA occupies GSA space comprising approximately 290 buildings including district offices, regional offices, laboratories, and resident posts across the nation and in Puerto Rico.

The GSA Rental program continues to ensure that the FDA workforce has the space necessary to carry out FDA's mission of protecting the public health in an efficient and effective manner.

During FY 2013 FDA acquired new leased office space in Silver Spring, Maryland, to accommodate staffing increases. FDA also:

- relocated a Drugs Program laboratory in St. Louis, Missouri
- acquired expansion space for one Office of Criminal Investigations Field Office
- acquired expansion space for one Resident Post
- relocated six Resident Posts
- vacated three Resident Posts.

During FY 2014, FDA will:

- occupy two new office buildings and two new lab buildings on White Oak Campus and one new leased office building in Rockville, Maryland
- vacate four leased headquarters office buildings
- vacate a CDER lab in Saint Louis
- co-locate two OCI field offices into one new leased location
- Open a new ORA Resident Post and one new Sample Processing Center
- acquire expansion space for one resident post
- relocate five resident posts
- vacate two resident posts.

FDA will work with HHS to ensure the appropriate square footage offset is in accordance with the Freeze the Footprint guidance issued by the Office of Management and Budget. FDA is working with HHS to promote maximum utilization of Federal workspace, consistent with mission requirements, and to maximize its value to the Government. FDA strives to be cost effective and energy efficient when it acquires the necessary space to meet the mission and nationally recognized standards.

Other Rent and Rent-Related Activities

The Other Rent and Rent-Related Activities account includes commercial rent and rent-related charges that are not part of the GSA Rental account. These funds cover costs for operating and maintaining FDA and GSA facilities located nationwide. Costs include:

- commercial rent
- operation and maintenance contracts
- janitorial and grounds maintenance contracts
- security and guard services contract costs
- standard utilities in FDA owned facilities
- overtime utilities in laboratories and data centers
- other services not provided by GSA in GSA-managed facilities.

These accounts help the FDA workforce meet its public health mission by providing safe, efficient, and secure facilities.

FDA is undertaking numerous energy saving projects to decrease long-term energy usage and associated operating and maintenance costs while increasing the life span and efficiency of facilities. These efficiencies will help FDA realize significant savings in the Other Rent and Rent-Related Activities account. The implementation of these projects supports Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. These projects contribute to meeting the requirements of HHS' Efficient Energy Management Assessments, the Energy Policy Act of 2005, HHS Sustainable and High Performance Buildings Policy, HHS Sustainable Buildings Plan, and the 2006 Federal Leadership in High Performance and Sustainable Buildings Memorandum of Understanding.

For the White Oak Campus, GSA entered into Energy Savings Performance Contracts (ESPC) with the Honeywell Corporation to build a Central Utility Plant (CUP), provide utilities, and perform operations and maintenance activities in a phased approach consistent with the construction and occupancy of the Campus. FDA entered into memoranda of understanding with GSA and committed to a long-term occupancy of the Campus, including an agreement to pay a share of the costs associated with the ESPCs.

FDA's share of these costs is less than FDA would have paid for utilities if the energy saving features provided by the ESPC were not implemented. The Other Rent and Rent-Related Activities account is used to pay these costs. When each ESPC phase begins to provide benefits to the Campus including utilities to FDA-occupied buildings, FDA is required to pay the agreed-upon share. The most recent example is GSA's "ESPC III" which covers the expansion of the CUP. The CUP expansion provides the utilities needed to occupy and operate the new Life Sciences-Biodefense Laboratory Complex (LSBC).

FDA investigates strategies to save Federal funding on overhead while efficiently supporting the FDA mission. FDA is implementing a second utility energy service contract (UESC) for the Muirkirk Road Campus in Laurel, Maryland, with Washington Gas. The estimated capital investment is $2,032,391, with utility cost savings of approximately $252,095 annually in water, sewer, electricity, and fuel costs. This change will generate a simple pay back in approximately 8.06 years.

FDA awarded a third UESC with Washington Gas at the Muirkirk Road Campus with a capital investment of $958,863 with utility cost savings of approximately $143,706 annually in water, sewer, electricity and fuel costs at a simple pay back of 6.7 years. FDA is also developing potential energy conversation measures that would be included in a fourth UESC with Washington Gas.

FDA also awarded a UESC for its owned site in Irvine, California, with Southern California Edison Electric Power Company with a capital investment of $2,570,000; cost savings will be about $254,741 per year with a simple pay back of 10.1 years.

GSA is performing audits in FDA occupied leased facilities, such as the Wiley building in College Park, Maryland, and in the Queens, New York lab. UESCs in these GSA-leased buildings will, if implemented, provide energy savings.

Awarding additional UESCs and procuring renewable energy will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance. FDA's activities related to UESCs and renewable energy will help reduce Scope 1 and 3 greenhouse gas emissions.

White Oak

FDA Headquarters' consolidation at the White Oak Campus is replacing and centralizing existing geographically disparate facilities with new, state-of-the art laboratories, office buildings and support facilities into one location. While the GSA appropriation funds the design and construction of the new buildings at White Oak, FDA's Budget Authority and PDUFA user fees, fund building infrastructure, fit-out, specialized equipment and move costs. FDA initiated relocation activities to White Oak in FY 2002.

The total number of employees assigned to the White Oak Campus is approximately 6,000. FDA plans to house an additional 3,000 employees in the Life Sciences-Biodefense Laboratory Complex on the White Oak Campus for a total White Oak population of approximately 9,000 by the end of FY 2014.

Construction is ongoing for the Life Sciences-Biodefense including Office Buildings 71 and 75, Laboratories 52 and 72 and an expanded Vivarium. The Complex will house Biologics, Drugs and Tobacco Control Act program requirements beginning in 2014.

FDA is working with GSA on a strategy to secure GSA design and construction funds for the remaining facilities in the FY 2009 Master Plan of the 130-acre White Oak Campus and for an updated Master Plan to design and construct the additional facilities needed. If possible, FDA will retain existing leases and attempt to absorb program growth in existing space until the White Oak facilities are available.

Most recently, FDA White Oak funding has been and will continue to be used to support move-in requirements for the LSBC including:

- relocation activities
- internal communications and information technology (infrastructure, equipment, cabling and audiovisual)
- security (infrastructure and equipment)
- surplus of furniture and equipment, above-standard GSA requirements
- decommissioning of laboratories FDA is vacating
- final commissioning and certification of the specialized laboratories prior to occupancy
- critical operational and logistical functions on the White Oak Campus including those to support the vital specialized equipment maintenance
- start up and continue operating the critically needed Safety Program to support the new Complex and for the security features to expand the CUP.

FUNDING HISTORY - WHITE OAK

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$41,874,000	$38,459,000	$3,415,000
FY 2012 Actual	$43,801,000	$40,386,000	$3,415,000
FY 2013 Actual	$57,159,000	$53,684,000	$3,475,000
FY 2014 Enacted	$61,922,000	$58,044,000	$3,878,000
FY 2015 Budget Request	$47,116,000	$43,044,000	$4,072,000

FUNDING HISTORY - GSA RENT

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$178,120,000	$150,763,000	$27,357,000
FY 2012 Actual	$187,655,000	$160,506,000	$27,149,000
FY 2013 Actual	$190,151,000	$149,970,000	$40,181,000
FY 2014 Enacted	$219,907,000	$162,076,000	$57,831,000
FY 2015 Budget Request	$236,076,000	$169,336,000	$66,740,000

FUNDING HISTORY - OTHER RENT AND RENT-RELATED ACTIVITIES

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$87,235,000	$61,095,000	$26,140,000
FY 2012 Actual	$89,803,000	$65,598,000	$24,205,000
FY 2013 Actual	$88,129,000	$64,058,000	$24,071,000
FY 2014 Enacted	$116,439,000	$74,674,000	$41,765,000
FY 2015 Budget Request	$120,862,000	$73,296,000	$47,566,000

BUDGET REQUEST

The FY 2015 Budget is $404,054,000, of which $285,676,000 is budget authority and $118,378,000 is user fees. This amount is $5,786,000 more than the FY 2014 Enacted level. This increase is associated with costs related to FY 2015 programmatic growth for food and medical product safety activities.

GSA Rental Payments

The FY 2015 Budget for GSA Rental Payments is $236,076,000, which is a $16,169,000 increase above the FY 2014 Enacted level. The GSA Rental increase includes $7,260,000 in budget authority and $8,909,000 in user fees. The total FY 2015 Budget includes $169,336,000 in budget authority and $66,740,000 in user fees.

The rental properties that provide office and laboratory space for FDA employees are essential facilities that allow FDA to perform its vital public health mission. The FY 2015 Budget for GSA Rental Payments covers the cost of rental payments to GSA for FDA's six million square feet of GSA rented office and laboratory space.

FDA will bring an additional 3,000 employees to campus from the Human Drugs, Biologics, and Tobacco Control Act Programs, increasing the Campus population to approximately 9,000 employees, beginning in the spring of 2014. FY 2015 GSA Rent Costs will increase disproportionately because FDA will be occupying four new buildings on White Oak for the full year rather than part of the year. The space is also more expensive than the vacated locations because GSA charges higher rent for newer, more modern facilities.

Other Rent and Rent-Related

The FY 2015 Budget for Other Rent and Rent-Related is $120,862,000, which is a $4,423,000 increase from the FY 2014 enacted level. The Other Rent and Rent-Related includes a decrease of $1,378,000 in budget authority and an increase of $5,801,000 in user fees. The total budget request includes $73,296,000 in budget authority and $47,566,000 in user fees.

It is important that FDA keep its infrastructure up-to-date and efficient to support FDA staff while executing its regulatory mission. The FY 2015 Budget allows FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner. The FY 2015 Budget will cover the escalating costs in commercial rent, security, service contracts, and utilities without reducing essential FDA programs.

The Budget includes funding for the White Oak Energy Savings Performance Contracts that are already providing Campus utilities and covers the expansion of the CUP. The CUP expansion provides the utilities needed to occupy and operate the new LSBC.

White Oak

The FY 2015 Budget for White Oak Consolidation is $47,116,000, a $14,806,000 decrease from the FY 2014 Enacted level. The White Oak Consolidation decrease includes a decrease of $15,000,000 in budget authority and $194,000 increase in user fees. The FY 2015 Budget includes $43,044,000 in budget authority and $4,072,000 in user fees.

The FY 2015 Budget supports mission support services for the White Oak Campus. By the end of FY 2014, there will be almost 9,000 employees occupying the Campus. This FY 2015 Budget will fund security equipment and communications networks, expanded support services, labor and loading dock services, and a centralized safety program. The FY 2015 Budget also provides funds for ongoing and expanded operational and logistical functions on the Campus including those vital to support the LSBC, such as specialized equipment maintenance and IT infrastructure and security for the CUP that provides the utilities for the Complex.

BUILDINGS AND FACILITIES

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+-FY2014
Buildings and Facilities (Budget Authority)	4,920	5,635	8,788	8,788	--

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act (42 U.S.C. §238); 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.*); Chief Financial Officers Act of 1990 (P.L. 101-576); Federal Financial Management Act of 1994 (P.L. 103-356); Energy Policy Act of 2005 (P.L. 109-058); Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

Allocation Methods: Direct Federal/Contract

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Building and Facilities Program (B&F) is a critical element of FDA's real property asset management program and directly supports FDA's public health mission. B&F also supports FDA's strategic goal to transform administrative systems and infrastructure.

B&F funding is used to construct new mission-critical laboratory, office, and support space, as well as renovate and repair site infrastructure and 85 existing FDA-owned facilities at six sites in the United States and Puerto Rico.

HHS developed a Real Property Asset Management Plan (AMP) which outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets.

The AMP contains performance measures and benchmarks that monitor key real property asset management criteria, including:

- mission criticality
- utilization
- facility condition
- operating costs.

The physical condition of FDA assets, which includes a substantial amount of laboratory facilities and site infrastructure, is critically important. A safe, suitable, and reliable work environment is essential for FDA to protect the Nation's health, security, and economy. Improving and maintaining facilities often results in a positive effect on associated utilization and operating costs.

An important component of FDA real property asset management is conducting facility condition assessments on a 3-year cycle, which evaluate:

- site infrastructure such as utility distribution systems, roads, and sidewalks
- buildings, including physical systems such as architectural, civil, mechanical, and electrical
- code compliance
- life and other safety conditions
- finishes and aesthetics.

The assessments result in:

- a list of maintenance and repair deficiencies with associated costs known as the Backlog of Maintenance and Repair (BMAR) for the site and its facilities
- a plant replacement value that is the cost to replace an infrastructure item or a facility
- a Facility Condition Index (FCI) score.

The BMAR identifies and estimates costs associated with addressing needed maintenance, repairs, and replacement of equipment and building systems that are approaching – or past – their useful life. The BMAR is used to identify and prioritize short- and long-term projects using B&F funding. At of the end of FY 2013, the BMAR for the six FDA-owned sites, including renewals, is approximately $120.9 million. Approximately 71 percent of FDA-owned assets have an FCI score below the HHS-established goal of 90 percent and require significant repairs and improvements.

FDA uses funds to accomplish both mission and BMAR-driven projects. The goal is to improve the condition of these assets and the site infrastructure, as well as to ensure the suitability and reliability of FDA-owned assets. Some of the sites, descriptions, and examples of the project work include:

The Muirkirk Road Complex (MRC) in Laurel, Maryland, is a campus shared by the Foods and Animal Drugs and Feeds programs to conduct research on:

- food and animal drug safety
- toxicology
- microbiology
- molecular biology.

In FY2013 FDA:

- awarded another Utility Energy Services Contract (UESC) for MRC, including an energy conservation measure (ECM) to replace all piping insulation in a main boiler room
- renovated a critical laboratory building to meet Animal Drugs and Feeds Program needs prior to occupancy
- renovated two walk-in freezers
- repaved a parking lot and roadway
- initiated a project to replace pneumatic HVAC controls with direct digital controls
- replaced elevator components on three elevators.

In FY 2014, FDA will:

- modify a steam vent to conserve energy
- replace electric front doors that are water damaged
- replace components and controls on two additional elevators
- increase emergency power capacity
- install Phoenix valves to better control environmental conditions in animal research rooms
- address accessibility issues.

The Jefferson Laboratories Complex in Jefferson, Arkansas, houses National Center for Toxicological Research (NCTR) and the Office of Regulatory Affairs (ORA) Arkansas Regional Laboratory (ARL). Details of the vital scientific research that takes place ARL can be found in the NCTR Narrative.

ARL provides analytical laboratory support to FDA's regulatory mission in the Southwest Region. In FY 2013, FDA continued its project to significantly improve an aged electrical infrastructure at ARL's site. This ongoing project began with a significant, campus-wide power outage in the winter of FY 2010 that led to a need to take immediate action to strategically replace the 60 year old electrical infrastructure, including the installation of needed emergency power. In addition, FDA continued its project to replace the three inefficient and maintenance-intensive boilers that serve the 1 million square foot campus with three dependable, more efficient, "right-sized" boilers.

In FY 2014, FDA will initiate additional site infrastructure projects including:

- replacing the site's main electrical switchgear and installing a new campus monitoring and control system for the site electrical infrastructure

- replacing the Northwest loop of the electrical distribution system
- replacing the third boiler in the main boiler plant.

Building improvement projects will also be initiated that include:

- completing the second phase of replacing the HVAC controls in a critical laboratory building
- upgrading the lighting and controls in various buildings for energy savings
- designing an improvement project for a critical animal processing area
- developing a Campus-wide Investment Grade Energy Audit.

The Pacific Regional Laboratory Southwest in Irvine, California, provides analytical laboratory support to FDA's regulatory mission in the Pacific Region. In FY 2013, FDA repaired excessive soil erosion beneath the parking area and awarded a UESC to complete energy conservation measures in the laboratory (including an ECM to install a power monitoring system) to improve energy efficiency and sustainability. In FY 2014, FDA will repair or replace the ceiling grid in a file room to eliminate a fire-code safety violation and correct drainage problems at stairwell landings caused by seismic activity.

The Winchester Engineering and Analytical Center in Winchester, Massachusetts, is a specialty laboratory used to:

- test the safety and performance of medical devices, microwaves, and radiopharmaceuticals
- conduct radionuclide testing with food samples
- ensure seafood freshness.

In FY 2013, FDA renovated two rooms to meet program needs, replaced the front entrance roof, and initiated a project to replace the main roof.

In FY 2014, FDA will:

- install a new fire alarm panel to meet safety code
- design a project to replace a main sanitary waste line
- renovate two additional rooms to meet program needs
- correct the humidity problem in several laboratories.

The Gulf Coast Seafood Laboratory located in Dauphin Island, Alabama, is FDA's sole marine laboratory, and represents 80 percent of FDA-research capacity for addressing seafood safety. In FY 2013, FDA painted the exterior of three buildings. In FY 2014, FDA plans to replace the handrails and concrete stairs at two entrances to meet accessibility codes.

FDA's San Juan District Office and the National Drug Servicing Laboratory are located in San Juan, PR. The laboratory specializes in pharmaceutical analysis. In FY 2013, FDA replaced the roofs on four buildings, replaced the domestic water storage tank, and corrected normal and emergency power code deficiencies. In FY 2014, FDA plans to replace the interior doors and frames of the main laboratory building.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	$12,747,000	$12,747,000	$0
FY 2012 Actual	$9,080,000	$9,080,000	$0
FY 2013 Actual	$5,635,000	$5,635,000	$0
FY 2014 Enacted	$8,788,000	$8,788,000	$0
FY 2015 Budget Request	$8,788,000	$8,788,000	$0

BUDGET REQUEST

The FY 2015 Budget is $8,788,000, all budget authority. This amount is equal to the FY 2014 Enacted level. FDA will use the requested resources to fund various projects at the six mission-critical sites FDA owns. For example, at the Jefferson Labs Complex, FDA will:

- complete the final phase of replacing HVAC controls in a critical laboratory building
- renovate an animal holding area
- replace an existing well used for domestic water supply
- upgrade the lighting and controls in various buildings
- design the replacement of various chillers in the Campus cooling loop.

At the Muirkirk Road Complex, FDA will:

- install enhanced room and point of use ventilation to improve safety associated with large animal necropsy and surgery
- renovate a dairy animal research facility to comply with Association for Assessment and Accreditation of Laboratory Animal Care requirements
- renovate space to create workstations for new hires in support of laboratory operations
- install more efficient valves and upgraded controls for the ventilation system in the cage washing area of the main laboratory.

In the Pacific Regional Laboratory Southwest, FDA will:

- repair surface systems damaged as a result of the large area of soil erosion
- replace the boiler expansion feed tank and building air conditioning controller
- replace existing drinking fountains with bottle filler stations to reduce water and energy consumption.

At the Gulf Coast Seafood Laboratory facility, FDA will support work on existing, emerging, and potential seafood safety issues, including continuing recovery efforts and research related to the 2010 Deepwater Horizon oil spill.

The following table provides an allocation plan by site for use of the FY 2015 funds.

FY 2015 BUILDINGS AND FACILITIES ALLOCATION PLAN

Site	Total
CFSAN Gulf Coast Seafood Laboratory	$520,000
Jefferson Laboratories Complex (NCTR & ARL) – Jefferson, AR	$4,767,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$2,858,000
ORA Pacific Regional Laboratory SW – Irvine, CA	$238,000
San Juan District Office and Laboratory – San Juan, PR	$145,000
Winchester Engineering and Analytical Center – Winchester, MA	$260,000
B&F Project Total	$8,788,000

In FY 2015, improving the condition of FDA-owned real property assets and site infrastructure will continue to be a priority. Completion of these projects enhances FDA's ability to achieve its critical mission of protecting and promoting the health of the American public. 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. In addition, several of these projects will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Performance Plan.

More specifically, projects planned in FY 2015 will help reduce Scope 1, 2, and 3 greenhouse gas emissions by:

- replacing aged, inefficient HVAC controls and equipment
- upgrading lighting in animal research buildings
- replacing all piping insulation in a main boiler room
- installing instantaneous water heaters to reduce boiler load in animal research buildings
- reprogramming air handlers for free cooling at cooler temperatures
- installing motion detectors to control lights in a vivarium
- replacing existing drinking fountains with bottle filler stations to reduce water and energy consumption in Irvine
- re-commissioning radiant heaters in offices
- replacing entrance doors and frames
- tinting windows
- implementing energy conservation measures identified in a recent energy audit in Dauphin Island.

PROGRAM ACTIVITY DATA[1]

Facility	Average FCI Score		
	FY 2013 Enacted	FY 2014 Request	FY 2015 Request
CFSAN Gulf Coast Seafood Laboratory[2]	94	94	94
Jefferson Laboratories Complex[3]	80	73	73
Muirkirk Road Complex[4]	82	81	82
ORA Pacific Regional Laboratory Southwest[5]	97	97	97
San Juan District Office and Laboratory[6]	80	78	78
Winchester Engineering And Analytic Center[7]	68	68	68

[1] The Backlog of Maintenance and Repairs (BMAR) at each site is significant. Funding is allocated to projects at each site in an effort to reduce the BMAR and improve the average Facility Condition Index (FCI) for the site. Without ongoing repair and improvement projects, the increase in BMAR each year would result in no change or a decrease in the FCI rather than an increase. Improvements may not be realized in the fiscal year the funds are received due to timing and complexity of the project.
[2] Based on funding levels in FY 2014 and FY 2015, the BMAR for this site will decrease by approximately $3.5K. Remaining BMAR for this site is approximately $274.5K.
[3] Based on funding levels in FY 2014 and FY 2015 the BMAR for this site will decrease by approximately $1.3M. Remaining BMAR total will be approximately $93.5M.
[4] Based on funding levels in FY 2014 and FY 2015 the BMAR for this site will decrease by approximately $747K. Remaining BMAR total will be approximately $16.6M.
[5] Based on funding levels in FY 2014 and FY 2015, the BMAR for this site will decrease by approximately $29.5K. Remaining BMAR for this site is approximately $959K.
[6] Based on funding levels in FY 2014 and FY 2015 the BMAR for this site will decrease by approximately $69K. Remaining BMAR total will be approximately $2.9M.
[7] Based on funding levels in FY 2014 and FY 2015, the BMAR for this site will decrease by approximately $122K. Remaining BMAR total will be approximately $4.4M.

OBJECT CLASSIFICATION

BUDGET AUTHORITY

(dollars in thousands)	FY 2013 Actuals	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	788,902	846,011	875,310	29,299
Other than full-time permanent (11.3)	97,303	104,347	107,961	3,614
Other personnel compensation (11.5)	45,783	49,097	50,797	1,700
Military personnel (11.7)	61,969	59,295	57,393	-1,902
Special personnel services payments (11.8)	645	692	716	24
Subtotal, Personnel Compensation	**994,602**	**1,059,442**	**1,092,177**	**32,735**
Benefits:				
Civilian benefits (12.1)	276,359	296,365	306,629	10,264
Military benefits (12.2)	32,346	30,950	29,957	-993
Benefits to former personnel (13.0)	7	335	338	3
Subtotal, Benefits	**308,712**	**327,650**	**336,924**	**9,274**
Total Personnel Compensation and Benefits	**1,303,314**	**1,387,092**	**1,429,101**	**42,009**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	38,155	43,068	41,970	-1,098
Transportation of things (22.0)	3,374	3,808	3,711	-97
Rental payments to GSA (23.1)	149,970	162,076	169,336	7,260
Rent payments to others (23.2)	4,475	5,292	5,157	-135
Communication, utilities, and misc. charges (23.3)	38,350	43,288	42,184	-1,104
Printing and reproduction (24.0)	1,019	1,150	1,121	-29
Subtotal, Contractual Services and Supplies	**235,343**	**258,682**	**263,479**	**4,797**
Other Contractual Services:				
Consulting services (25.1)	49,033	55,347	53,935	-1,412
Other services (25.2)	278,517	314,376	306,363	-8,013
Purchase of goods and svcs from Govt Acts. (25.3)	141,995	160,278	156,191	-4,087
Operation and maintenance of facilities (25.4)	65,759	74,226	72,333	-1,893
Research and Development Contracts (25.5)	29,782	33,617	32,760	-857
Operation and maintenance of equipment (25.7)	62,495	70,542	68,743	-1,799
Subtotal, Other Contractual Services	**627,581**	**708,386**	**690,325**	**-18,061**
Supplies and Materials:				
Supplies and materials (26.0)	32,717	36,930	35,988	-942
Equipment (31.0)	57,424	64,818	63,165	-1,653
Land and Structures (32.0)	834	941	917	-24
Grants, subsidies, and contributions (41.0)	91,238	102,986	100,360	-2,626
Insurance claims and indemnities (42.0)	740	835	814	-21
Interest and dividends (43.0)	20	23	22	-1
Subtotal, Supplies and Materials	**182,973**	**206,533**	**201,266**	**-5,267**
Total Contractual Services and Supplies	**1,045,897**	**1,173,601**	**1,155,070**	**-18,531**
Total Budget Authority by Object Class	**2,349,211**	**2,560,693**	**2,584,171**	**23,478**

USER FEE

(dollars in thousands)	FY 2013 Actuals	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	386,248	506,540	594,571	88,031
Other than full-time permanent (11.3)	42,944	56,318	66,105	9,787
Other personnel compensation (11.5)	19,933	26,141	30,684	4,543
Military personnel (11.7)	27,704	32,329	35,230	2,901
Special personnel services payments (11.8)	268	351	412	61
Subtotal, Personnel Compensation	**477,097**	**621,679**	**727,002**	**105,323**
Benefits:				
Civilian benefits (12.1)	132,875	174,257	204,541	30,284
Military benefits (12.2)	14,417	16,824	18,334	1,510
Benefits to former personnel (13.0)	---	---	---	---
Subtotal, Benefits	**147,292**	**191,081**	**222,875**	**31,794**
Total Personnel Compensation and Benefits	**624,389**	**812,760**	**949,877**	**137,117**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	8,465	7,119	8,521	1,402
Transportation of things (22.0)	551	463	555	92
Rental payments to GSA (23.1)	40,181	57,831	66,740	8,909
Rent payments to others (23.2)	2,189	1,076	1,288	212
Communication, utilities, and misc. charges (23.3)	13,020	10,950	13,107	2,157
Printing and reproduction (24.0)	511	430	514	84
Subtotal, Contractual Services and Supplies	**64,917**	**77,869**	**90,725**	**12,856**
Other Contractual Services:				
Consulting services (25.1)	519,659	436,475	523,115	86,640
Other services (25.2)	164,820	138,616	165,916	27,300
Purchase of goods and svcs from Govt Acts. (25.3)	215,012	180,828	216,442	35,614
Operation and maintenance of facilities (25.4)	28,261	23,768	28,449	4,681
Research and Development Contracts (25.5)	15,398	12,950	15,500	2,550
Operation and maintenance of equipment (25.7)	19,012	15,989	19,138	3,149
Subtotal, Other Contractual Services	**962,162**	**808,626**	**968,560**	**159,934**
Supplies and Materials:				
Supplies and materials (26.0)	13,686	11,510	13,777	2,267
Equipment (31.0)	25,296	21,274	25,464	4,190
Land and Structures (32.0)	25	21	25	4
Grants, subsidies, and contributions (41.0)	111,185	93,508	111,924	18,416
Insurance claims and indemnities (42.0)	468	394	471	77
Interest and dividends (43.0)	4	3	4	1
Subtotal, Supplies and Materials	**150,664**	**126,710**	**151,665**	**24,955**
Total Contractual Services and Supplies	**1,177,743**	**1,013,205**	**1,210,950**	**197,745**
Total Reibursables by Object Class	**1,802,132**	**1,825,965**	**2,160,827**	**334,862**

TOTAL PROGRAM

(dollars in thousands)	FY 2013 Actuals	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,175,150	1,352,551	1,469,881	117,330
Other than full-time permanent (11.3)	140,247	160,665	174,066	13,401
Other personnel compensation (11.5)	65,716	75,238	81,481	6,243
Military personnel (11.7)	89,673	91,624	92,623	999
Special personnel services payments (11.8)	913	1,043	1,128	85
Subtotal, Personnel Compensation	**1,471,699**	**1,681,121**	**1,819,179**	**138,058**
Benefits:				
Civilian benefits (12.1)	409,234	470,622	511,170	40,548
Military benefits (12.2)	46,763	47,774	48,291	517
Benefits to former personnel (13.0)	7	335	338	3
Subtotal, Benefits	**456,004**	**518,731**	**559,799**	**41,068**
Total Personnel Compensation and Benefits	**1,927,703**	**2,199,852**	**2,378,978**	**179,126**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	46,620	50,187	50,491	304
Transportation of things (22.0)	3,925	4,271	4,266	-5
Rental payments to GSA (23.1)	190,151	219,907	236,076	16,169
Rent payments to others (23.2)	6,664	6,368	6,445	77
Communication, utilities, and misc. charges (23.3)	51,370	54,238	55,291	1,053
Printing and reproduction (24.0)	1,530	1,580	1,635	55
Subtotal, Contractual Services and Supplies	**300,260**	**336,551**	**354,204**	**17,653**
Other Contractual Services:				
Consulting services (25.1)	568,692	491,822	577,050	85,228
Other services (25.2)	443,337	452,992	472,279	19,287
Purchase of goods and svcs from Govt Acts. (25.3)	357,007	341,106	372,633	31,527
Operation and maintenance of facilities (25.4)	94,020	97,994	100,782	2,788
Research and Development Contracts (25.5)	45,180	46,567	48,260	1,693
Operation and maintenance of equipment (25.7)	81,507	86,531	87,881	1,350
Subtotal, Other Contractual Services	**1,589,743**	**1,517,012**	**1,658,885**	**141,873**
Supplies and Materials:				
Supplies and materials (26.0)	46,403	48,440	49,765	1,325
Equipment (31.0)	82,720	86,092	88,629	2,537
Land and Structures (32.0)	859	962	942	-20
Grants, subsidies, and contributions (41.0)	202,423	196,494	212,284	15,790
Insurance claims and indemnities (42.0)	1,208	1,229	1,285	56
Interest and dividends (43.0)	24	26	26	---
Subtotal, Supplies and Materials	**333,637**	**333,243**	**352,931**	**19,688**
Total Contractual Services and Supplies	**2,223,640**	**2,186,806**	**2,366,020**	**179,214**
Total Program Level by Object Class	**4,151,343**	**4,386,658**	**4,744,998**	**358,340**

SALARIES AND EXPENSES

(dollars in thousands)	FY 2013 Actuals	FY 2014 Enacted	FY 2015 President's Budget	FY 2015 +/- FY 2014
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	788,902	846,011	875,310	29,299
Other than full-time permanent (11.3)	97,303	104,347	107,961	3,614
Other personnel compensation (11.5)	45,783	49,097	50,797	1,700
Military personnel (11.7)	61,969	59,295	57,393	-1,902
Special personnel services payments (11.8)	645	692	716	24
Subtotal, Personnel Compensation	**994,602**	**1,059,442**	**1,092,177**	**32,735**
Benefits:				
Civilian benefits (12.1)	276,359	296,365	306,629	10,264
Military benefits (12.2)	32,346	30,950	29,957	-993
Benefits to former personnel (13.0)	7	335	338	3
Subtotal, Benefits	**308,712**	**327,650**	**336,924**	**9,274**
Total Personnel Compensation and Benefits	**1,303,314**	**1,387,092**	**1,429,101**	**42,009**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	38,155	43,068	41,970	-1,098
Transportation of things (22.0)	3,374	3,808	3,711	-97
Rental payments to GSA (23.1)	149,970	162,076	169,336	7,260
Rent payments to others (23.2)	4,475	5,292	5,157	-135
Communication, utilities, and misc. charges (23.3	38,350	43,288	42,184	-1,104
Printing and reproduction (24.0)	1,019	1,150	1,121	-29
Subtotal, Contractual Services and Supplies	**235,343**	**258,682**	**263,479**	**4,797**
Other Contractual Services:				
Consulting services (25.1)	49,033	55,347	53,935	-1,412
Other services (25.2)	278,517	314,376	306,363	-8,013
Purchase of goods and svcs from Govt Acts. (25.3	141,995	160,278	156,191	-4,087
Operation and maintenance of facilities (25.4)	65,759	74,226	72,333	-1,893
Research and Development Contracts (25.5)	29,782	33,617	32,760	-857
Operation and maintenance of equipment (25.7)	62,495	70,542	68,743	-1,799
Subtotal, Other Contractual Services	**627,581**	**708,386**	**690,325**	**-18,061**
Supplies and Materials:				
Supplies and materials (26.0)	32,717	36,930	35,988	-942
Subtotal, Supplies and Materials	**32,717**	**36,930**	**35,988**	**-942**
Total Contractual Services and Supplies	**895,641**	**1,003,998**	**989,792**	**-14,206**
Total Salaries and Expenses Account	**2,198,955**	**2,391,090**	**2,418,893**	**27,803**
Direct FTE	**9,798**	**10,325**	**10,534**	**209**

* Does not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, 9 IDDA FTE and the associated funds.

DETAIL OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT

	FY 2013 Actual			FY 2014 Estimate			FY 2015 Estimate		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Food Safety and Applied Nutrition	885	38	923	910	38	948	1,119	38	1,157
Center for Drug Evaluation and Research	3,077	396	3,473	3,845	400	4,245	4,108	400	4,508
Center for Biologics Evaluation and Research	1,051	64	1,115	1,073	65	1,138	1,075	65	1,140
Center for Veterinary Medicine	503	6	509	515	6	521	532	6	538
Center for Devices and Radiological Health	1,481	101	1,582	1,564	102	1,666	1,621	102	1,723
National Center for Toxicological Research	255	---	255	281	---	281	282	---	282
Office of Regulatory Affairs	4,261	301	4,562	4,666	304	4,970	4,946	304	5,250
Headquarters and Office of the Commissioner	986	55	1,041	1,251	56	1,307	1,332	56	1,388
Export Certification	18	---	18	22	---	22	22	---	22
Color Certification	38	---	38	37	---	37	37	---	37
Family Smoking Prevention and Tobacco Control Act	437	21	458	549	21	570	672	21	693
Total	**12,992**	**982**	**13,974**	**14,713**	**992**	**15,705**	**15,746**	**992**	**16,738**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2011	13
FY 2012	13
FY 2013	13
FY 2014	13
FY 2015	13

* Total does not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, and 9 IDDA FTE.

The FY 2015 FTE increase is 1,033 FTE above the FY 2014 estimated level due to the impact of FTE annualization of personnel hired in FY 2014 (+52 FTE), current law user fee increases in FY 2015 (+362 FTE), proposed user fee increases (+462 FTE), and budget authority initiative increases for Food Safety Modernization (+21 FTE) and Pharmacy Compounding (+89 FTE). The 56 FTE that were proposed in FY 2014 for the Medical Products Reinspection User Fee are not being re-proposed in FY 2015. The FY 2015 increase also reflects base programmatic adjustments (+77 FTE) that are offset by the impact of the pay absorption (-30 FTE). The increase above FY 2014 of 1,033 FTE is entirely on the civilian side.

DETAIL OF POSITIONS

	FY 2013 Actual	FY 2014 Base	FY 2015 President's Budget
Executive Level			
Executive Level I	---	---	---
Executive Level II	---	---	---
Executive Level III	---	---	---
Executive Level IV	1	1	1
Executive Level V	---	---	---
Total Executive Level	**1**	**1**	**1**
Executive Service (ES)			
Executive Service	61	69	74
Total Executive Service	**61**	**69**	**74**
General Schedule (GS)			
GS-15	1,042	1,180	1,263
GS-14	2,768	3,135	3,355
GS-13	3,836	4,344	4,649
GS-12	2,316	2,623	2,807
GS-11	727	823	881
GS-10	23	26	28
GS-9	542	614	657
GS-8	102	116	124
GS-7	384	435	465
GS-6	52	59	63
GS-5	78	88	95
GS-4	89	101	108
GS-3	40	45	48
GS-2	15	17	18
GS-1	2	2	2
Total General Schedule	**12,016**	**13,608**	**14,563**
Administrative Law Judges (AL)	---	---	---
Scientific/Senior Level (ST/SL)	3	3	4
Research Scientist (RS)	40	45	48
Commissioned Corps (CC):			
Commissioned Corps - 08/07/06	236	238	238
Commissioned Corps - Other	746	754	754
Total Commissioned Corps	**982**	**992**	**992**
Administratively Determined (AD) (includes Title 42)	828	938	1,004
Wage Grade	27	31	33
Consultants[2]	16	18	19
Total FTE (End of Year)[1]	**13,974**	**15,705**	**16,738**
Average ES Level	3	3	3
Average ES Salary	166,893	168,562	170,248
Average GS grade	13	13	13
Average GS Salary	98,135	99,116	100,107

[1] Does not include an estimated 116 reimbursable, 2 CRADA, 40 PEPFAR, and 9 IDDA FTE.

[2] Includes consultants appointed under 5 U.S.C. 3109, those appointed under similar authorities, and those appointed to serve as advisory committee members.

FEDERAL EMPLOYMENT FUNDED BY THE AFFORDABLE CARE ACT

Program	Section	FY 2011			FY 2012			FY 2013			FY 2014			FY 2015		
		Total	FTEs	CEs	Total	FTEs	CEs	Total	FTEs	CEs	Total	FTEs	CEs	Total	FTEs	CEs
FDA																
Discretionary		---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Mandatory		---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

PHYSICIANS' COMPARABILITY ALLOWANCE WORKSHEET

		FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
1) Number of Physicians Receiving PCAs		1	1	0
2) Number of Physicians with One-Year PCA Agreements		0	0	0
3) Number of Physicians with Multi-Year PCA Agreements		1	1	0
4) Average Annual PCA Physician Pay (without PCA payment)		$144,385	$145,829	0
5) Average Annual PCA Payment		$27,000	$27,000	0
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position	0	0	0
	Category II Research Position	1	1	0
	Category III Occupational Health	0	0	0
	Category IV-A Disability Evaluation	0	0	0
	Category IV-B Health and Medical Admin.	0	0	0

* FY 2015 data will be updated during FY 2014.

7) If applicable, list and explain the necessity of any additional physician categories designated by your agency (for categories other than I through IV-B). Provide the number of PCA agreements per additional category for the PY, CY and BY.

FDA will not have a need for additional physician categories other than those listed above.

8) Provide the maximum annual PCA amount paid to each category of physician in your agency and explain the reasoning for these amounts by category.

FDA utilizes the Category 2 to hire physicians that are not eligible for Title 38 PDP. The maximum annual PCA for this category for FY 2013 was $27,000 for the employee receiving PCA. The amounts were determined based upon the qualifications of the physician.

9) Explain the recruitment and retention problem(s) for each category of physician in your agency (this should demonstrate that a current need continues to persist).

(*Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)*
FDA made a decision in 2008 to convert all eligible physicians to Title 38, which is useful in allowing FDA to effectively recruit and retain medical officers across the FDA. The minimal continued use of PCA allowed FDA the ability to recruit physicians who are not eligible for Title 38 PDP. In FY 2015, FDA projects that use of PCA will not be required.

10) Explain the degree to which recruitment and retention problems were alleviated in your agency through the use of PCAs in the prior fiscal year.

(*Please include any staffing data to support your explanation, such as number and duration of unfilled positions and number of accessions and separations per fiscal year.)*
FDA did not experience recruitment or retention problems as the PCA is used sparingly across FDA. FDA uses PCA as a means to recruit candidates that are not eligible for Title 38 PDP.

11) Provide any additional information that may be useful in planning PCA staffing levels and amounts in your agency.

FDA uses PCA as an additional authority to hire physicians that are not eligible for Title 38 PDP.

HOUSE APPROPRIATIONS COMMITTEE SIGNIFICANT ITEMS

FY 2014 HOUSE REPORT 113-116

Dated June 18, 2013

Item 1 - Spending Plans

Within 30 days of enactment, the Commissioner shall notify the Committees on Appropriations of both Houses of Congress on the allocation of the funds provided herein, by account, and within each account by program, project, and activity.

FDA Response
FDA will provide the report that the Committee requested.

Item 2 - FDA User Fee Collections/Obligations

The Committee is concerned about the large unobligated balances that continue to occur in FDA's user fee programs. While Congress did allow for some exemptions from fiscal year limitations and for some amounts to be carried forward into subsequent fiscal years, it could not have been anticipated that FDA would be carrying in excess of $1,000,000,000 in unobligated user fees halfway into any fiscal year. In the Tobacco user fee program alone, the fiscal year 2012 unobligated balance that carried over into fiscal year 2013 was $600,000,000. While FDA estimates this figure will drop to $250,000,000 by the end of fiscal year 2013, the Committee remains skeptical that this will occur. The Committee directs that not later than November 1, 2013, and each month thereafter through the months covered by this Appropriations Act, the Commissioner to submit to the Committees on Appropriations of the House and the Senate a report on user fees collected for each user fee program included in the bill. The report shall also include monthly obligations incurred against such fee collections. The first report shall include a distinct categorization of the user fee balances that are being carried forward into fiscal year 2014 for each user fee account as well as a detailed explanation of what accounts for the balance and what the balance will be used for.

FDA Response
FDA will provide the report that the Committee requested.

Item 3 - Transparency Concerns. (OC/OP/CDER Review)

The Committee is concerned about the unpredictable nature and pace at which FDA moves guidance, rules, and regulations through the process. The Agency must understand that FDA is often viewed as a primary source of information for consumer decisions that impact their health and wellbeing. The Committee understands that many rules and regulations get through the agency and the department only to languish at the Office of Management and Budget (OMB). On the other hand, FDA has discretion to issue advisories and guidance without the need for OMB clearance. In a number of critical health areas, American consumers and industry are faced with no guidance at all or inconsistent messages on many important issues. The following is a list of examples: seafood advisory for pregnant women; sunscreen ingredients; new dietary ingredients for dietary supplements; and, Bisphenol A. The Committee directs FDA to report to the Committees on Appropriations by September 1, 2013, on how the agency plans to develop new methods of communicating with its stakeholders on future actions affecting critical policy issues, including estimated timeframes for when regulations, advisories, and guidance are planned for release and what decision points are necessary before these policy documents can be made.

FDA Response
FDA will provide the report that the Committee requested.

Item 4 - Neglected Tropical Diseases (NTD)

The Committee has become aware that Chagas disease is not on the list of neglected diseases as defined by FDA. The Committee urges FDA to make the necessary modifications to include Chagas disease in its list of neglected diseases in line with World Health Organization's list of NTDs. Additionally, the Committee directs that FDA build stronger partnerships with global regulatory stakeholders and strengthen its internal capacity to review products for neglected diseases.

FDA Response
FDA is in the process of drafting a proposed rule to add to the list of tropical diseases in Section 524 of the FD&C Act, and Chagas disease is being considered in this rulemaking. FDA strives to keep its review staff current on topic areas in infectious diseases, including neglected tropical diseases.

CDER has offered a Forum for International Drug Regulatory Authorities every spring and fall since 2005. The CDER forum was established for the exchange of drug regulatory information between review staff in FDA's Center for Drug Evaluation and Research and its counterpart agencies in other countries. It is a 5 day program and provides information about the U.S. drug regulatory processes in an organized and integrated manner. To date there have been 16 CDER Forums with over 600 drug regulatory authorities from more than 70 countries participating.

Item 5a - Guidance for Industry

The Committee directs the Secretary of Health and Human Services to finalize Guidance for Industry (GFI) #213 prior to January 1, 2014. The Committee directs the Secretary of Health and Human Services to publish a report not later than one year following the date of finalization of GFI #213 that (1) lists the following, for each medically important antimicrobial new animal drug administered in feed or water to food-producing animals with one or more approved production claims (including any growth promotion, feed efficiency, or weight gain claims) and/ or that are approved for over-the-counter (OTC) marketing, provided that such antimicrobial is in a class of drugs that FDA determines accounts for 10 percent or more of all physician prescriptions: (a) the drug's new animal drug application (NADA) number(s), (b) sponsor, (c) all antimicrobial active ingredients contained in the drug, and, (d) all production claims approved for the drug; and (2) specifies the number of sponsors of the new animal drugs listed that have notified FDA of their intent to participate in the voluntary process described in GFI #213.

FDA Response
FDA finalized and published Guidance for Industry (GFI) #213 on December 12, 2013.

FDA has published a list of NADA numbers, sponsors, and active ingredients for all medically important antimicrobial new animal drug administered in feed or water to food-producing animals with one or more approved production claims (including any growth promotion, feed efficiency, or weight gain claims) and that are approved for over-the-counter (OTC) marketing, including those under 10 percent of the physicians prescriptions. FDA will update this list [33]as necessary throughout the 3-year implementation period of GFI #213.

Item 5b - Guidance for Industry

The Committee further directs the Secretary, beginning not later than one year following the finalization of GFI #213, to publish annual reports that (1) specify the number of antimicrobial new animal drugs for which sponsors have submitted applications under GFI #213 to change existing approvals, broken out by type of change sought (removal of production claims; addition of treatment, control, and prevention

[33] The list is available at:
http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM378330.pdf

claims; and removal of OTC marketing status); and (2) list the applications submitted under GFI #213 that have been approved by the agency by NADA number, and if not approved or rejected, indicate whether the inaction was a result of insufficient FDA resources, insufficient information from sponsors or some other reason.

FDA Response
CVM has concerns regarding the implications of parts of the reporting requirement in Report Language 3 ("list the applications submitted under GFI #213 that have been approved by the agency by NADA number, and if not approved or rejected, indicate whether the inaction was a result of insufficient FDA resources, insufficient information from sponsors, or some other reason"). FDA publishes certain information about approved applications, but FDA's confidentiality regulations preclude the agency from releasing information about individual unapproved applications (see 21 CFR 514.11 and 514.12). However, FDA believes it may be possible to share aggregate information about such applications in a manner that would still be protective of confidential commercial information.

Item 6a - Nutrition Labeling

The Committee remains concerned with FDA's proposed rule to regulate Nutrition Labeling of Standard Menu Items at Chain Restaurants. The Committee urges FDA to use the proposed alternative Option 2 definition of the rule which only applies to restaurants or retail establishments where the primary and majority of business is the selling of food for consumption or the selling of food that is processed or prepared on the premises. The Committee believes the agency should take into account the increased costs and logistical challenges chain restaurants will face in meeting the requirements of the proposed rule.

FDA Response
FDA is aware of the Committee's concerns about FDA's definition of "restaurant" and similar retail food establishment; FDA is also aware of the Committee's support for FDA's alternate definition in the proposed rule. That definition would encompass only establishments where the primary business is the selling of food for immediate consumption or selling food that is prepared and processed on the premises. FDA received many comments on the proposed definition of "restaurant and similar retail food establishment," ranging from comments similar to the Committee's comments supporting FDA's proposed definition, and comments supporting a definition to include all facilities that serve restaurant and restaurant-type foods. FDA is proceeding in a deliberative manner to ensure that all comments are fully evaluated and their views considered before a final regulation is issued.

Item 6b - Nutrition Labeling

To meet the requirements of the law, FDA should consider a clear, conspicuous statement of required nutritional information on a prominently displayed poster adjacent to the menu board and nutritional information to be provided in pamphlet form prominently displayed next to drive-through menu boards as meeting such requirements.

FDA Response
FDA is aware of the Committee's recommendation regarding placement and prominence of the required nutrition information. FDA received several comments on where and how the required nutrition information should be displayed for indoor menu boards, foods on display, and outdoor drive through menu boards. FDA is proceeding in a deliberative manner to ensure that all comments are fully evaluated and their views considered before a final regulation is issued.

Item 7 - Food Safety Monitoring

The Committee notes that the National Agriculture and Food Defense Strategy Plan is being finalized as required by Section 108 of Public Law 111–353. As research needs are identified to carry out this section, the Committee encourages FDA to consider funding research that would provide portable and

technologically advanced testing platforms needed to effectively monitor and protect against intentional adulteration of the food supply.

FDA Response
The latest draft of the proposed Coordinated Research Agenda (CRA), as part of the National Agriculture and Food Defense Strategy (NAFDS - Section 108 of Public Law 111–353), documents ongoing research projects (or activities) that would provide portable and technologically advanced testing platforms (modular and expandable detection platform for adulterants; detection system for detection of Bio-threat agents in food; and, evaluation of chemical hazards screening methods) needed to effectively enhance monitoring and protecting against intentional adulteration. FDA will continue to review advancements in research and technology, and work with state and government agencies in the development of in-field tools that can promote and assist in food safety efforts, including those applicable and specific to seafood.

Item 8 - Regulations

The Committee appreciates FDA's acknowledgement that exclusive tobacco products may raise different questions of public health and may need to be treated differently. Further, the Committee notes that there are key differentiating and unique characteristics of premium cigars and that any effort to bring these products under the ''deeming'' rule should proceed with these factors being taken into consideration.

FDA Response
The Family Smoking Prevention and Tobacco Control Act provides FDA with the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The law also permits FDA to issue regulations deeming other "tobacco products," such as e-cigarettes, certain dissolvable tobacco products, cigars, pipe tobacco, hookah, etc., to be subject to Chapter IX of the Food Drug & Cosmetic Act (FD&C Act). In the February 2012 edition of the Unified Agenda, FDA included an entry for a proposed rule that would deem products meeting the statutory definition of "tobacco product" to be subject to Chapter 9 of the FD&C Act and would clarify additional restrictions under the FD&C Act. FDA realizes that although all cigars are harmful and potentially addictive, different kinds of cigars have the potential for varying effects on public health, if there are differences in how often they are smoked, the degree of inhalation, and their effects on youth initiation and their use by youth and young adults. To ensure FDA understand the issues, it has had repeated meetings with representatives of the premium cigar industry (manufacturers and retailers) who have pointed out what they see as the differentiating characteristics of their products.

While the Agency cannot comment on the details related to a pending rulemaking, the Committee can be assured that FDA will continue to carefully consider the public health impact of the proposed rule, especially as it pertains to youth.

Item 9 – Sunscreen

Approximately two million cases of skin cancer are diagnosed each year and an estimated one in five Americans may develop skin cancer during their lifetime. Since sunscreen use can help prevent this disease, the Committee is concerned that FDA has taken no final action to approve new sunscreen ingredients under the Time and Extent Applications (TEA) process. The Committee understands that new sunscreen ingredient TEAs have been pending at FDA for more than 10 years without any approvals despite their widespread safe and effective use in other countries. FDA has listed final action on sunscreen ingredient applications in its Unified Agenda every year since 2008; however, no such action has ever been taken. Therefore, FDA shall take final action on all sunscreen ingredient applications pending by June 1, 2014, and shall work with Congress and stakeholders—including ingredient manufacturers, finished product manufacturers, dermatologists, cancer prevention organizations and others—to develop a new process that will allow safe and effective sunscreen ingredient market applications to receive a final decision from FDA within one year of application date.

FDA Response
FDA's goal is to respond to applicants of all pending sunscreen TEAs by June 1, 2014. The Agency is also discussing improved pathways for bringing new sunscreens to market with Members and Congressional staff and providing technical assistance on proposed legislation. Furthermore, FDA plans to hold a public meeting in the spring of 2014 to discuss the safety and standards for sunscreen products. The public meeting discussion will assist FDA in the ongoing development of Guidance for Industry on the scientific data requirements for sunscreens.

While diligently working on applications and issues related to sunscreens, FDA is simultaneously evaluating the current Over-the-Counter (OTC) Monograph Process. Recognizing the challenges and the changed environment from when the current process was initially adopted, FDA has been discussing alternate pathways for all ingredients, including sunscreens, marketed under the OTC monograph system. FDA plans to hold an additional public meeting in the spring of 2014 to obtain input on how to improve the OTC Monograph Process and discuss the feasibility of other alternative pathways.

Item 10 - New Dietary Ingredients

The Committee notes that FDA has not addressed issues relating to its July 2011 draft guidance on New Dietary Ingredients (NDI) for Dietary Supplements despite this Committee's urging it to do so last year. The Committee continues to be concerned that this guidance is being utilized by FDA for enforcement activities despite the document only being draft guidance. The Committee directs FDA to report back within 60 days of enactment of this Act with a timeline on how it intends to re-engage the dietary supplement community to develop a final guidance on what constitutes a NDI.

FDA Response
FDA announced in July 2012 that it will be reissuing a revised NDI draft guidance for comment in order to add clarity where there was confusion regarding FDA's interpretation of the statutory authority in the NDI provision. Over the past 18 months FDA has held multiple meetings with the Dietary Supplement trade associations to identify and clarify issues of concern. FDA is completing the revisions to the draft guidance and plans to publish in 2014.

FDA announced in July 2012 that it will be reissuing a revised NDI draft guidance for comment in order to add clarity where there was confusion regarding FDA's interpretation of the statutory authority in the NDI provision.

Item 11 - Food Safety Centers of Excellence

The funding provided for CFSAN supports the base funding for the CFSAN Centers of Excellence at the FY 2011 level, including Food Safety Modernization Act collaborative efforts with these Centers. The Committee encourages FDA to maintain an appropriate funding level for both Food Safety Modernization Act related and other food safety related activities performed by these Centers of Excellence.

FDA Response
FDA will maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

Item 12 - Cosmetics

The Committee directs the Office of Cosmetics and Colors to respond by September 30, 2013, to a citizen petition setting safety levels for trace amounts of lead in cosmetics.

FDA Response
Although the available data to FDA do not suggest that the amount of lead in lipstick or other cosmetic products is a significant public health issue, FDA sponsored additional studies to address data gaps. FDA is evaluating data from these studies and other information regarding trace amounts of lead in cosmetic products to develop a full response to the citizen petition.

Item 13 - Food and Drug Safety and Innovation Act

The Committee is aware that shortages of critical drugs persist following the enactment of the Food and Drug Safety and Innovation Act. Surveys conducted by the American Association of Nurse Anesthetists, the American Hospital Association, and the American Society of Health-System Pharmacists report persistent shortages of drugs used in anesthesia care, oncology, and other services, owing primarily to problems in manufacturing, which impair patient access to care and patient experiences in the healthcare system, delay surgical procedures, and possibly increase overall healthcare costs. The Committee directs the Commissioner to continue to prioritize the public reporting of manufacturing shortages and to work with industry to prevent conditions that might lead to drug shortages.

FDA Response
Assuring that patients who are in need have access to critical and life-saving drugs is central to FDA's mission – and a top priority. While significant progress has been made recently, drug shortages continue to impact many patients in need of critical treatment.

FDA has taken a number of recent steps to enhance our response to this significant public health challenge. The Agency has issued a long-term strategic plan, required by FDASIA, which focuses on preventing many of the underlying causes of most drug shortages. The plan outlines the Agency's strategy for improving its response to early notifications of a potential shortage, as well as long-term tactics to address the underlying causes of shortages.

FDA has also issued a proposed rule that, if finalized, will expand the requirement for drug and biologic manufacturers to notify FDA early about issues that could lead to a potential shortage. The proposed rule, Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products, would implement the expanded early notification requirements included in FDASIA.

Specifically, the proposed rule would require all manufacturers of certain medically necessary prescription drugs provide six-month's advance notice to FDA of a permanent discontinuance or a temporary interruption of manufacturing. The rule also extends this requirement to manufacturers of biologics.

Early notification is a critical tool for FDA in its efforts to mitigate or prevent a potential shortage and its impact on patients. It gives FDA: time to work with manufacturers to investigate the issue leading to the disruption; identify other manufacturers who can make up all or part of the shortfall; and expedite inspections and reviews of submissions from manufacturers of drugs that may prevent or mitigate a shortage.

Item 14 - Food and Veterinary Medicine

The Committee is aware of the important support provided to FDA's food and veterinary medicine programs and through its research and program relations with their centers of excellence. The Committee encourages FDA to maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

FDA Response
FDA will maintain an appropriate funding level for both Food Safety Modernization Act related activities and the base work performed by these centers.

Item 15 - Compounded Drugs

The Committee is concerned by the quantity and volume of recalls of compounded sterile products and therapies. The Committee awaits the results of a study by GAO providing updated information on state and Federal oversight of compounding. Furthermore, the Committee encourages FDA and the States to work together to improve and strengthen oversight and enforcement of compounding pharmacies.

FDA Response
FDA shares the Committee's concern about the quantity and volume of recalls of compounded sterile drug products. Further, FDA continues to identify serious deficiencies in compounders' processes for the production of sterile drugs, which put patients at risk.

FDA recognizes the importance of working with the States to regulate compounding pharmacies in a way that protects the public health. Accordingly, the Agency is taking steps to support and strengthen its relationships with the States on pharmacy compounding issues and strengthen its oversight and enforcement of compounding pharmacies. During the past year, the Agency has collaborated with the States on inspections it has conducted of compounding facilities. FDA is also planning a second 50-state meeting in the first quarter of 2014 to update the States about plans for implementation of the new legislation and to engage with them on how to better coordinate activities to oversee compounded drugs.

On January 8 and 9, 2014, Commissioner Hamburg sent letters regarding the pharmacy compounding provisions of the Drug Quality and Security Act (DQSA) to State officials, including governors, State boards of pharmacy and health departments. The purpose of the letters is to inform these important stakeholders of the recent passage of new federal legislation affecting the oversight of compounded human drugs, and to encourage them to take steps to encourage compounders that produce sterile drugs to register with FDA as outsourcing facilities.

Commissioner Hamburg's letter to governors asks them to consider how they can encourage compounding pharmacies located outside their States that ship compounded sterile drugs into their States to register with FDA as an outsourcing facility. Once registered, States would be assured that these facilities will be inspected on a risk-based schedule by FDA, would be subject to good manufacturing practices requirements, and would be required to submit adverse events reports that FDA could monitor - thereby helping to improve the overall quality of the drugs compounded at these facilities.

Further, FDA is implementing, in consultation with the National Association of Boards of Pharmacy, the DQSA section that requires the Secretary to establish a mechanism to receive submissions from State boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting inconsistently with Section 503A. This section of the law also requires that FDA notify State boards of pharmacy when the Secretary receives certain State board of pharmacy submissions or makes a determination that a compounding pharmacy is acting inconsistently with the provisions of 503A.

Item 16 - Food Product Tracing

Pursuant to Section 204 of the Food Safety Modernization Act, FDA initiated pilot projects for improving product tracing along the food supply system and the establishment of recordkeeping requirements for high-risk foods. These pilots were conducted by the Institute of Food Technologists, in consultation with various industry sectors, USDA, state agencies, and consumer groups. A report on these projects was published on March 4, 2013, and that report affirmed that industry and government continue to pursue traceability goals on separate tracks and with little collaboration. The Committee directs the Commissioner, in consultation with the Secretary of Agriculture, to create a science-based, international food traceability initiative through a collaborative public-private partnership model. Furthermore, the Committee directs the Commissioner to provide a report within 180 days of enactment of this Act detailing the structure, goals, and implementation status of such traceability initiative.

FDA Response
FDA will provide the report that the Committee requested.

Item 17 - Center for Tobacco Products Performance

The Committee understands that GAO is conducting a study of FDA's premarket review of tobacco products. The Committee directs that, upon publication of that study, FDA shall use it to identify a set of

regulatory performance standards that will address pending and new substantial equivalent applications, pending and new modified risk applications, citizen petitions, and meeting requests. The Committee further directs FDA to report to the Committees on Appropriations by March 31, 2014, on the implementation of such performance standards.

FDA Response
FDA will provide the report that the Committee requested.

Item 18 - Low-Risk, Expedited Imports

The current fiscal environment and the growing number of import entries require that efforts to enhance safety must be directed towards the most serious compliance infractions. The Committee strongly encourages FDA to establish a pilot project to expedite imports for importers with strong safety records. Such project could be modeled on the Customs and Border Protection (CBP) Customs-Trade Partnership Against Terrorism and Importer Self-Assessment programs which address security of imported products. The goal would be new trade facilitation methods for low-risk importers that provide accurate and reliable data, have a history of importing compliant products, and low risk cargo that could be incorporated into the import inspection process, thereby enabling FDA to better leverage financial resources. FDA is strongly encouraged to provide clear guidelines for those importers that are low-risk and to collaborate with CBP and other relevant agencies to enhance information sharing between agencies on this work. FDA is directed to provide a report to the Committee on its efforts in this regard by December 1, 2013.

FDA Response
In an environment of increasing import entries, FDA has engaged in the process of implementing three programs that will help facilitate the import entry of products from highly compliant importers: 1) the Voluntary Qualified Importer Program (VQIP) for Food and Feed; and 2) the Secure Supply Chain Pilot Program (SSCPP) for Pharmaceuticals and 3) PREDICT.

VQIP is a formal voluntary program under which importers may submit evidence of regulatory compliance and safety controls in exchange for those products imported into the U.S. in return for the expedited release of entries. FDA continues to work on the operational design of VQIP authorized under FSMA and will implement in coordination with the third party accreditation rule, which is one of the requirements of the program. Along with the operational design FDA is also developing the IT requirements needed to support VQIP and importer user fees that are also required under FSMA.

The SSCPP will expedite pharmaceutical products originating from known sources destined for known US entities for importers with strong safety records. This program will facilitate the entry of low-risk pharmaceutical imports from importers who provide accurate and reliable data, have implemented procedures to assure the physical security of shipments, and have a history of importing compliant products. FDA is in the process of evaluating applications for the pilot. The SSCPP is scheduled to be piloted for 2 years, from February 2014 through February 2016.

In addition to VQIP and SSCPP, PREDICT is a an admissibility screening system designed to improve the entry review process by preventing the entry of adulterated, misbranded, or otherwise violative goods while expediting the entry of non-violative goods. PREDICT is designed to recognize shipments from firms and importers that have good compliance history as well as products that are low risk. This will help expedite the entry of products with a good history of compliance and allow the Agency to focus import inspections on higher-risk shipments.

Item 19 - Cough and Cold Products for Children

The Committee is concerned that FDA has not issued a proposed rule revising the monograph regulating the labeling of over-the-counter cough and cold products for children. The Committee directs the agency to publish a proposed rule by December 31, 2013, based on scientific evidence for safety and efficacy in

pediatric populations and taking into consideration the October 19, 2007, joint recommendations of its Pediatric Advisory Committee and Nonprescription Drugs Advisory Committee.

FDA Response
FDA is working on a proposed rule that will provide requirements for clinical safety and efficacy studies for cough and cold products used by children. Such cough and cold products would be classified as Category II (not generally recognized as safe and effective or unacceptable indications) if adequate data has not been submitted to support their safety and effectiveness.

Item 20 - Data Collection

To assist efforts intended to address antibiotic use, the Committee directs the Secretaries of Health and Human Services and Agriculture to require appropriate agencies to collaborate to (1) identify approaches for collecting detailed data on antibiotic use in food-producing animals, (2) seek stakeholder and broad public input to develop a proposal for collecting this information, and (3) use the data to assess the effectiveness of policies to curb antibiotic resistance. The Committee further directs FDA to ensure that ARS continues to analyze, characterize, and report on data collected through NARMS.

FDA Response
FDA published an advance notice of proposed rulemaking (ANPRM) in the July 27, 2012 Federal Register, soliciting comments from the public on possible enhancements to the existing requirements related to the collection of antimicrobial drug sales and distribution data and on alternative methods for monitoring antimicrobial use in food-producing animals. Based on an in-depth analysis of the submissions from a wide range of stakeholders, FDA developed enhancements to the annual Summary Report on Antimicrobial Sales and Distribution for Use in Food Producing Animals and on September 26, 2013 published another Federal Register Notice seeking additional public comment on proposed additional data tables. Also, based on input from the 2012 ANPRM, FDA is developing regulations to enhance the collection of antimicrobial sales data. Further, FDA is collaborating with its NARMS partners at CDC and USDA – including the Agricultural Research Service – to develop approaches to collecting data on antibiotic use in food-producing animals that can be used to assess the effectiveness of policies to curb antibiotic resistance. FDA intends to seek stakeholder and broad public input while developing these approaches.

Item 21 - Seafood Advisory

FDA must publish a final seafood advisory in conjunction with all applicable parties as directed in House Report 112–101 and Senate Report 112–73. The advisory must be consistent with USDA's dietary guidelines and be completed and available to the public by June 30, 2013.

FDA Response
Updating the 2004 fish consumption advice in keeping with the latest science remains a priority for FDA. FDA looks forward to issuing the advice as a draft along with its quantitative assessment of the net effects of fish consumption during pregnancy and then engaging the public on this matter. In addition to a public comment period on the draft advice, the agency is contemplating at least one public meeting and a consultation with the FDA Advisory Committee on Risk Communication. FDA hopes that these important documents publish in the near future.

Item 22 - User Fees

The Committee is concerned about subjecting FDA user fees to sequestration as these fees are not normal tax revenue. It is important to maintain the integrity and industry support for user fee programs. The Committee encourages FDA to reevaluate its calculations of sequestration in regard to user fees.

FDA Response
FDA's calculation of sequestration represents the Administration's current legal understanding of the Balanced Budget and Emergency Deficit Control Act of 1985 relative to implementing sequestration.

The FY 2014 appropriation restores $124 million in budget authority to FDA lost due to the FY 2013 sequestration and rescission cuts. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

Item 23 - Statutory Deadlines

The Committee is aware the Administration continues to miss statutory deadlines for rulemaking to implement Public Law 111–353. The Committee expects the Administration to meet the statutory timelines for implementing Public Law 111–353 and directs FDA to provide a report every 180 days detailing the reasons and justification for any proposed rule or final regulation being 120 days or more beyond its statutory deadline.

FDA Response
FDA will provide the report that the Committee requested.

Item 24 - Mammography Quality

The Committee urges FDA to follow up the November 2011 meeting of the National Mammography Quality Assurance Advisory Committee by promptly reviewing the evidence supporting including information related to an individual's breast density in the mammogram patient report and physician report.

FDA Response
FDA has drafted regulation amendments under internal review that it believes will address the breast density reporting issue. FDA plans to publish these amendments in 2014.

Item 25 - Canned Tuna

The Committee directs FDA to revise the standard of identity for canned tuna to adopt the drained weight fill of container standard as requested in the 1994 ''Citizens Petition to Amend Canned Tuna Standard of Identity, 21 CFR 161.190, Docket No. FDA–2011–P–0763.'' According to the Congressional Research Service, the United States is the only country that uses the pressed cake weight fill of container standard that requires outdated 1950s technology. CODEX, the Association of Official Analytical Chemists, and all other countries use the drained weight fill of container. FDA shall revise the standard of identity for canned tuna to replace the pressed cake weight method with the drained weight method by December 31, 2013. FDA shall approve temporary marketing permits that adopt the drained weight method consistent with international standards until such time as final regulations are published updating the standard of identity for canned tuna.

FDA Response
FDA has granted one TMP for canned tuna to deviate from the standard of identity for a fill of container based on a drained weight method rather than a pressed cake method as required by the standard. One purpose of this TMP is to allow the applicant time to measure consumer acceptance of the product and assess the product's commercial feasibility. FDA is concerned that industry will need time to market test the product in order to gather information in support of changing the canned tuna standard. The TMP application process gives the applicant 15 months to market test the product once the TMP is granted. If the applicant needs more time to market test the product in order to gather more data, the applicant submits a request to extend the TMP and at that time petitions the agency to amend the standard. The test market will not be completed by December 31, 2013. The applicant should be given time to complete the test market and confirm the feasibility and particulars of any amendments to the standard of identity for canned tuna before FDA initiates rulemaking to amend the standard of identity. FDA worked continuously with the TMP applicant over the last several years to assist it in completing the TMP application and will continue to work with them throughout the test market process.

Item 26 - Impact on Small Businesses

The Committee is concerned by unintended consequences of the Generic Drug User Fee Act (GDUFA) fee structure. While the Committee understands that user fees provide the resources to facilitate generic drug approvals, the Committee believes FDA should study the impact of smaller generic manufacturers' ability to pay at the same level as large manufacturers. The Committee directs FDA to provide a report to the Committees on Appropriations on the impact of the GDUFA fee structure on smaller generic drug manufacturers within 180 days of enactment of this Act.

FDA Response
FDA understands that additional financial obligations represent differing relative costs to industry participants – and may be absorbed more easily by larger entities. FDA also shares the Committee's commitment to balance any potential changes to the GDUFA fee structure with overall industry support for the nascent Generic Drug User Fee Program.

Industry and FDA GDUFA negotiators sought to keep fees low by spreading the costs of the entire GDUFA program over a large fee-paying base of all manufacturers to reduce administrative costs and complexity. Both Congress and GDUFA negotiators specifically considered the issue of a fee waiver or reduction mechanism and decided not to include either.

FDA looks forward to considering changes to the fee structure, and other issues, during the next round of generic drug user fee negotiations and hopes to have a better sense of the impact of user fees on industry participants. FDA will again invite industry trade associations to participate in negotiations and hold open public meetings – and it encourages all interested stakeholders to provide input.

Item 27 - Abuse-Deterrent Drugs

The Committee supports FDA's recent efforts to ensure that certain opioids are kept off the market and commends the agency for removal of those products for reasons of safety or effectiveness. The Committee understands that FDA established draft guidance in January 2013 entitled Evaluation and Labeling of Abuse-Deterrent Opioids, and encourages the agency to move expediently to finalize such guidance.

FDA Response
Prescription opioid analgesics are an important component of modern pain management. Abuse and misuse of these products, however, have created a serious and growing public health problem. FDA shares the Committee's commitment to address this problem while ensuring that patients in pain have appropriate access to opioid analgesics.

The science of abuse deterrence is relatively new, and both the formulation of technologies and the analytical, clinical, and statistical methods for evaluating those technologies are rapidly evolving. The draft guidance referenced above is designed to facilitate development of potentially abuse-deterrent formulations (ADFs) by outlining a flexible, adaptive regulatory approach to evaluation and labeling of these products. FDA recently participated in a scientific meeting to hear comments about issues pertaining to the ADF guidance. FDA intends to finalize the guidance as soon as possible.

In addition, FDA is directly supporting research into ADFs internally at FDA labs and externally at scientific research institutions and working with manufacturers as they develop new ways to prevent misuse and abuse.

Item 28 - Artificial Pancreas

The Committee applauds FDA for its final guidance for artificial pancreas device systems, released in November 2012, which provides clear and reasonable guidance for research and premarket review of such systems, which could transform the lives of those living with type 1 diabetes. The Committee urges FDA to ensure that the flexible, science-based approach reflected in its guidance is implemented consistently in

the IDE and PMA review process to ensure that safety and effectiveness of innovative systems can be tested without delay and improved devices can become available to those with type 1 diabetes in the near future.

FDA Response
FDA believes that the development of an Artificial Pancreas (AP) is within technological reach and has assigned significant resources to facilitate such development. At the beginning of 2012, FDA streamlined the applicable review structure. This move has resulted in quicker turnaround times in the review of investigational protocols and in review of premarket submissions. To date, the group has reviewed more than 50 investigational protocols within its 30 day goal, without a single disapproval. Among those, FDA has approved several outpatient studies in adults and a diabetes camp study in children.

FDA co-sponsored a public workshop with the National Institutes of Health -NIH- and Juvenile Diabetes Research Foundation (JDRF) in March of 2013. The workshop initiated a multidisciplinary discussion which will help to accelerate the development and delivery of an AP. FDA continues to pursue outreach efforts with investors, researchers, clinicians, policymakers, manufacturers and patient advocates to help clarify expectations, and help solve challenges as they arise. FDA looks forward to working together with the diabetes community to advance quickly towards an approved AP.

Item 29 - Compounding of Sterile Injectable Prescription Drugs

The Committee urges the Food and Drug Administration to use its existing authority to closely inspect and supervise large-scale compounding and repackaging of sterile injectable drugs and biological products, especially those administered into areas where there is tempered immunity.

FDA Response
FDA is using its existing authorities and in coordination with State officials, is conducting proactive, risk-based inspections of compounding pharmacies that are known to have produced sterile drugs, as well as inspections in response to a State's request for assistance or when it receives complaints or reports of significant adverse events. FDA is inspecting firms and prioritizing potential compliance or enforcement actions based on risk. Since October 2012, FDA has inspected over 80 firms, over 35 firms have conducted recalls, five warning letters have issued, one firm signed a consent decree of permanent injunction, and other regulatory actions are under consideration.

Further, the Drug Quality and Security Act (DQSA) creates a new Section 503B in the FDCA. Under Section 503B, a compounder can become an "outsourcing facility" and will be able to qualify for exemptions from the FDA approval requirements and certain labeling requirements. Outsourcing facilities are subject to current good manufacturing practices (CGMP) requirements, will be inspected by FDA according to a risk-based schedule, and must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

FDA plans to inspect newly registered outsourcing facilities after initial registration, if the facility has not been recently inspected. Subsequent inspections will depend on the findings from the first inspection and other factors including, but not limited to: the compliance history of the outsourcing facility; the record, history, and nature of any recalls linked to the outsourcing facility; the inherent risk of the drugs compounded at the outsourcing facility; the inspection frequency and whether the outsourcing facility has been inspected within the last four years; and whether the outsourcing facility has registered as an entity that intends to compound drugs in shortage.

Item 30 - Food Additive Petition

The Committee understands that a Food Additive Petition has been submitted to the agency regarding the fortification of corn masa flour with folic acid to prevent neural tube defects such as spina bifida. The Committee encourages the agency to consider this petition expeditiously and, if further data or

information is needed from the petitioners, to request it in a timely fashion to ensure that the petition is not unduly delayed.

FDA Response
Following receipt of the petition to allow the addition of folic acid to corn masa flour, the Agency began its review and published a notice of filing in the Federal Register of June 13, 2012 (77 FR 35317). With any petition attempting to demonstrate the safety of a food additive, it is common for there to be important safety questions not addressed in the material initially submitted. FDA identified deficiencies in the folic acid petition during its review, which was communicated to the petitioners. All of FDA's questions on unresolved issues have been forwarded to the petitioners, and FDA is currently waiting for their full response. FDA will continue to work as expeditiously as possible to complete action on this petition and reach a fair and scientifically sound decision on it.

Item 31 - Pediatric Device Consortia Program

The Committee is pleased with the success of the Pediatric Device Consortia Grant Program, authorized under Section 305 of Public Law 110–85. The program funds consortia to assist innovators in developing medical and surgical devices designed for the unique needs of children, needs that often go unmet by devices available on the market. The consortia funded by this program have assisted in the development of over 219 pediatric device ideas since its inception. The Committee urges the FDA's continued support of this important program.

FDA Response
FDA has and will continue to support this important program. The consortia funded by this program have assisted in the evaluation and/ or development of over 252 potential pediatric devices since the program's inception. One hundred and fifteen of these proposed devices continue to receive input from the consortia as active projects.

SENATE APPROPRIATIONS COMMITTEE SIGNIFICANT ITEMS

FY 2014 SENATE REPORT 113-000

Dated June 2013

Item 1- Antimicrobial Drugs

The Commissioner is directed to develop enhancements to FDA's annual summary of data reported under Section 105 of the Animal Drug User Fee Act. To the extent possible, enhanced summaries should include information about the weight of antimicrobial active ingredient sold, categorized by medical importance, dosage form, marketing status, and target animals, and may include other cross-tabulations.

FDA Action
On September 26, 2013, CVM published a Federal Register Notice (78 FR 59308) seeking public input on proposed additional tables to include in FDA's annual summary report on antimicrobials sold or distributed for use in food-producing animals. These additional tables included categorization of active ingredient sold by medical importance, dosage form, marketing status, and indication. The comment period for this Federal Register Notice closed on November 25, 2013; CVM is analyzing comments and is planning on incorporating the proposed tables into its next report on the 2012 sales and distribution data.

Item 2 - Artificial Pancreas

The Committee applauds FDA for its final guidance for artificial pancreas device systems, released in November 2012, which provides clear and reasonable guidance for research and premarket reviews of such systems, which could transform the lives of those living with type one diabetes. The Committee urges FDA to ensure that the flexible, science-based approach reflected in its guidance is implemented consistently in the Investigational Device Exemption and Premarket Approval review process and to ensure that safety and effectiveness of innovative systems can be tested without delay and improved devices can become available to those with type one diabetes in the near future.

FDA Action
FDA believes that the development of an Artificial Pancreas (AP) is within technological reach and has assigned significant resources to facilitate such development. At the beginning of 2012, FDA streamlined the applicable review structure. This move has resulted in quicker turnaround times in the review of investigational protocols and in review of premarket submissions. To date, the group has reviewed more than 50 investigational protocols within its 30 day goal, without a single disapproval. Among those, FDA has approved several outpatient studies in adults and a diabetes camp study in children.

FDA co-sponsored a public workshop with the National Institutes of Health -NIH- and Juvenile Diabetes Research Foundation (JDRF) in March of 2013. The workshop initiated a multidisciplinary discussion which will help to accelerate the development and delivery of an AP. FDA continues to pursue outreach efforts with investors, researchers, clinicians, policymakers, manufacturers and patient advocates to help clarify expectations, and help solve challenges as they arise. FDA looks forward to working together with the diabetes community to advance quickly towards an approved AP.

Item 3 - Dietary Supplements

The Committee is aware that U.S. consumers widely use plant-derived dietary supplements, and that FDA inspects manufacturers and distributors that are responsible for ensuring that such products are not adulterated or contaminated, and do no cause harm to the consumer. The Committee believes that methods and standards are needed to verify source plants and ingredients and to detect toxic contaminants. The Committee encourages FDA to develop guidance for industry on such methods and standards, which would enhance FDA's ability to inspect and assess industry practices for manufacturing botanical dietary supplements.

FDA Action
FDA's Center of Excellence at the University of Mississippi is conducting extensive work on methodologies for identification of botanicals. The Center's work in this area will inform FDA's next steps.

Item 4 - Drug Shortages

By Executive Order, the President has instructed FDA to broaden its reporting of potential shortages and speed reviews of applications to begin or alter production of drugs in short supply. As part of this enhanced activity, the Committee encourages FDA to increase its communication with medical practitioners through specialty-specific list-serves and other means of targeted communications to provide information on potential shortages, the anticipated length time of the shortage, and options for obtaining therapies while drugs are in short supply.

Additionally, the Committee directs the Food and Drug Administration [FDA] to continue the work of the FDA intra-agency Task Force to address drug shortages. The Task Force should continue to seek input from other government agencies and external stakeholders, including pediatric and other specialists, whenever necessary to more fully analyze the sources and potential responses to drugs shortages.

Further, the Committee directs the Food and Drug Administration to continue to consult with the Secretary of HHS and other relevant agencies, including international regulatory agencies, about drug shortages. Important aspects of these discussions should include the steps international regulatory counterparts can take to mitigate or prevent such shortages, and relevant differences in regulations between those countries and the United States, and how those differences may impact shortages.

FDA Action
Assuring that patients who are in need have access to critical and life-saving drugs is central to FDA's mission – and a top priority. While significant progress has been made recently, drug shortages continue to impact many patients in need of critical treatment.

FDA has expanded the drug shortage program to 11 full time staff dedicated to coordination efforts for prevention and mitigation of shortages. FDA prevented over 170 shortages in FY 2013. FDA prevented these shortages through working with firms on specific quality problems as well as through expedited reviews, asking other manufacturers to increase production, and also through temporary availability from alternate sources.

FDA has further expanded its program to include additional experts from throughout the Agency and now has a highly skilled team that can be called upon for specific shortage issues including manufacturing experts, chemists, microbiologists, pharmacologists and clinicians including pediatric experts and other disciplines needed to help resolve and prevent specific issues. Furthermore, FDA has enhanced intra-Agency communications with the field staff (investigators) as well as its Office of Compliance regarding any issues that are potentially impacting supply at the manufacturers. In addition, FDA is in regular, if not daily, contact with various stakeholder groups, regarding products in shortage and drug shortage issues.

Drug shortages are not unique to FDA or the U.S., but a global problem. FDA works closely with other regulatory authorities (European Medicines Agency, Therapeutic Goods Administration, Medicines and Healthcare Products Regulatory Agency, and Health Canada) on existing drug shortage problems. During these discussions, under shared confidentiality agreements, crucial information regarding the availability of important drug products and potential alternate facilities is shared. Additionally, when a shortage is triggered by quality problems or manufacturing constraints to limited production capacity, FDA and other regulatory authorities exchange information regarding the quality issues identified or leading to the drug shortage, and communicate when necessary, with the company to explore options that will ensure the availability of drug products, while also ensuring that the drug is safe and effective.

Item 5 - Energy Drinks

The Committee is aware that FDA has declared an intent to review any risks associated with consumption of energy drinks. The Committee expects FDA to conclude the review and report findings to the Senate Committee on Appropriations as soon as practicable.

FDA Action
FDA will provide the report that the Committee requested.

Item 6 - Food Traceability

The Committee directs the Commissioner, in consultation with the Secretary of Agriculture, to create a science-based international food traceability initiative through a public-private partnership model. The initiative should include public and private sector stakeholders from the food industry, government, academia, solution providers, and consumer groups.

FDA Action
FDA will provide the Committee an update on this initiative as it is developed.

Item 7 - Global Health

The Committee encourages FDA, as resources allow, to expand its capacity building programs abroad to help build strong regulatory authorities in other nations, including regulators, industry, and other relevant stakeholders to support the development of safe and effective global health tools.

FDA Action
FDA recognizes that to meet its domestic mandate in the context of globalization of supply chains, stronger regulatory systems are needed globally. FDA raises awareness with multilateral organizations and development organizations of the need for greater investments in regulatory systems and to identify effective approaches to strengthening regulatory systems based on sound assessments of regulatory functions. FDA provides technical expertise on good regulatory practices, and supports the development of global information sharing platforms related to safety surveillance and regulatory cooperation. FDA supports and advises regional and sub-regional approaches to harmonization, and has spearheaded an effort to develop a global regulatory curriculum. In the area of scientific capacity, and in conjunction with the NCTR-initiated annual Global Summits on Regulatory Science, NCTR has led the development of the Global Coalition of Regulatory Research Scientists (Coalition). The Coalition was formed in 2013 to work collaboratively to build knowledge, promote the development of regulatory science, and discover novel ways to clearly define research needs that would strengthen product safety around the world. The Coalition, thus far, has representatives from eight countries and consists of invited leaders from National Regulatory Authorities. Additionally, an Executive Committee has been formed and held its first official meeting.

Item 8 - Global Health

The Committee is aware that Chagas disease is not on the list of neglected diseases as defined by FDA. The Committee encourages FDA to make the necessary modifications to include Chagas disease in its list of neglected diseases.

FDA Action
FDA is in the process of drafting a proposed rule to add to the list of tropical diseases in section 524 of the FD&C Act, and Chagas disease is being considered in this rulemaking. FDA strives to keep its review staff current on topic areas in infectious diseases, including neglected tropical diseases.

CDER has offered a Forum for International Drug Regulatory Authorities every spring and fall since 2005. The CDER forum was established for the exchange of drug regulatory information between review staff in FDA's Center for Drug Evaluation and Research and its counterpart agencies in other countries. It is a 5 day program and provides information about the U.S. drug regulatory processes in an organized and integrated manner. To date there have been 16 CDER Forums with over 600 drug regulatory authorities from more than 70 countries participating.

Item 9 - Honey Labeling and Production Standards

The Committee recognizes that honey is produced in the United States, traded internally and consumed as both a packaged food and as a food ingredient. However, there have been instances where manufacturers have been marketing products illegally as ''honey'' or ''pure honey'' that contained other ingredients. The Committee believes that guidance about the composition and labeling of honey is needed to protect consumers from misbranded honey and honey-derived products that are entering the U.S. market and to remind manufacturers of honey about the misbranding and adulteration provisions of the Federal Food, Drug and Cosmetic Act. Further, the Committee directs FDA to expedite the publication of the draft guidance for industry on the proper labeling of honey and honey products.

FDA Response
FDA understands the concerns presented by the Committee and is working on drafting the guidance on honey. FDA will provide an update to the Committee when the draft guidance is ready to be published.

Item 10 – Hydrocodone

The Committee strongly encourages the Food and Drug Administration to act without delay to complete their scientific and medical evaluation of a 14-year-old petition to reschedule hydrocodone combination products from Schedule III to Schedule II of the Controlled Substances Act.

FDA Response:
As the abuse and misuse of opioid products has sadly reached epidemic levels in certain areas of this country, FDA has become increasingly concerned about how to balance continued access to patients who rely on ongoing pain relief with appropriate safeguards.

In October, FDA announced its intent to recommend that hydrocodone combination products be reclassified as a more restrictive Schedule II drug. This determination was based on a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which FDA received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

In December, the Department of Health and Human Services concurred with the Agency's recommendation and notified the Drug Enforcement Agency (DEA). DEA will make a final decision on the appropriate scheduling of hydrocodone products.

Going forward, FDA will continue working with professional organizations, consumer and patient groups, and industry to ensure that prescriber and patient education tools are readily available so that these products are properly prescribed and appropriately used by the patients who need them most.

Item 11a - Nanotechnology

The Committee recognizes that FDA possesses the facilities and expertise to study nanotechnology at the National Center for Toxicological Research [NCTR] and its consolidated headquarters at White Oak. The Nanotechnology Regulatory Science Program was established within the Food and Drug Administration Safety and Innovation Act (Public Law 112–144). The Committee directs FDA to carry out the activities described in Section 1126 of Public Law 112–144 to address issues relevant to the regulation of nano-enabled products, including the potential toxicology of such nanomaterials, the potential benefit of new

therapies derived from nanotechnology, the effects of such nanomaterials on biological systems and the interaction of such nanomaterials with biological systems, at these facilities.

FDA Response
FDA has strengthened its regulatory capability for Nanotechnology Regulatory Science by using Congressionally appropriated funding in three Agency-wide areas of effort: (1) Staff knowledge and expertise in nanotechnology has increased with increasing hires of staff with formal nanotechnology-based training, staff have received education and exposure at local, regional and national scientific symposia, and the Agency has an internal "hands on" training program where FDA staff receive training from nanotechnology experts with laboratory experience (since 2011). (2) The Agency has developed core infrastructure with equipment and expertise to provide FDA regulatory scientists with experience, support, and knowledge in nanotechnology. This is clearly demonstrated at FDA's Jefferson Laboratory Campus which is fully operational, supporting FDA research and toxicology projects since 2010, and the White Oak Campus facility which is operational since 2012. (3) Agency scientists continue to collaboration on research projects addressing nanomaterial safety issues key to the FDA's needs.

Item 11b – Nanotechnology

Additionally, the Committee encourages FDA to support collaborative research with universities and industry on the toxicology of nanotechnology products and processes in accordance with the National Nanotechnology Initiative Environment, Health and Safety Research Strategy as updated in October 2011, including ensuring appropriate technology is available to facilitate this research.

FDA Response
The FDA CORES program was established in 2011 and includes other US government agencies within the National Nanotechnology Initiative (NNI) and academic institutions. Investments to date have provided a sound base for FDA policy and decision making. With continued investments, FDA will build upon the base that has been established for Nanotechnology Regulatory Science. This investment will ensure that the FDA's role in maintaining public safety regarding nanomaterial products by providing FDA with the tools to accomplish this goal. The continued support will further enhance the FDA mission to (i) provide additional understanding on the extent of toxicity of specific nanomaterials, (ii) develop procedures to detect and characterize nanomaterials, and (iii) address the challenge to FDA of detection and quantification of nanomaterials in complex matrices.

Item 11c – Nanotechnology

In connection with the expenditure of funds to upgrade the facilities at NCTR, FDA is directed to permit NCTR to enter into agreements with adjacent facilities for connection to its utilities and infrastructure at its NCTR facility such as gas, electrical, potable water, waste, and sewage as necessary; use or expansion of FDA's infrastructure, including secure access, roadways, or parking as necessary; and FDA is directed to provide utility easements as necessary.

FDA Response
This arrangement will provide NCTR the ability to expand partnerships within the State of Arkansas. Specifically, it will allow NCTR to partner with the Economic Development Alliance for Jefferson County, Bioplex Technology Center (BTC) and provide scientific mentorship and technical assistance and advice on lab specification, design, layout and equipment needs, infrastructure, and utilities. The success of the BTC will provide opportunity for federal, state, and local governments, academia, and industry to develop collaboration vehicles to share research, knowledge, equipment, and facilities to:

- share technology
- facilitate research and innovation
- foster technology transfer
- improve educational resources

- enhance regulatory science thorough the FDA's and AR state's global collaboration.

The BTC partnership has potential to impact public health through promoting innovation in the biomedical sciences.

Item 12 - National Agriculture and Food Defense Strategy

The Committee remains concerned over the safety of our nation's food supply and recognizes the importance of revising and updating the National Agriculture and Food Defense Strategy Plan. To that end, FDA is encouraged to fund research that would develop in-field tools that can provide differential detection and accurate identification tests, including those applicable to seafood, which will assist in advancing food safety efforts and help provide a more secure food supply chain.

FDA Response
The latest draft of the proposed Coordinated Research Agenda (CRA), as part of the National Agriculture and Food Defense Strategy (NAFDS - Section 108 of Public Law 111–353), documents ongoing research projects (or activities) that would provide portable and technologically advanced testing platforms (modular and expandable detection platform for adulterants; detection system for detection of Bio-threat agents in food; and, evaluation of chemical hazards screening methods) needed to effectively enhance monitoring and protecting against intentional adulteration. FDA will continue to review advancements in research and technology, and work with state and government agencies in the development of in-field tools that can promote and assist in food safety efforts, including those applicable and specific to seafood.

Item 13a - Office of Cosmetics and Colors

The Committee provides not less than $11,700,000 for cosmetics activities, including not less than $7,200,000 for the Office of Colors and Cosmetics [OCAC]. Funding provided for OCAC is for direct support of the operation, staffing, compliance, research, and international activities performed by this office. The Committee further directs the Office of Colors and Cosmetics to respond by March 7, 2014, to a citizen petition setting safety levels for trace amounts of lead in cosmetics. Additionally, the Committee understands China has become the source of an increasing number of cosmetic products and ingredients being marketed to U.S. consumers.

FDA Response
The Office of Cosmetics and Colors (OCAC) will use FY 2014 funding for direct support of the operation, staffing, compliance, research, and international activities performed by this office. Although the data available to FDA do not suggest that the amount of lead in lipstick or other cosmetic products is a significant public health issue, FDA sponsored additional studies to address data gaps. FDA is evaluating data from these studies and other information regarding trace amounts of lead in cosmetic products to develop a full response to the citizen petition.

OCAC has established a collaborative relationship with China regulators on cosmetic safety issues and continues to maintain an interactive dialogue.

Item 13b - Office of Cosmetics and Colors

In light of China's importance to U.S.- based manufacturers and consumers, the Committee recommends FDA establish a bilateral technical dialogue with Chinese regulators on cosmetic safety issues.

FDA Response
FDA has established a collaborative relationship with China regulators on cosmetic safety issues and continues to maintain an interactive dialogue.

Item 14 - Pediatric Device Grants

The Committee is pleased with the success of the Pediatric Device Consortia Grant Program, authorized under section 620 of the Food and Drug Administration Safety and Innovation Act of 2012 (Public Law

112–144). The program funds consortia to assist innovators in developing medical and surgical devices designed for the unique needs of children, needs that often go unmet by devices available on the market. The consortia funded by this program have assisted in the development of over 227 pediatric device ideas since its inception in 2009. The Committee urges the FDA's continued support of this important program, as the development of children's medical devices continues to lag those manufactured for adults by several years.

FDA Response
FDA has and will continue to support this important program. The consortia funded by this program have assisted in the evaluation and/ or development of over 252 potential pediatric devices since the program's inception. One hundred and fifteen of these proposed devices continue to receive input from the consortia as active projects.

Item 15 - Seafood Advisory

The Committee is concerned that despite repeated direction from Congress over the past several years, the FDA 2004 seafood advisory still has not been updated and made available to the public. The Committee understands that the advisory is now undergoing further intra-departmental review. It has been well over 2 years since HHS and USDA jointly released new dietary guidelines that communicated the nutritional benefits of healthy seafood consumption for pregnant women and mothers of young children. Commitments from the Secretary of the Department of Health and Human Services and the FDA Commissioner that the revised seafood advisory would be completed in 2011 and 2012 have been missed. As a result, pregnant women are presented with conflicting advice between the 2004 seafood advisory and the 2010 dietary guidelines. The Committee directs the Commissioner and Secretary to personally engage to resolve all pending issues and authorize FDA to issue its seafood advice to pregnant women consistent with the latest science as soon as possible thereafter.

FDA Response
Updating the 2004 fish consumption advice in keeping with the latest science remains a priority for FDA. FDA looks forward to issuing the advice as a draft along with its quantitative assessment of the net effects of fish consumption during pregnancy and then engaging the public on this matter. In addition to a public comment period on the draft advice, the agency is contemplating at least one public meeting and a consultation with the FDA Advisory Committee on Risk Communication. FDA hopes that these important documents publish in the near future.

Item 16 - Seafood Economic Integrity

The Committee recognizes the importance of seafood to a healthy diet, but is concerned that FDA does not focus sufficient attention on economic integrity issues, particularly with respect to mislabeling of species, weights, and treatment. The Committee encourages FDA to work with sates and the Department of Commerce to more aggressively combat fraud in parts of the seafood industry.

FDA Response
FDA continues to invest in significant technical improvements to enhance its ability to identify seafood species using DNA sequencing. DNA sequencing capabilities greatly improve the Agency's ability to identify misbranded seafood products in interstate commerce. FDA continues to expand its capacity for DNA sequencing to regional field laboratories and trains analysts from United States Customs and Border Protection and NOAA Fisheries in its new DNA-based species identification methodology. FDA implements better-targeted and more efficient sampling strategies to identify seafood misbranding and adulteration.

Item 17 - Sodium

In 2011, FDA and USDA's Food Safety and Inspection Service [FSIS] issued a Federal Register notice requesting comments, research, data, and other information to better inform both Agencies about current

and emerging practices by the private sector regarding sodium consumption practices; motivation and barriers in reducing sodium in consumers' food intakes; and issues associated with the development of targets for sodium reduction in foods to promote reduction in excess sodium intake. The Committee directs that FDA, in coordination with FSIS, submit an analysis of the significance of the 2013 Institutes of Medicine [IOM] report on ''Sodium Intake in Populations'' for broad, gradual sodium reduction efforts, within 120 days.

FDA Response
FDA will submit an analysis of the significance of this report within 120 days, and will communicate with FSIS during the preparation of this analysis.

Item 18 - Sunscreen Labeling

The Committee is pleased that FDA finalized regulations establishing labeling and testing requirements for products marketed under FDA's monograph for over-the-counter sunscreen drug products. The Committee directs FDA to work expeditiously to evaluate the data and information, including proposed testing protocols, submitted in response to its proposed rule to limit the maximum Sun Protection Factor [SPF] to ''50'' or ''50+''. Additionally, the Committee encourages FDA to issue a proposed rule to establish appropriate conditions of use for various formulations of over-the-counter sunscreen drug products, including spray formulations.

FDA Response
FDA's goal is to respond to applicants of all pending sunscreen TEAs by June 1, 2014. The Agency is also working with Members and Congressional staff to discuss improved pathways for bringing new sunscreens to market and providing Technical Assistance on proposed legislation. Furthermore, FDA plans to hold a public meeting in the spring of 2014 to discuss the safety and standards for sunscreen products. The public meeting discussion will assist FDA in the ongoing development of a Guidance for Industry on the scientific data requirements for sunscreens.

While diligently working on applications and issues related to sunscreens, FDA is simultaneously evaluating the current Over-the-Counter (OTC) Monograph Process. Recognizing the challenges and the changed environment from when the current process was initially adopted, FDA has been discussing alternate pathways for all ingredients, including sunscreens, marketed under the OTC monograph system. FDA plans to hold an additional public meeting in the spring of 2014 to obtain input on how to improve the OTC Monograph Process and discuss the feasibility of other alternative pathways.

Item 19 - Trade Facilitation and Interagency Cooperation

The FDA Safety and Innovation Act provided FDA several new tools to meet the challenges of globalization. Section 713 of the Act allows FDA to require, as a condition of granting admission to a drug imported or offered for import into the United States, that an importer electronically submit information demonstrating that the drug complies with applicable requirements of the Federal Food, Drug, and Cosmetic Act. Section 713 of the Act also authorizes FDA to establish a partnership program for highly compliant importers. Such a program would enable FDA to know more about highly compliant drug importers, incentivize greater compliance with FDA regulations, and facilitate entry of low risk products. The Committee strongly encourages FDA to expeditiously implement section 713 and to keep the Committee advised on its efforts and progress in this regard.

FDA Response
The additional authorities provided in FDASIA are vital to enhance the safety of the global supply chain. In July, 2013, FDA held a public meeting to discuss how the Agency will implement certain sections of FDASIA to protect the drug supply chain, including Section 713. The public meeting provided important input from stakeholders to inform the Agency's development of regulations. FDA also opened a public docket on Section 713 and has reviewed written comments submitted by stakeholders.

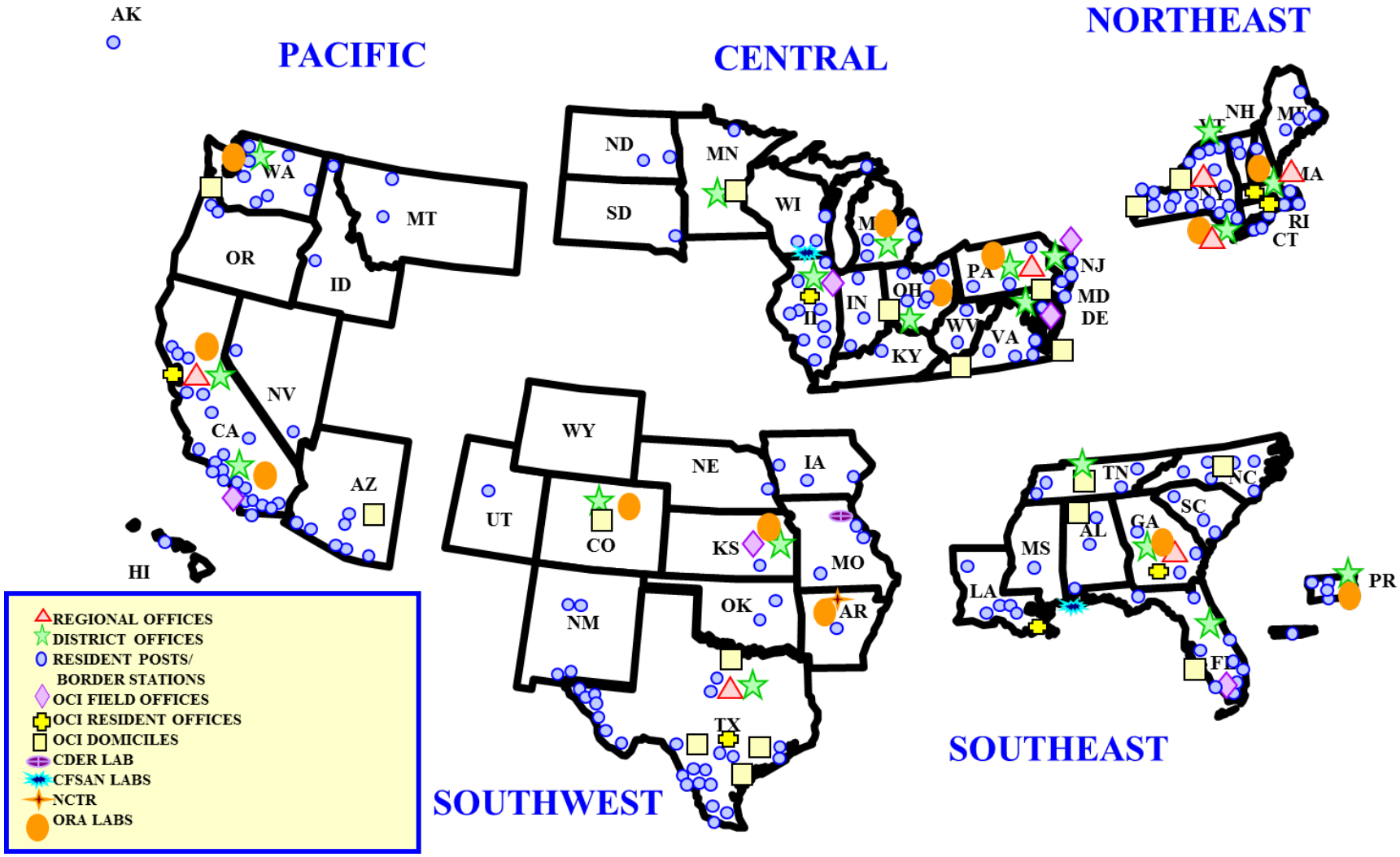
As you know, Section 713 grants FDA discretion to consider differences among importers and types of imports, and based on the risk level posed by the imported drug, provide for expedited clearance for importers that volunteer to participate in partnership programs for highly compliant companies. On August 20, 2013, FDA published a Federal Register notice announcing the launch of the Secure Supply Chain Pilot Program (SSCPP) which will enable qualified firms to expedite the importation of active pharmaceutical ingredients and finished drug products into the United States. The program's goal is to enable FDA to focus its imports surveillance resources on preventing the entry of high-risk drugs that are the most likely to compromise the quality and safety of the U.S. drug supply. Industry stakeholders have provided positive feedback and shown great interest in the SSCPP. FDA has received roughly 15 applications for Active Pharmaceutical Ingredients and, in total, FDA has received about 70 applications to participate in the pilot program. FDA plans to begin the two-year pilot in February 2014. Conducting and evaluating the pilot will allow FDA to assess the feasibility of developing the types of voluntary partnership programs described in Section 713.

Item 20 - User Fees

The Committee is aware that FDA user fee programs have been subjected to sequester, and is concerned because these user fees are not normal tax revenue. The Committee believes that it is important to maintain industry support for user fee programs, and for FDA to continue to meet negotiated performance standards. Therefore, the Committee encourages the Administration to reconsider the inclusion of FDA user fees when calculating sequester.

FDA Response
FDA's calculation of sequestration represents the Administration's current legal understanding of the Balanced Budget and Emergency Deficit Control Act of 1985 relative to implementing sequestration. Section 747 of the FY 2014 appropriation also includes funding for the FY 2013 sequestered user fees.

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES



HIV/AIDS FUNCTIONAL TABLE

Program	FY 2011 Actual	FY 2012 Actual	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Human Drugs	$36,572	$32,243	$31,658	$31,658	$31,658
Biologics	33,189	34,122	32,852	32,852	32,852
Medical Devices	1,697	1,721	1,088	1,088	1,088
Field Activity	38,586	37,720	37,887	37,887	37,887
Toxological	132	---	---	---	---
Other Activities	3,469	3,476	3,410	3,410	3,410
Total HIV/AIDS	**$113,645**	**$109,282**	**$106,895**	**$106,895**	**$106,895**

CROSSCUTTING INFORMATION

(dollars in thousands)	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Antimicrobial Resistance	**25,937**	**28,330**	**28,559**
Budget Authority (non-add)	*24,262*	*26,466*	*26,642*
Biosimilars	**28,041**	**41,268**	**41,990**
Budget Authority (non-add)	*28,041*	*20,552*	*20,976*
Bioterrorism	**224,460**	**242,118**	**242,118**
Food Defense (non-add)	217,489	217,489	217,489
Medical Countermeasures Initiative (MCMi) (non-add)	*21,779*	*24,552*	*24,504*
Physical Security (non-add)	6,971	6,971	6,971
Life Sciences-Biodefense Complex (non-add)	---	17,658	17,658
Blood Safety	**115,309**	**126,179**	**127,258**
Budget Authority (non-add)	*84,416*	*90,008*	*89,413*
Dietary Supplements	**28,397**	**29,140**	**28,247**
Budget Authority (non-add)	*28,397*	*29,140*	*28,247*
Drug Marketing, Advertising, and Communication Activities	**16,371**	**16,953**	**17,127**
Budget Authority (non-add)	*8,618*	*8,891*	*8,895*
Drug Safety	**1,026,530**	**1,189,661**	**1,227,937**
Budget Authority (non-add)	*521,858*	*546,378*	*559,981*
Pre-market Drug Review (non-add)	*932,789*	*1,094,259*	*1,116,664*
Office of Surveillance & Epidemiology (non-add)	*23,232*	*24,618*	*24,618*
Pre-market	618,077	724,305	739,292
Post-market	408,453	465,356	488,645
Food Labeling	**11,228**	**11,287**	**11,314**
Budget Authority (non-add)	*11,228*	*11,287*	*11,314*
Food Safety	**1,134,212**	**1,217,676**	**1,481,071**
Food Defense (non-add)	*217,489*	*217,489*	*217,489*
Budget Authority (non-add)	*1,106,050*	*1,188,117*	*1,211,761*
Human Generic Drugs Program	**329,001**	**446,533**	**452,999**
Budget Authority (non-add)	*143,482*	*143,482*	*143,482*
Immunization	**24,651**	**27,574**	**27,992**
Budget Authority (non-add)	*15,393*	*16,541*	*16,472*
Medical Device Surveillance	**23,728**	**24,114**	**23,740**
Budget Authority (non-add)	*18,159*	*18,539*	*18,158*
Over-the-Counter Drugs	**11,406**	**12,376**	**12,482**
Budget Authority (non-add)	*5,425*	*6,207*	*6,181*
Pandemic Influenza	**32,109**	**33,304**	**32,972**
Budget Authority (non-add)	*27,020*	*28,190*	*27,840*
Tissues	**16,330**	**16,775**	**16,746**
Budget Authority (non-add)	*15,172*	*15,617*	*15,588*
Women's Health	**85,087**	**93,224**	**92,421**
Budget Authority (non-add)	*39,343*	*41,022*	*39,173*
Office of Women's Health (non-add)	*4,442*	*4,442*	*4,442*
Breast Cancer (MQSA) (non-add)	*28,678*	*33,314*	*33,701*

CENTRAL ACCOUNT

FY 2013 ACTUALS

Programs (dollars in thousands)	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
Foods	**7,911**	-	**3,728**	-	**9,542**	-	**9,099**	-	**30,280**	-
Center	2,745	-	1,293	-	3,310	-	3,157	-	10,505	-
Field	5,166	-	2,435	-	6,232	-	5,942	-	19,775	-
Human Drugs	**7,277**	**13,387**	**3,429**	**6,308**	**8,777**	**18,168**	**8,370**	**15,397**	**27,853**	**53,261**
Center	5,890	12,894	2,776	6,076	7,104	17,468	6,774	14,831	22,544	51,269
Field	1,387	493	654	232	1,673	700	1,595	567	5,308	1,992
Biologics	**3,842**	**2,980**	**1,811**	**1,404**	**4,635**	**4,183**	**4,419**	**3,427**	**14,707**	**11,994**
Center	3,405	2,890	1,605	1,362	4,107	4,054	3,916	3,324	13,033	11,629
Field	437	90	206	42	527	129	503	104	1,674	365
Animal Drugs & Feed	**1,384**	**314**	**652**	**148**	**1,669**	**379**	**1,591**	**362**	**5,296**	**1,203**
Center	839	314	396	148	1,012	379	965	362	3,213	1,203
Field	544	-	256	-	656	-	626	-	2,083	-
Devices and Radiological Health	**3,549**	**1,001**	**1,672**	**472**	**4,281**	**1,859**	**4,082**	**1,152**	**13,584**	**4,484**
Center	2,663	950	1,255	448	3,212	1,764	3,063	1,093	10,193	4,255
Field	886	51	417	24	1,068	95	1,019	59	3,390	229
National Center For Toxicological Research	**455**	-	**215**	-	**549**	-	**524**	-	**1,743**	-
FDA Headquarters	**5,902**	**274**	**2,781**	**129**	**7,119**	**338**	**6,789**	**315**	**22,592**	**1,057**
Total	**30,320**	**17,957**	**14,288**	**8,462**	**36,572**	**24,928**	**34,873**	**20,653**	**116,053**	**71,999**

FY 2014 ESTIMATES

Programs (Dollars in Thousands)	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
Foods	**7,056**	-	**3,435**	-	**11,720**	-	**4,017**	-	**26,227**	-
Center	2,211	-	1,077	-	3,673	-	1,259	-	8,220	-
Field	4,844	-	2,358	-	8,046	-	2,758	-	18,007	-
Human Drugs	**6,766**	**16,741**	**3,294**	**8,150**	**11,238**	**30,026**	**3,852**	**9,532**	**25,150**	**64,449**
Center	5,465	16,073	2,661	7,824	9,079	28,819	3,112	9,152	20,317	61,868
Field	1,300	669	633	326	2,160	1,207	740	381	4,834	2,582
Biologics	**3,403**	**2,794**	**1,657**	**1,360**	**5,653**	**5,060**	**1,938**	**1,591**	**12,650**	**10,804**
Center	2,993	2,744	1,457	1,336	4,972	4,970	1,704	1,562	11,126	10,612
Field	410	50	200	24	681	90	233	28	1,524	192
Animal Drugs & Feed	**1,315**	**326**	**640**	**159**	**2,184**	**954**	**749**	**186**	**4,887**	**1,625**
Center	804	318	392	155	1,336	928	458	181	2,991	1,582
Field	510	8	248	4	848	26	291	5	1,897	42
Devices and Radiological Health	**3,159**	**1,337**	**1,538**	**651**	**5,248**	**2,855**	**1,799**	**761**	**11,745**	**5,603**
Center	2,329	1,305	1,134	635	3,869	2,787	1,326	743	8,657	5,469
Field	831	32	404	16	1,380	68	473	18	3,087	134
National Center For Toxicological Research	**429**	-	**209**	-	**713**	-	**245**	-	**1,597**	-
FDA Headquarters	**3,812**	**2,695**	**1,856**	**1,312**	**6,332**	**4,494**	**2,170**	**1,535**	**14,170**	**10,036**
Total	**25,940**	**23,893**	**12,627**	**11,631**	**43,088**	**43,390**	**14,770**	**13,604**	**96,425**	**92,518**

FY 2015 ESTIMATES

Programs (Dollars in Thousands)	PSC		Facilities		Information Technology		Support Services		Total	
	BA	UF	BA	UF	BA	UF	BA	UF	BA	UF
Foods	**6,341**	-	**813**	-	**10,532**	-	**3,610**	-	**21,297**	-
Center	1,987	-	255	-	3,301	-	1,132	-	6,675	-
Field	4,353	-	558	-	7,231	-	2,479	-	14,622	-
Human Drugs	**6,080**	**18,529**	**780**	**2,376**	**10,100**	**32,995**	**3,462**	**10,550**	**20,422**	**64,449**
Center	4,912	17,788	630	2,282	8,159	31,669	2,797	10,128	16,497	61,868
Field	1,169	740	150	95	1,941	1,325	665	421	3,925	2,582
Biologics	**3,058**	**3,092**	**392**	**397**	**5,080**	**5,555**	**1,741**	**1,760**	**10,272**	**10,804**
Center	2,690	3,037	345	390	4,468	5,456	1,532	1,729	9,034	10,612
Field	368	55	47	07	612	99	210	31	1,238	192
Animal Drugs & Feed	**1,182**	**361**	**152**	**46**	**1,963**	**1,012**	**673**	**206**	**3,969**	**1,625**
Center	723	352	93	45	1,201	985	412	200	2,428	1,582
Field	459	9	59	1	762	27	261	5	1,540	42
Devices and Radiological Health	**2,839**	**1,479**	**364**	**190**	**4,716**	**3,092**	**1,617**	**842**	**9,537**	**5,603**
Center	2,093	1,444	268	185	3,477	3,018	1,192	822	7,030	5,469
Field	746	35	96	5	1,240	74	425	20	2,507	134
National Center For Toxicological Research	**386**	-	**50**	-	**641**	-	**220**	-	**1,296**	-
FDA Headquarters	**3,426**	**2,983**	**439**	**383**	**5,690**	**4,972**	**1,951**	**1,698**	**11,506**	**10,036**
Total	**23,312**	**26,443**	**2,990**	**3,392**	**38,723**	**47,626**	**13,274**	**15,056**	**78,298**	**92,518**

HHS CHARGES AND ASSESSMENTS

Assessments	**$1,737,855**
Interagency Council Funds Funding to support government-wide financial, information technology, procurement, human capital, and other management activities	$87,072
NIH eRA Grants Management System Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System	$161,456
Office of Commissioned Corps Force Management SGLI reimbursement	$74,302
Department Ethics Program The Office of General Counsel provides legal and related support services to FDA	$1,414,240
Federal Audit Clearinghouse	$785
Fee For Service	**$33,921,692**
Program Support Center/ Office of the Secretary Provides various services to the FDA, including some Information and Systems Management Services	$17,567,021
Financial Management Services (FMS)	$619,163
Strategic Acquisition Service	$3,265,192
Administrative Operations Service Includes costs for security, building operations, shredding, storage, graphics, property disposal, trans-share, mail and payroll services	$11,572,788
Federal Occupational Health (FOH) FDA agency health units and services	$2,109,878
Information & System Management Services	$16,354,671
Freedom of Information (FOIA)	$277,319
Unified Financial Management Systems (UFMS) The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.	$5,700,028
HCAS Operations and Maintenance HCAS O&M services provide support for daily operations of the HCAS application.	$2,228,530
Telecommunication Services Telecommunications team offers expertise on technical design & support for customer systems	$551,924
HHS NET	$668,598
Enterprise Application Services include activities for HHS' civilian employees and Commissioned Corps Officers, and maintenance and operation of the systems housing current and historical pay and leave records	$4,396,014
Human Resource Center – Rockville, Maryland	$2,532,258

Jointly Funded Projects	**$5,963,832**
Enterprise Information Management FDA's contribution to the HHS Enterprise Infrastructure Fund. Funds are used for Enterprise Information Technology programs/projects outlined in the Enterprise Information Technology Strategic Plan or benefitting the corporate enterprise, such as enterprise buys/licenses.	$2,893,013
International Health Bilateral Agreement 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	$1,148,338
CFO Audit of Financial Statements Audit services to be performed at the FDA in support of the fiscal year 2010 financial statement audit of the Department of Health and Human Services (HHS) contracted and monitored by Office of the Inspector General (OIG) and its components, and related services.	$374,300
Office of Public Health/Blood Safety Agreement to provide funding for the advisory committee on Blood Safety	$300,000
Regional Health Administrators IAG with OS/Office of Public Health & Science to support ten Regional Health Administrators. Their core mission is to promote understanding of and control functions within their respective regions improvements in public health and to conduct specific management.	$308,010
President's Council on Bioethics TAP to fund the council which advises the President of Bioethical issues related to the advances in biomedical science and technology	$294,000
Media Monitoring Provides Agency leadership and staff with the latest analysis of what the media is reporting about Department-wide and Agency-specific priorities, initiatives, and programs	$134,731
Intra-department Council on Native American Affairs IAG with HHS, Administration on Children and Families, for staff and administrative support for the Interdepartmental Council for Native American Affairs Committee meetings and assignments.(ICNAA), to conduct semi-annual Council meetings, Executive	$15,909
National Science Advisory Board for Biosecurity 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	$325,000
NIH Negotiation of Indirect Cost Rates (New) Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations	$3,600
HHS Broadcast Studio (New) It is a communication tool used for departmental messaging, both to internal and external audiences and is key to the government-wide open government initiative.	$100,000
OPM USAJOBS Fees charged by OPM to Federal Agencies to cover the cost of providing Federal Employment Information and services. OPM assesses an annual per-capita-fee based on each OPDIV percentage of the Departments total FTE on all paid employees with access to USAJOBS. The cost is distributed within HHS.	$66,931

FY 2013 ACTUALS

Activity	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Assessments	**$ 1,737,855**	**$ 1,802,565**	**$ 1,835,834**
Fee for Service	**$ 33,921,692**	**$ 30,868,570**	**$ 34,957,381**
Program Support Center/OS	$ 15,457,143	$ 10,727,718	$ 12,640,381
Federal Occupational Health	$ 2,109,878	$ 2,748,281	$ 3,049,000
Information System Management Service	$ 16,354,671	$ 17,392,571	$ 19,268,000
Jointly Funded Services	**$ 5,963,832**	**$ 4,760,393**	**$ 4,816,613**
Enterprise Information Management	$ 2,893,013	$ 1,644,990	$ 1,646,000
International Health - Bilateral Agreement	$ 1,148,338	$ 1,148,338	$ 1,148,338
Other Jointly Funded Projects	$ 1,922,481	$ 1,967,065	$ 2,022,275
Total	**$ 41,623,379**	**$ 37,431,528**	**$ 41,609,827**

* PSC/OS estimates are subject to change yearly due to the rates and usage of billable services agreed upon between FDA and

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GLOSSARY OF ACRONYMS

3D	3-Dimensional
ACOMS	Advisory Committee Oversight and Management Staff
ACSI	American Customer Satisfaction Index
ADE	Adverse Drug Experience
ADEPT	Autonomous Diagnostics to Enable Prevention and Therapeutics
ADHD	Attention-Deficit / Hyperactivity Disorder
ADUFA	Animal Drug User Fee Act
AGDUFA	Animal Generic Drug User Fee Act
AMP	Real Property Asset Management Plan
ANDA	Abbreviated New Drug Application
ANPRM	Advance Notice of Proposed Rulemaking
APEC	American Customer Satisfaction Index
ARL	Arkansas Regional Laboratory
ARS	Agriculture Research Service
ARS	Acute Radiation Syndrome
B&F	Buildings and Facilities
BA	Budget Authority
BACPAK	Bacterial Pathogen Knowledge Base
BARDA	Biomedical Advanced Research and Development Authority
BIMO	Bioresearch Monitoring
BLA	Biologic License Application
BMAR	Backlog of Maintenance and Repairs
BPA	Bisphenol A
BPCA	Best Pharmaceuticals for Children Act
BRF	Beltsville Research Facility
BsUFA	Biosimilars User Fee Act
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CERSIs	Centers of Excellence in Regulatory Science and Innovation
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
cGMP	current Good Manufacturing Practice
CIADM	Centers for Innovation in Advanced Development and Manufacturing
CIO	Chief Information Officer
CMS	Centers for Medicare & Medicaid Services
CMV	Cytomegalovirus
CORE	Coordinated Outbreak Response and Evaluation
CORES	Collaborative Opportunities for Research Excellence in Science
CRADA	Cooperative Research & Development Agreement (CRADA
CSU	Central Shared Use
CT	Computed Tomography Imaging

CTP	Center for Tobacco Products
CUP	Central Utility Plant
CVM	Center for Veterinary Medicine
CY	Calendar Year
DARPA	Defense Advanced Research Projects Agency
DHRD	Division of Human Resource Development
DHS	Department of Homeland Security
DILI	Drug-Induced Liver Injury
DIO	Division of Import Operations
DNA	DeoxyriboNucleic Acid
DOD	Department of Defense
DSC	Drug Safety Communication
DTC	Direct-To-Consumer
DTRA	Defense Threat Reduction Agency
DxOD	Diagnostics on Demand
EADB	Estrogenic Activity Database
EDKB	Endocrine Disruptor Knowledge Base
EDR	Electronic Data Room
EDSR	Electronic Document Submission and Review
EIR	Entrepreneurs in Residence
EMA	Economically Motivated Adulteration
eMDR	Electronic Medical Device Reporting
E.O.	Executive Order
EON	Emergency Operations Network
EON IMS	Emergency Operations Network Incident Management System
ESPC	Energy Savings Performance Contract
ESRD	End-Stage Renal Disease
ETASU	Elements to Assure Safe Use
EUA	Emergency Use Authorizations
FACA	Federal Advisory Committee Act
FAERS	FDA Adverse Event Reporting System
FAO	Food and Agriculture Organization
FATA	Federal Anti-Tampering Act
FCC	Forensic Chemistry Center
FCI	Facility Condition Index
FCN	Food Contact Substance Notification
FD&C Act	Federal Food, Drug and Cosmetic Act
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act
FDASIA	Food and Drug Administration Safety and Innovation Act
FDA-TRACK	FDA-wide performance management system
FDCA	Federal Food, Drug and Cosmetic Act
FEMP	Federal Energy Management Program
FERN	Food Emergency Response Network
FFDM	Full-Field Digital Mammography

FMT	Fecal Microbiota Transplantation
FOI	Freedom of Information Act
FOIA	Freedom of Information Act
FPC	Federal Partners Collaboration
FSIS	Food Safety Inspection Service
FSMA	Food Safety Modernization Act
FSVP	Foreign Supplier Verification Programs
FTE	Full Time Equivalent
FVM	Foods and Veterinary Medicine
FY	Fiscal Year
GDUFA	Generic Drug User Fee Amendments
GFI	Guidance for Industry
GIS	Geographic Information System
GMP	Good Manufacturing Practices
GO	Global Regulatory Operations and Policy Directorate
GSA	General Services Administration
GUDID	Global UDI Database
HDE	Humanitarian Device Exemption
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HQ	FDA Headquarters
HRWG	High Risk Working Group
HSP	Human Subject Protection
HUD	Humanitarian Use Device
HVAC	Heating, Ventilation, and Air Conditioning
ICCR	International Cooperation on Cosmetics Regulation
ICH	International Conference on Harmonization
ICOR	International Consortium of Orthopedic Registries
IDE	Investigational Device Exemption
IFT	Institute of Food Technologists
IMDRF	International Medical Device Regulators Forum
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
IT	Information Technology
ITACS	Import Trade Auxiliary Communications System
IVD	In Vitro Diagnostics
JLC	Jefferson Labs Complex
LSBC	Life Sciences-Biodefense Laboratory Complex
MAQC	MicroArray Quality Control
MCM	Medical Countermeasure
MCMi	Medical Countermeasures initiative

MDE	Medical Device Epidemiology
MDIC	Medical Device Innovation Consortium
MDR	Medical Device Reporting
MDSAP	Medical Device Single Audit Program
MDSP	Medical Device Shortages Program
MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
MERS-CoV	Middle East Respiratory Syndrome
MFRPS	Manufactured Food Regulatory Program Standards
microRNA	Micro Ribonucleic Acid
MIT/HST	Massachusetts Institute of Technology/Health Science and Technology
MOD	Module
MQSA	Mammography Quality Standards Act
MRI	Magnetic Resonance Imaging
MRTP	Modified Risk Tobacco Product
NA	Not Approvable
NADA	New Animal Drug Application
NARMS	National Antimicrobial Resistance Monitoring System
NCBI	National Center for Biotechnology Information
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NGO	Non-governmental Organization
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NME	New Molecular Entity
NSABB	National Science Advisory Board for Biosecurity
NSAID	Non-Steroidal Anti-Inflammatory Drugs
NSE	Not Substantially Equivalent
NYTS	National Youth Tobacco Survey
OBE	Office of Biostatistics and Epidemiology, CBER
OC	Office of the Commissioner
OCAC	Office of Cosmetics and Colors
OCC	Office of the Chief Counsel
OCE	Office of Compliance and Enforcement
OCET	Office of Counterterrorism and Emerging Threats
OCI	Office of Criminal Investigations
OCM	Office of Crisis Management
OCP	Office of Combination Products
OCS	Office of the Chief Scientist
OCT	Optical Coherence Tomography
OCTC	Office of the Counselor to the Commissioner
OEA	Office of External Affairs
OECD	Organization for Economic Co-Operation and Development
OFVM	Office of Foods and Veterinary Medicine
OGCP	Office of Good Clinical Practice
OGROP	Office of Global Regulatory Operations and Policy
OHCA	Office of Health and Constituent Affairs

OIM	Office of Information Management
OIP	Office of International Programs
OIR	Office of In Vitro Diagnostics and Radiological Health
OL	Office of Legislation
OMA	Office of Media Affairs
OMB	Office of Management and Budget
OMPT	Office of Medical Products and Tobacco
OO	Office of Operations
OOPD	Office of Orphan Products Development
OPP	Office of Policy and Planning
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs
ORISE	Oak Ridge Institute for Science and Education
ORRR	Other Rent and Rent Related
ORSI	Office of Regulatory Science and Innovation
OSE	Office of Surveillance and Epidemiology, CDER
OSI	Office of Scientific Integrity
OSMP	Office of Special Medical Programs
OSPD	Office of Scientific and Professional Development
OTC	Over-the-counter
PAC	Pediatric Advisory Committee
PAD	Program Activity Data
PAHO	Pan American Health Organization
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
PATH	Population Assessment of Tobacco and Health
PB	President's Budget
PC	Preventive Control
PDC	Pediatric Device Consortia
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PHEMCE	Public Health and Emergency Countermeasures Enterprise
PIC/S	Pharmaceutical Inspection Convention and Cooperation Scheme
PMA	Premarket Approval Application
PREA	Pediatric Research Equity Act
PREDICT	Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting
PRISM	Post-Licensure Rapid Immunization Safety Monitoring
PTN	Pediatric Trials Network
QSDAR	Quantitative Spectroscopic Data-Activity Relationships
REMS	Risk Evaluation and Mitigation Strategy
RFCTG	Regulators Forum Cell Therapy Group
RTA	Refusal to Accept
SE	Substantially Equivalent (when used by Device and Biologics Programs)
SEQCSE	Sequencing Quality Control Substantial Equivalence
SLEPSEQC	Shelf Life Extension Program Sequencing Quality Control
SNSSLEP	Strategic National Stockpile Shelf Life Extension Program

SPSNS	Strategic Priority Strategic National Stockpile
SRL SP	Southeast Regional Laboratory (SRL) Strategic Priority
SWSRL	Southwest Southeast Regional Laboratory (SRL)
SW	Southwest
TB	Tuberculosis
TCORSTB	Tobacco Centers of Regulatory Science Tuberculosis
TIMSTCORS	Tobacco Inspection Management System Tobacco Centers of Regulatory Science
TPMPTIMS	Tobacco Product Manufacturing Practice Tobacco Inspection Management System
TPSACTPMP	Tobacco Product Scientific Advisory Committee Tobacco Product Manufacturing Practice
TPSAC	Tobacco Product Scientific Advisory Committee
UDI	Unique Device Identification
UESCUDI	Utility Energy Service Contract Unique Device Identification
UFUESC	User Fee Utility Energy Service Contract
UNUF	United Nations User Fee
USAMRIIDUN	United States Army Medical Research Institute for Infectious Diseases United Nations
USCUSAMRIID	United States Code United States Army Medical Research Institute for Infectious Diseases
USDAUSC	United States Department of Agriculture United States Code
USPUSDA	U.S. Pharmacopoeia United States Department of Agriculture
USP	U.S. Pharmacopoeia
VAERS	Vaccine Adverse Event Reporting System
VICHVAERS	Veterinary International Conference on Harmonization Vaccine Adverse Event Reporting System
VKAVICH	Vitamin K Antagonist Veterinary International Conference on Harmonization
VKA	Vitamin K Antagonist
WD	Withdrawn
WEACWD	Winchester Engineering and Analytical Center Withdrawn
WHOWEAC	World Health Organization Winchester Engineering and Analytical Center
WHO	World Health Organization