DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2016

Food and Drug Administration

Justification of
Estimates for
Appropriations Committees

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LETTER FROM THE COMMISSIONER

I am pleased to present the FY 2016 Food and Drug Administration (FDA) Budget.

FDA fulfills its important mission to promote and protect health in an increasingly complex and globalized world in many ways. The scope of our work includes assuring that foods are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, vaccines and other biological products, and medical devices intended for human use are safe and effective; and regulating tobacco products. We also play a lead role in protecting the public from electronic product radiation and assuring that cosmetics and dietary supplements are safe and properly labeled. Finally, we have devoted – and will continue to devote – substantial resources to advancing the public health by helping to speed product innovations.

FDA's responsibilities continue to expand as we work to fulfill the mandates of groundbreaking legislation passed in recent years, including the Family Smoking Prevention and Tobacco Control Act of 2009, the Patient Protection and Affordable Care Act of 2010, the Food Safety Modernization Act (FSMA) of 2011, the FDA Safety and Innovation Act (FDASIA) of 2012, and the Drug Quality and Security Act of 2013. Further, with so many FDA-regulated products manufactured in whole or in part outside of our borders, FDA is keenly focused on the complexities of regulating in a global marketplace.

In FY 2014, we took important steps to finalize a key set of proposed food safety rules; worked to improve the safety of compounded pharmaceutical products by conducting more than 90 inspections and implementing compounding legislation through proposed regulations, guidances, and other actions; published the "deeming rule" to extend FDA's tobacco authority; and collaborated with federal, international, and industry partners to expedite the development and availability of medical products. In addition, FDA has worked intensively to respond to the Ebola epidemic in West Africa by facilitating the development and availability of investigational diagnostics, therapeutics, and vaccines with the potential to help combat the epidemic.

FDA continues to seek new ways to obtain the most public health value for the federal dollar as we implement expanded authorities. The products that FDA regulates are essential to public health, safety, and quality of life and represent over 20 cents of every consumer dollar spent on products in the United States. Yet, in terms of our FDA budget, each American taxpayer contributes approximately $8 per year for the vast array of protections and services provided by FDA.

In FY 2016, we are requesting essential and timely resources to address critical food and medical product safety issues. Mindful of the fiscal environment, we have identified targeted reductions where possible and identified long-term needs for additional user fees to balance budget authority growth. FDA is requesting a total of $4.9 billion to support our various mandates to protect the American people. This includes a $148 million budget authority increase to focus on the following:

- delivering a farm-to-table system of prevention, including improved oversight of imported foods, through effectively implementing the final rules required by FSMA;
- combating the growing threat of antibiotic resistance – in which drugs become less effective, or ineffective, against harmful bacteria;
- promoting the development and appropriate use of reliable molecular and genetic diagnostics – precision medicine tools – to "personalize" the diagnosis, treatment, and prevention of disease;
- implementing key FDASIA requirements to improve medical product review and inspections;
- addressing the safety of compounded drugs;
- continuing implementation of new requirements for review of sunscreen ingredients under the Sunscreen Innovation Act; and
- supporting modern facilities to provide the laboratories and office space needed to meet FDA's expanded legislative mandates.

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

Margaret A. Hamburg

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

TABLE OF CONTENTS

SIGNIFICANT ITEMS

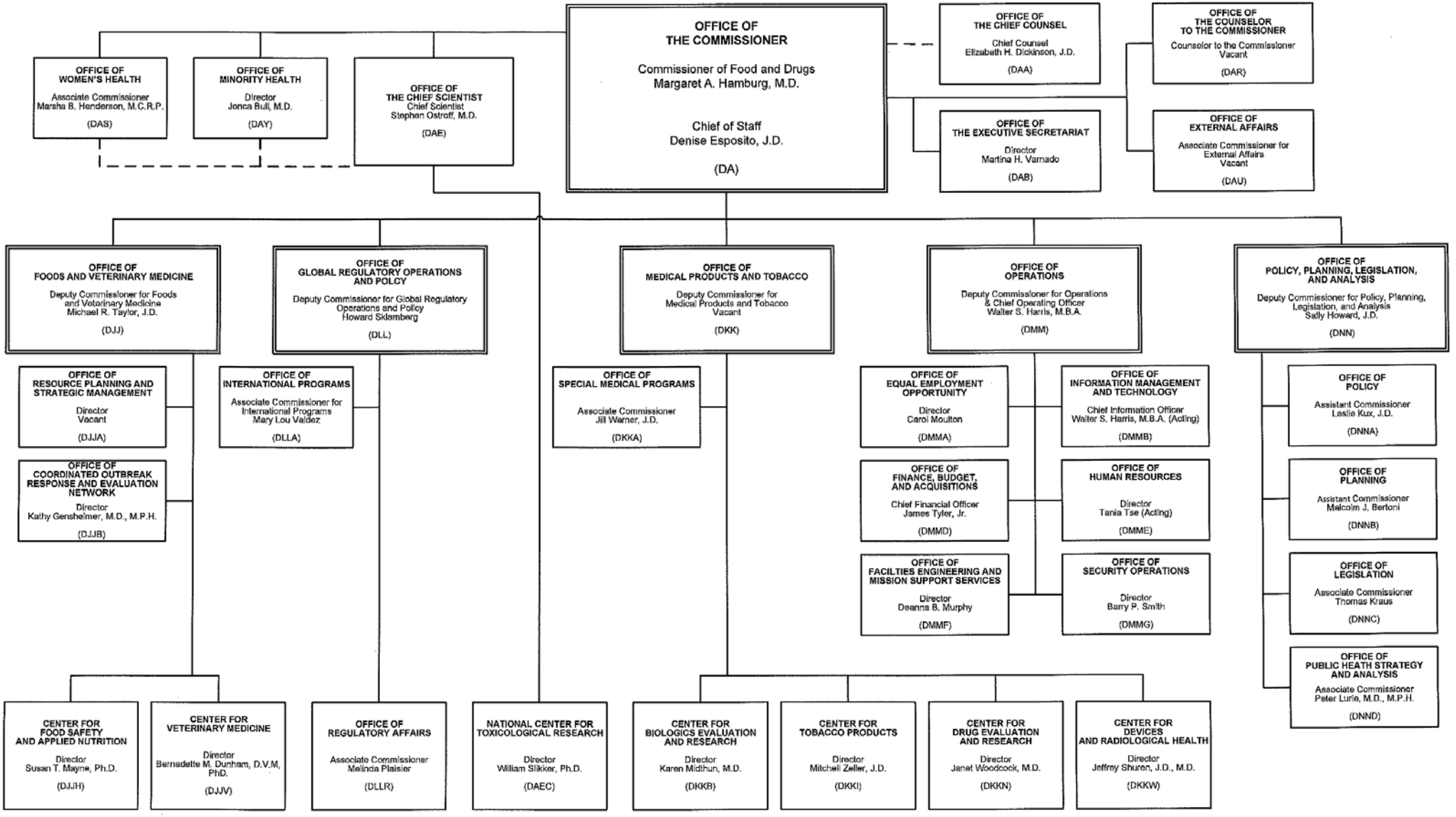
FDA SPECIFIC ITEMS

GLOSSARY

FOOD AND DRUG ADMINISTRATION

4/28/15

Approved by the FDA Reorganization Coordinator and Principal Delegation Control Officer



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EXECUTIVE SUMMARY

This Executive Summary describes the fiscal year (FY) 2016 Budget for the U.S. Food and Drug Administration (FDA). FDA is the agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting and promoting the public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of food and feed, cosmetics, and radiation-emitting products; and regulating tobacco products.

RECENT ACCOMPLISHMENTS

FDA delivers significant, quantifiable results that help Americans every day and is a sound investment. A selection of significant, recent accomplishments is presented below.

Food Safety

FDA published seven major proposed rules and, based on stakeholder feedback, four supplemental proposals to implement the Food Safety Modernization Act (FSMA). FDA also completed 8,607 high-risk food establishment inspections in FY 2014, exceeding the target of 6,507 inspections by 32 percent. These actions are key steps toward implementing FSMA's risk-based, prevention approach to reducing foodborne illness and strengthening public confidence in the food supply.

Drug Quality and Security Act (DQSA)

During fiscal year 2014, FDA continued to conduct inspections of compounding facilities, including outsourcing facilities, issued numerous warning letters, initiated several enforcement actions, and continued to develop the framework to implement the new law. Since the DQSA was passed in November 2013, FDA has issued numerous policy documents to implement both section 503A, as amended by the DQSA to remove uncertainty regarding its validity, as well as the new section 503B covering outsourcing facilities. FDA continues to work on numerous additional rules and guidances. In addition, FDA has announced the membership of a Pharmacy Compounding Advisory Committee which will provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B.

FDA has also published several draft guidances to support implementation of Title II of DQSA, the Drug Supply Chain Security Act and is continuing to implement the law and further enhance the safety of the drug supply chain. Ten years after enactment of DQSA, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain.

Tobacco Regulation

FDA published the proposed "deeming rule" to extend FDA's tobacco authority to additional tobacco products, including e-cigarettes. FDA advanced outreach to 1,500 industry and public health stakeholder groups, generating media coverage in more than 1,844 online and print media outlets. FDA has received over 135,000 comments to the proposed rule and is reviewing these comments in preparation of the final rule. Public health-based regulation of these products can help reduce the death and disease toll from tobacco use.

Product Safety and Quality

FDA expanded surveillance of medical products under the Sentinel Initiative, which 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. Monitoring the safety of its regulated products is a major part of FDA's mission to protect public health. The Sentinel system enables FDA to actively query diverse automated healthcare data holders – like electronic health record systems, administrative and insurance claims databases, and registries – to evaluate possible medical product safety issues quickly and securely.

Ebola Epidemic Response

FDA has used its authorities to the fullest extent possible to protect and promote the public health, both domestically and abroad, in response to the Ebola epidemic in West Africa. FDA contributed to national and global policy development, helped expedite the development and availability of investigational medical products for Ebola – including providing regulatory advice and guidance to commercial developers and U.S. agencies that support medical product development – to accelerate development programs, collaborated extensively with the World Health Organization and several international regulatory counterparts to support international response efforts, facilitated access to investigational medical products for patients with Ebola when requested by clinicians, and authorized the use of seven investigational diagnostic tests for Ebola under FDA's Emergency Use Authorization authority. FDA also monitored for fraudulent products that claim to prevent or treat Ebola and took action, as warranted, to protect public health.

Medical Product Application Review

FDA established a new review program for New Molecular Entity (NME) new drug applications and original Biologics License Applications (BLAs) under the Prescription Drug User Fee Act (PDUFA). The latest PDUFA reauthorization, PDUFA V, authorizes the program from October 1, 2012, through October 1, 2017. PDUFA V will enhance FDA's capacity to fulfill its mission of bringing to market novel drug products for patients. The goals of the program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval. As of September 30, 2014, FDA has received more than 100 applications through this program, which involves a more interactive review with applicants. All of the FY 2014 program cohort applications that received actions by September 30, 2014, were reviewed and acted on within the goal date.

The Medical Device User Fee Amendments of 2012 (MDUFA III) was designed to provide aggressive premarket performance goals and enhance the accountability, predictability, and transparency of the Devices Program. FDA has met or exceeded all FY 2014 MDUFA III performance goals for 510(k) submissions and Premarket Approval (PMA) applications. At the same time, FDA has decreased the overall median time to full Investigational Device Exemption (IDE) approval by over 50 percent, demonstrating FDA's commitment to increase the efficiency with which medical devices are developed and made available to U.S. patients.

FDA also exceeded all performance goals and completed the review and action on 99.8 percent of original New Animal Drug Applications (NADAs) and other ADUFA sentinel submissions within timeframes specified by ADUFA for applications reviewed in FY 2013. 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 2013.

OVERVIEW OF THE BUDGET REQUEST

The FY 2016 President's Budget Request for FDA is $4.9 billion, an overall increase of nine percent or $424.8 million compared to the FY 2015 Enacted level. The total Budget Request includes $2.7 billion for budget authority – an increase of six percent or $147.7 million compared to the FY 2015 Enacted level – and $2.2 billion for user fees – an increase of 15 percent or $277.2 million compared to the FY 2015 Enacted level.

Budget Structure and Strategic Plan Framework

The Budget is described in terms of Budget Authority and User Fees and is broken down into the following major activities.

- Food Safety – ensures the food and feed supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled
- Medical Product Safety – ensures that safe and effective human and animal drugs, biological products, devices, and radiological products are available to improve the health of the people in the U.S.
- Medical Countermeasures (MCM) – ensures that medical countermeasures – including drugs, vaccines and diagnostic tests – to counter chemical, biological, radiological, nuclear, and emerging infectious disease threats are safe, effective, and secure
- Other Activities – includes FDA White Oak Consolidation, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act activities, and Color Certification activities.

The Budget is also structured around FDA's strategic plan framework. On September 30, 2014, FDA published the *FDA Strategic Priorities 2014-2018*[1] on FDA's goals and priorities, providing the strategic direction to help us continue to serve and protect the American people. FDA's Strategic Goals include improving and safeguarding access to – and making better informed decisions about – the products FDA regulates, as well as providing effective oversight of these products. FDA will integrate Strategic Priorities – regulatory science, globalization, safety and quality, smart regulation and stewardship – within these goals. All FDA Centers and Offices link program-specific actions to support these priorities within the core mission goal areas.

[1] http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm

Food and Drug Administration
Major Activities
(Dollars in Thousands)

Program	FY 2015 Enacted				FY 2016 President's Budget				FY 2016 Request +/- FY 2015 Enacted			
	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	**903,403**	---	---	**903,403**	**987,328**	---	---	**987,328**	**83,925**	---	---	**83,925**
Human Drugs	---	**476,267**	**6,020**	**482,287**	---	**478,658**	**6,020**	**484,678**	---	**2,391**	---	**2,391**
Biologics	---	**208,987**	**2,395**	**211,382**	---	**212,626**	**2,395**	**215,021**	---	**3,639**	---	**3,639**
Animal Drugs and Feeds	**112,730**	**34,847**	---	**147,577**	**125,305**	**40,447**	---	**165,752**	**12,575**	**5,600**	---	**18,175**
Devices and Radiological Health	---	**316,824**	**4,001**	**320,825**	---	**323,759**	**4,001**	**327,760**	---	**6,935**	---	**6,935**
National Center for Toxicological Research	**10,233**	**53,098**	---	**63,331**	**5,900**	**53,098**	---	**58,998**	**-4,333**	---	---	**-4,333**
FDA Headquarters	**73,285**	**79,765**	**10,312**	**173,362**	**77,783**	**83,219**	**10,312**	**181,314**	**4,498**	**3,454**	---	**7,952**
FDA White Oak Consolidation		---	---	**43,044**	---	---	---	**48,044**	---	---	---	**5,000**
Other Rent and Rent Related	**36,682**	**35,325**	**936**	**72,943**	**44,831**	**43,370**	**936**	**89,137**	**8,149**	**8,045**	---	**16,194**
GSA Rental Payments	**78,145**	**89,849**	**888**	**168,882**	**82,789**	**93,006**	**888**	**176,683**	**4,644**	**3,157**	---	**7,801**
SUBTOTAL, BA Salaries and Expenses	**1,214,478**	**1,294,962**	**24,552**	**2,587,036**	**1,323,936**	**1,328,183**	**24,552**	**2,734,715**	**109,458**	**33,221**	---	**147,679**
Building and Facilities				**8,788**				**8,788**	---	---	---	---
Total BA	**1,214,478**	**1,294,962**	**24,552**	**2,595,824**	**1,323,936**	**1,328,183**	**24,552**	**2,743,503**	**109,458**	**33,221**	---	**147,679**
Total User Fees	**14,415**	**1,320,635**		**1,909,351**	**206,197**	**1,372,165**		**2,186,501**	**191,782**	**51,530**	---	**277,150**
Current Law	14,415	1,320,635	---	1,909,351	15,815	1,363,924	---	1,987,878	1,400	43,289	---	78,527
Proposed	---	---	---	---	190,382	8,241	---	198,623	190,382	8,241	---	198,623
Total Program Level	**1,228,893**	**2,615,597**	**24,552**	**4,505,175**	**1,530,133**	**2,700,348**	**24,552**	**4,930,004**	**301,240**	**84,751**	---	**424,829**

* Total Budget Authority includes $10 million for the China Initiative. FDA White Oak Consolidation, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification User Fees are not included in Food Safety, Medical Product Safety, and Medical Countermeasures activities.

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

*** FY 2015 Enacted level is $12.5 million lower than the fee collections estimated in FDA's FY 2015 User Fee Federal Register notices.

**** The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

***** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

****** FTE figures do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR. FY 2015 and FY 2016 estimated FTE levels in the APT have been updated based on FY 2014 actual year to date usage information.

******* FY 2016 Medical Product Safety total includes restoration of $1.5 million transferred from FDA to HHS OIG in FY 2015.

FOOD SAFETY

The FY 2016 Budget provides $1.5 billion for food and feed safety, an increase of $301.2 million above the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $109.5 million. This amount includes $5.8 million in reductions. In addition, user fees increase by $191.8 million.

FDA has proactively reprioritized current resources, including the FY 2016 increase, to ensure they are directed to the highest priorities for food and feed safety modernization. FSMA remains a largely underfunded mandate. Therefore, it is not practical for FDA to offset this funding to accommodate the additional activities outlined in the initiative.

Without the requested budget authority, FDA will be unable to:

- implement fundamental FSMA requirements for domestic food and feed safety on a timely basis
- acquire the technical staffing needed to support FSMA implementation
- train FDA and state inspectors in the new FSMA prevention paradigm and preventive controls system, as needed to ensure effective and consistent inspections

- provide the necessary guidance and technical assistance to industry, particularly small producers and businesses, on how to meet the new requirements resulting from the shift toward preventing food and feed contamination
- adequately support the FSMA goal of strengthening state roles in a national integrated food safety system
- adequately assure the safety of imported food by building and implementing the import safety system mandated by FSMA.

BUDGET AUTHORITY

Food Safety: FY 2016 Budget Authority Request
(Dollars in thousands)

	Inspection Modernization and Training		National Integrated Food Safety System		Education and Technical Assistance for Industry		Technical Staffing and Guidance Development		Import Safety - FSVP Implementation		Risk Analytics and Evaluation		Infrastructure		Increase Subtotal		Reductions and Program Changes		Total Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																				
Foods	**17**	**21,700**	**21**	**25,800**	**12**	**10,000**	**10**	**4,000**	**78**	**22,425**	---	---	---	---	**138**	**83,925**	---	---	**138**	**83,925**
Center	3	3,000	4	2,000	12	10,000	10	4,000	8	5,000	---	---	---	---	37	24,000	---	---	37	24,000
Field	14	18,700	17	23,800	---	---	---	---	70	17,425	---	---	---	---	101	59,925	---	---	101	59,925
Animal Drugs and Feeds	**3**	**3,300**	**8**	**6,200**	**5**	**1,500**	---	---	**12**	**3,075**	---	---	---	---	**28**	**14,075**	---	**-1,500**	**28**	**12,575**
Center	---	---	5	2,000	5	1,500	---	---	---	---	---	---	---	---	10	3,500	---	-1,500	10	2,000
Field	3	3,300	3	4,200	---	---	---	---	12	3,075	---	---	---	---	18	10,575	---	---	18	10,575
NCTR	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	**-4,333**	---	**-4,333**
FDA Headquarters	---	---	---	---	---	---	---	---	---	---	**3**	**4,498**	---	---	**3**	**4,498**	---	---	**3**	**4,498**
Other Rent and Rent Related	---	---	---	---	---	---	---	---	---	---	---	---	---	**8,149**	---	**8,149**	---	---	---	**8,149**
GSA Rental Payments	---	---	---	---	---	---	---	---	---	---	---	---	---	**4,644**	---	**4,644**	---	---	---	**4,644**
Total Budget Authority	**20**	**25,000**	**29**	**32,000**	**17**	**11,500**	**10**	**4,000**	**90**	**25,500**	**3**	**4,498**	---	**12,793**	**169**	**115,291**	---	**-5,833**	**169**	**109,458**
Non-Field Activities	3	3,000	9	4,000	17	11,500	10	4,000	8	5,000	3	4,498	---	---	50	31,998	---	-5,833	50	26,165
Field Activities	17	22,000	20	28,000	---	---	---	---	82	20,500	---	---	---	---	119	70,500	---	---	119	70,500
Rent Activities	---	---	---	---	---	---	---	---	---	---	---	---	---	12,793	---	12,793	---	---	---	12,793

**Does not include 19 annualized FTE and an additional 104 FTE due to Foods Program realignment to meet FSMA implementation and other mandates.*

Increases

Inspection Modernization and Training

This funding supports the development of new inspection models and tools, needed FDA culture change, and essential training of FDA and state inspection and compliance staff to implement FSMA's new prevention paradigm and ensure consistency in federal and state inspections conducted under FSMA.

National Integrated Food Safety System

To leverage resources and improve nationwide consistency in food safety oversight, FSMA mandated that FDA assess and strengthen state, local, territorial, and tribal food safety capacity and build a national integrated food safety system. This funding is an investment in the capacity and partnerships that are essential for such a system, with a focus on federal and state partnerships to strengthen state coordination, improve information sharing capacity with the states, and build lab capacity by supporting laboratory accreditation.

Education and Technical Assistance for Industry

This funding will support FDA's commitment to "educate before and while we regulate" by providing training, advice, and technical assistance to industry to facilitate understanding and compliance with the new standards. This compliance assistance will be carried out collaboratively with state partners, industry, extension services, academia, and other institutions that can deliver educational and technical assistance.

Technical Staffing and Guidance Development
This funding will invest in staff and contractor support for FSMA guidance development and technical capacity to support technical assistance for industry, and technical support for FDA and state inspectors and compliance staff implementing the new FSMA standards.

Import Safety – Foreign Supplier Verification Program (FSVP) Implementation
This funding is essential to hire staff with new audit skills, conduct training, and build information and management systems to implement FSMA's Foreign Supplier Verification Program (FSVP) requirement. The FSVP is the foundation for FSMA's new import safety system and key to assuring a level playing field of food safety standards and oversight for U.S. consumers and industry. The FSVP requires importers to verify, subject to FDA audit, that imported foods are produced consistent with U.S. safety standards.

Risk Analytics and Evaluation
One key element of FSMA is the vision of future regulatory action being focused on the degree of risk posed by a given food or feed. FDA is developing new tools that will provide the information needed to focus decisions and resources on areas of greatest risk to health. This includes new tools for ranking risks, prioritizing program activities based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution processes.

Reductions

As part of the FY 2016 Budget, FDA will reduce $5.8 million of current food safety activities in order to support the highest priorities for FY 2016. These reductions target lower priority enforcement, surveillance, and research activities for the Animal Drugs and Feeds Program and National Center for Toxicological Research (NCTR).

USER FEES

Increases

Proposed Food Import User Fee
FDA will use $103.3 million in new resources provided by the proposed import user fee to facilitate the entry of safe food through enhanced border staffing, improved information systems and other importer support and port of entry streamlining. FDA has reduced the amount requested for this fee, compared to the import fee requested in the FY 2015 President's Budget, as a result of the Foreign Supplier Verification Program (FSVP) funding being requested as budget authority.

Proposed Food Facility Registration and Inspection User Fee
The $60.1 million proposed fee will provide resources to further modernize the FDA inspection program through the further development and implementation of new inspection models and tools, including training in the new models and information technology to improve targeting and risk-based efficiency of inspection. The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide.

Proposed Cosmetics User Fee
FDA will use $19.9 million in new resources to support FDA cosmetic safety responsibilities. The proposed user fee will promote greater safety and understanding of cosmetic products.

Proposed Food Contact Substance Notification User Fee (FCN)
FDA will use $5.1 million in new resources to provide a stable, long-term source of funding to supplement budget authority. FDA has statutory responsibility for the safety of all food contact substances in the United States. The Federal Food Drug and Cosmetic Act specifies that the FCN program can operate only if adequately funded.

MEDICAL PRODUCT SAFETY

The FY 2016 Budget provides $2.7 billion for medical product safety, an increase of $84.8 million above the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $33.2 million. This amount includes $10.1 million in reductions and restoration of $1.5 million transferred from FDA to the HHS Office of the Inspector General in FY 2015. In addition, user fees increase by $51.5 million.

The Medical Product Safety increase will improve the entire continuum of medical products in the United States, including drugs, biologics, and medical devices. These products are crucial to the health care system and impact nearly every aspect of medical care in the United States. By seeking to improve safety and quality across the spectrum of FDA regulated products, FDA will address emerging and recurring public health needs as well as provide better oversight of the global product supply chain.

BUDGET AUTHORITY

Medical Product Safety: FY 2016 Budget Authority Request
(Dollars in thousands)

	FDASIA Implementation		Combating Antibiotic Resistant Bacteria		Precision Medicine		Compounding		Sunscreen		Infrastructure		Increase Subtotal		Reductions and Program Changes		Total Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																		
Human Drugs	---	---	**2**	**5,000**	---	---	---	**717**	---	**716**	---	---	**2**	**6,433**	---	**-4,042**	**2**	**2,391**
Center	---	---	2	5,000	---	---	---	717	---	716	---	---	2	6,433	---	---	2	6,433
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	-4,042	---	-4,042
Biologics	**4**	**3,035**	**6**	**2,232**	---	---	---	---	---	---	---	---	**10**	**5,267**	**-5**	**-1,628**	**5**	**3,639**
Center	3	1,930	6	2,232	---	---	---	---	---	---	---	---	9	4,162	-5	-1,206	4	2,956
Field	1	1,105	---	---	---	---	---	---	---	---	---	---	1	1,105	---	-422	1	683
Animal Drugs and Feeds	---	---	**7**	**7,100**	---	---	---	---	---	---	---	---	**7**	**7,100**	---	**-1,500**	**7**	**5,600**
Center	---	---	7	7,100	---	---	---	---	---	---	---	---	7	7,100	---	-1,500	7	5,600
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Devices and Radiological Health	**1**	**1,965**	---	**500**	**14**	**7,358**	---	---	---	---	---	---	**15**	**9,823**	---	**-2,888**	**15**	**6,935**
Center	---		---	500	14	7,358	---	---	---	---	---	---	14	7,858	---	-2,037	14	5,821
Field	1	1,965	---	---	---	---	---	---	---	---	---	---	1	1,965	---	-851	1	1,114
FDA Headquarters	---	---	---	---	**4**	**1,954**	---	---	---	---	---	---	**4**	**1,954**	---	**1,500**	4	3,454
Other Rent and Rent Related	---	---	---	---	---	**145**	---	---	---	---	---	**7,900**	---	**8,045**	---	---	---	8,045
GSA Rental Payments	---	---	---	---	---	**247**	---	---	---	---	---	**2,910**	---	**3,157**	---	---	---	3,157
Subtotal, Salaries and Expenses Account	**5**	**5,000**	**15**	**14,832**	**18**	**9,704**	---	**717**	---	**716**	---	**10,810**	**38**	**41,779**	**-5**	**-8,558**	**33**	**33,221**
Total Budget Authority	**5**	**5,000**	**15**	**14,832**	**18**	**9,704**	---	**717**	---	**716**	---	**10,810**	**38**	**41,779**	**-5**	**-8,558**	**33**	**33,221**
Non-Field Activities	3	1,930	15	14,832	18	9,312	---	717	---	716	---	---	36	27,507	-5	-3,243	31	24,264
Field Activities	2	3,070	---	---	---	---	---	---	---	---	---	---	2	3,070	---	-5,315	2	-2,245
Rent Activities	---	---	---	---	---	392	---	---	---	---	---	10,810	---	11,202	---	---	---	11,202

**Does not include 18 annualized FTE.*

Increases

FDASIA Implementation – Unique Facility Identifier / Unique Device Identifier
The Unique Facility Identifier (UFI) is mandated under Sections 701 and 702 of FDASIA and ensures the accuracy and coordination of FDA databases. $1.1 million of the request will allow the Biologics Program to enhance FDA IT systems for UFI, which will improve analysis of the riskiest products, combat counterfeiting, and improve regulatory oversight. Additionally, $2 million of the request will allow the Devices Program to continue with the implementation of a Unique Device Identifier (UDI) system under section 614 of the FDA Safety and Innovation Act (FDASIA). Once implemented, this system will provide a consistent, standardized, unambiguous way to identify medical devices and allow FDA to quickly and efficiently identify marketed devices when recalled and improve the accuracy and specificity of adverse event reports.

FDASIA Implementation - Electronic Biological Product Application Submission
FDA regulates many biologic products not covered by user fees. The Electronic Biological Product Application Submission supports non-user fee biological products. FDA will implement Section 1136 of FDASIA requiring electronic application submission in 2016. The requested $1.9 million supports infrastructure to process electronic New Drug Applications, Abbreviated New Drug Applications, Biologic License Applications, and Investigational New Drug submissions for biological products.

Combating Antibiotic Resistant Bacteria
As part of the National Strategy for Combating Antibiotic Resistant Bacteria (CARB), FDA will evaluate new antibacterial drugs for patient treatments, streamline clinical trials, help phase out the use of medically important antimicrobials in food-producing animals, develop better vaccines for antibiotic resistant organisms, and strengthen capacities to detect antibiotic resistance.

Precision Medicine
Precision medicine is guided by comparing an individual's profile to a massive data network that includes information about other patients as well as data from research studies. This funding will permit FDA to keep pace with scientific advancements and help speed the development of promising new therapeutics that are needed for integrating genetic information into device development.

Compounding
FDA will continue implementation of the Federal Food Drug and Cosmetic Act provisions related to compounding, including those added by the DQSA, through inspections and enforcement, policy development and implementation, and state collaboration and coordination. The requested resources will also support development 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.

Sunscreen
This funding supports the evaluation of over the counter (OTC) sunscreen products, including activities related to reviewing the validity and outcome of new pharmacology and toxicology data, conducting searches of public literature and data, and writing summaries of relevant pharmacology and toxicology data.

Reductions

As part of the FY 2016 Budget, FDA will reduce $10.1 million of current medical product safety activities in order to support the highest priorities for FY 2016. These reductions target lower priority enforcement, surveillance, research, outreach, and risk analysis activities for the Human Drugs Program, Biologics Program, Devices and Radiological Health Program, Animal Drugs and Feeds Program, and Office of Regulatory Affairs.

OTHER ACTIVITIES

The following items support both food and medical product safety activities and are presented below for ease of review and to prevent duplication of content.

Rental Payments

A $33.8 million program level increase for GSA Rental Payments and Other Rent and Rent Related costs supports increased FTE levels and facility costs related to real estate taxes, rental rates, maintenance, and utilities. Rent costs for FDA's 16,000 employees increase beyond our control. FDA cannot absorb these costs and still meet increasing responsibilities. Without this funding, FDA will reduce program activities to pay rent, thus hampering implementation of food safety and medical product safety priorities. Of the total requested, $2.4 million in budget authority supports the GSA rent and Other Rent and Rent Related costs for new hires associated with the Food Safety and Precision Medicine increases. The remaining $31.4 million addresses escalating rent and related costs for existing FDA staff, including facility operations costs for the National Center for Toxicological Research.

White Oak Consolidation

The FY 2016 Budget Request is a program level of $52.2 million – including $5.0 million in budget authority above the FY 2015 Enacted level – for a feasibility study to update and issue a revised Master Plan for FDA's expanded workforce as a result of recently enacted responsibilities and resources. The feasibility study will provide the options necessary to assess the most cost effective way to house FDA's current and projected personnel.

Proposed International Courier User Fee

FDA will use new resources to increase surveillance of FDA-regulated commodities at express courier hubs. About 20 percent, or $1.2 million, of this proposed fee will support imported food safety. Almost 80 percent, or $4.7 million, of this proposed fee will support imported medical product safety.

Export Certification Fee Legislative Proposal

FDA is proposing an increase of $4.3 million for the export certification program by increasing the statutory maximum for the certification fee from $175 to $600 per certification and including an inflation adjustment factor for the statutory maximum. 21 U.S.C. § 381(e)(4), originally enacted in 1996, currently limits the maximum export certification fee to $175 per certification. Because of this cap and increases in the costs of maintaining the export certification program since the program's inception, the certification program expenditures significantly exceed the current revenue of the program. Increasing the maximum fee to an inflation-adjusted $600 per certification will allow the Agency to fully recover its costs in implementing this program.

Current Law User Fees

FDA requests a $78.5 million increase for the review of animal drugs and the review and surveillance of human drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases, infrastructure, and inflation. These increases will fund options for treating and curing diseases and strategies to reduce the costs 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

The *FDA Strategic Priorities 2014-2018*[2] focus efforts to achieve FDA's public health mission and to fulfill its role in supporting HHS' larger mission and strategic goals. The FY 2016 Budget is also structured around these priorities and goals, as discussed in the Overview of the Budget Request.

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:

- Transparency – provides interested parties an unprecedented look into how FDA performs its work
- Results – highlights performance measures and results related to the agency's public health mission
- Accountability – 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
- Credibility – 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
- Knowledge-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.

[2] http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm

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 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 include:

- FDA-iRISK, an innovative risk-assessment tool that supports a systematic, faster way of comparing and ranking risks in the food supply
- Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), an electronic screening tool for import operations that 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.
- FDALabel, an application that allows FDA to manage and analyze drug-label information and enhances drug-safety assessments for demographic subgroups.

ALL PURPOSE TABLE

(dollars in thousands)	FY 2014 Final		FY 2014 Actuals		FY 2015 Enacted		FY 2016 President's Budget			
							Request		+/- FY 2015 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,551**	**900,259**	**3,650**	**882,814**	**3,744**	**913,784**	**4,196**	**1,166,636**	**452**	**252,852**
Budget Authority	***3,551***	***882,817***	***3,650***	***882,814***	***3,720***	***903,403***	***3,977***	***987,328***	***257***	***83,925***
User Fees	---	***17,442***	---	---	***24***	***10,381***	***219***	***179,308***	***195***	***168,927***
Center	925	266,893	943	266,406	1,014	280,480	1,243	355,007	229	74,527
Budget Authority	925	266,408	943	266,406	1,013	279,994	1,158	303,994	145	24,000
User Fees	---	485	---	---	1	486	85	51,013	84	50,527
Food and Feed Recall	---	*485*			*1*	*243*	*1*	*243*	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	*243*	*1*	*243*	*1*	---
Third Party Auditor Program					---	---	---	*64*	---	*64*
Food Facility Registration and Inspection	---	---	---	---	---	---	*28*	*23,279*	*28*	*23,279*
Food Import	---	---	---	---	---	---	*6*	*9,790*	*6*	*9,790*
Cosmetics	---	---	---	---	---	---	*42*	*12,755*	*42*	*12,755*
Food Contact Substance Notification	---	---	---	---	---	---	*7*	*4,639*	*7*	*4,639*
Field	2,626	633,366	2,707	616,408	2,730	633,304	2,953	811,629	223	178,325
Budget Authority	2,626	616,409	2,707	616,408	2,707	623,409	2,819	683,334	112	59,925
User Fees	---	16,957	---	---	23	9,895	134	128,295	111	118,400
Food and Feed Recall	---	*9,823*	---	---	*4*	*1,000*	*4*	*1,000*	---	---
Food Reinspection	---	*7,134*	---	---	*19*	*4,575*	*19*	*4,575*	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	*4,320*	*18*	*4,320*	*18*	---
Third Party Auditor Program					---	---	*6*	*1,141*	*6*	*1,141*
Food Facility Registration and Inspection	---	---	---	---	---	---	*20*	*27,376*	*20*	*27,376*
Food Import	---	---	---	---	---	---	*46*	*84,530*	*46*	*84,530*
International Courier	---	---	---	---	---	---	*3*	*765*	*3*	*765*
Cosmetics	---	---	---	---	---	---	*18*	*4,588*	*18*	*4,588*
Human Drugs	**4,648**	**1,289,304**	**4,639**	**1,210,709**	**5,503**	**1,338,599**	**5,516**	**1,371,580**	**13**	**32,981**
Budget Authority	***2,043***	***466,374***	***2,076***	***466,303***	***2,152***	***482,287***	***2,163***	***484,678***	***11***	***2,391***
User Fees	***2,605***	***822,930***	***2,563***	***744,406***	***3,351***	***856,312***	***3,353***	***886,902***	***2***	***30,590***
Center	3,739	1,097,515	3,792	1,062,552	4,523	1,135,258	4,531	1,169,906	*8*	*34,648*
Budget Authority	1,310	339,838	1,361	339,773	1,399	346,080	1,407	352,513	*8*	*6,433*
User Fees	2,429	757,677	2,431	722,779	3,124	789,178	3,124	817,393	---	28,215
Prescription Drug (PDUFA)	*2,067*	*534,526*	*2,102*	*536,041*	*2,400*	*561,252*	*2,400*	*583,688*	---	*22,436*
Generic Drug (GDUFA)	*339*	*207,475*	*329*	*185,066*	*664*	*211,625*	*664*	*216,996*	---	*5,371*
Biosimilars (BsUFA)	*23*	*15,676*	---	*1,672*	*59*	*15,900*	*59*	*16,298*	---	*398*
Outsourcing Facility					*1*	*401*	*1*	*411*	---	*10*
Field	909	191,789	847	148,157	980	203,341	985	201,674	*5*	*-1,667*
Budget Authority	733	126,536	715	126,530	753	136,207	756	132,165	*3*	*-4,042*
User Fees	176	65,253	132	21,627	227	67,134	229	69,509	*2*	*2,375*
Prescription Drug (PDUFA)	*44*	*10,908*	*46*	*6,109*	*48*	*11,453*	*48*	*11,910*	---	*457*
Generic Drug (GDUFA)	*132*	*53,023*	*86*	*15,518*	*173*	*54,083*	*173*	*55,456*	---	*1,373*
Biosimilars (BsUFA)	---	*1,322*	---	---	*5*	*1,348*	*5*	*1,382*	---	*34*
Outsourcing Facility					*1*	*250*	*1*	*250*	---	---
International Courier	---	---	---	---	---	---	*2*	*511*	*2*	*511*
Biologics	**1,302**	**337,543**	**1,319**	**321,064**	**1,326**	**344,267**	**1,337**	**350,457**	***11***	***6,190***
Budget Authority	***815***	***210,928***	***835***	***210,912***	***837***	***211,382***	***846***	***215,021***	***9***	***3,639***
User Fees	***487***	***126,615***	***484***	***110,152***	***489***	***132,885***	***491***	***135,436***	***2***	***2,551***
Center	1,081	292,586	1,093	278,091	1,099	298,979	1,108	307,254	*9*	*8,275*
Budget Authority	604	170,744	616	170,733	617	171,096	624	174,052	*7*	*2,956*
User Fees	477	121,842	477	107,358	482	127,883	484	133,202	*2*	*5,319*
Prescription Drug (PDUFA)	*431*	*109,993*	*432*	*96,253*	*432*	*115,493*	*434*	*120,107*	*2*	*4,614*
Medical Device (MDUFA)	*42*	*10,301*	*42*	*10,211*	*43*	*10,549*	*43*	*11,208*	---	*659*
Generic Drug (GDUFA)	*3*	*774*	*3*	*671*	*4*	*1,052*	*4*	*1,078*	---	*26*
Biosimilars (BsUFA)	*1*	*774*	---	*223*	*3*	*789*	*3*	*809*	---	*20*
Field	221	44,957	226	42,973	227	45,288	229	43,203	*2*	*-2,085*
Budget Authority	211	40,184	219	40,179	220	40,286	222	40,969	*2*	*683*
User Fees	10	4,773	7	2,794	7	5,002	7	2,234	---	*-2,768*
Prescription Drug (PDUFA)	*9*	*4,581*	*7*	*2,618*	*6*	*4,810*	*6*	*2,022*	---	*-2,788*
Medical Device (MDUFA)	*1*	*192*	---	*176*	*1*	*192*	*1*	*212*	---	*20*

(dollars in thousands)	FY 2014 Final		FY 2014 Actuals		FY 2015 Enacted		FY 2016 President's Budget Request		+/- FY 2015 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Animal Drugs and Feed	**787**	**173,207**	**837**	**164,313**	**854**	**174,783**	**906**	**197,192**	***52***	***22,409***
Budget Authority	***671***	***141,566***	***727***	***141,566***	***735***	***147,577***	***773***	***165,752***	***38***	***18,175***
User Fees	***116***	***31,641***	***110***	***22,747***	***119***	***27,206***	***133***	***31,440***	***14***	***4,234***
Center	528	115,461	527	110,546	537	119,314	568	130,103	*31*	*10,789*
Budget Authority	415	87,846	417	87,845	424	93,505	443	101,105	*19*	*7,600*
User Fees	113	27,615	110	22,701	113	25,809	125	28,998	*12*	*3,189*
Animal Drug (ADUFA)	*85*	*20,768*	*83*	*17,281*	*85*	*19,814*	*85*	*19,527*	---	*-287*
Animal Generic Drug (AGDUFA)	*28*	*6,302*	*27*	*5,420*	*28*	*5,995*	*28*	*6,414*	---	*419*
Food and Feed Recall	---	*545*			---	---	---	---	---	---
Food Facility Registration and Inspection	---	---	---	---	---	---	*6*	*1,557*	*6*	*1,557*
Food Import	---	---	---	---	---	---	*6*	*1,500*	*6*	*1,500*
Field	259	57,746	310	53,767	317	55,469	338	67,089	*21*	*11,620*
Budget Authority	256	53,720	310	53,721	311	54,072	330	64,647	*19*	*10,575*
User Fees	3	4,026	---	46	6	1,397	8	2,442	*2*	*1,045*
Animal Drug (ADUFA)	*2*	*472*	---	*31*	*2*	*404*	*2*	*399*	---	*-5*
Animal Generic Drug (AGDUFA)	*1*	*220*	---	*15*	*1*	*186*	*1*	*198*	---	*12*
Food and Feed Recall	---	*668*	---	---	---	---	---	---	---	---
Food Reinspection	---	*2,666*	---	---	*3*	*807*	*3*	*807*	---	---
Food Facility Registration and Inspection	---	---	---	---	---	---	*2*	*1,038*	*2*	*1,038*
Devices and Radiological Health	**2,045**	**427,998**	**2,087**	**417,583**	**2,086**	**440,010**	**2,135**	**456,148**	**49**	**16,138**
Budget Authority	***1,582***	***320,825***	***1,620***	***320,815***	***1,620***	***320,825***	***1,642***	***327,760***	***22***	***6,935***
User Fees	***463***	***107,173***	***467***	***96,768***	***466***	***119,185***	***493***	***128,388***	***27***	***9,203***
Center	1,560	332,528	1,585	325,537	1,584	344,278	1,615	354,965	31	10,687
Budget Authority	1,115	240,345	1,136	240,336	1,136	240,345	1,155	246,166	19	5,821
User Fees	445	92,183	449	85,201	448	103,933	460	108,799	12	4,866
Medical Device (MDUFA)	*414*	*86,180*	*418*	*80,251*	*417*	*97,810*	*429*	*102,550*	*12*	*4,740*
Mammography Quality Standards Act (MQSA)	*31*	*6,003*	*31*	*4,950*	*31*	*6,123*	*31*	*6,249*	---	*126*
Field	485	95,470	502	92,046	502	95,732	520	101,183	18	5,451
Budget Authority	467	80,480	484	80,479	484	80,480	487	81,594	3	1,114
User Fees	18	14,990	18	11,567	18	15,252	33	19,589	15	4,337
Medical Device (MDUFA)	*10*	*1,913*	*10*	*1,780*	*10*	*1,913*	*10*	*2,148*	---	*235*
Mammography Quality Standards Act (MQSA)	*8*	*13,077*	*8*	*9,787*	*8*	*13,339*	*8*	*13,612*	---	*273*
International Courier	---	---	---	---	---	---	*15*	*3,829*	*15*	*3,829*
National Center for Toxicological Research (BA Only)	**242**	**62,494**	**286**	**62,488**	**287**	**63,331**	**288**	**58,998**	**1**	**-4,333**
August 2009 reprogramming (BA) to TOBACCO										
Family Smoking Prevention and Tobacco Control Act	**640**	**501,476**	**592**	**570,536**	**773**	**531,527**	**962**	**564,117**	**189**	**32,590**
Center (UF Only)	570	486,487	559	561,776	693	515,640	812	547,454	*119*	*31,814*
Field (UF Only)	70	14,989	33	8,760	80	15,887	150	16,663	*70*	*776*
FDA Headquarters	**1,326**	**275,439**	**1,090**	**244,990**	**1,179**	**277,453**	**1,234**	**299,453**	**55**	**22,000**
Budget Authority	***978***	***172,107***	***748***	***172,021***	***767***	***173,362***	***777***	***181,314***	***10***	***7,952***
User Fees	***348***	***103,332***	***342***	***72,969***	***412***	***104,091***	***457***	***118,139***	***45***	***14,048***
Prescription Drug (PDUFA)	*172*	*46,323*	*185*	*43,520*	*211*	*48,639*	*212*	*50,583*	*1*	*1,944*
Medical Device (MDUFA)	*30*	*6,485*	*30*	*6,588*	*30*	*6,733*	*30*	*6,113*	---	*-620*
Generic Drug (GDUFA)	*65*	*23,988*	*62*	*10,337*	*80*	*24,205*	*80*	*24,819*	---	*614*
Biosimilars (BsUFA)	---	*1,321*	---	*5*	*5*	*1,321*	*5*	*1,354*	---	*33*
Animal Drug (ADUFA)	*4*	*944*	*4*	*795*	*4*	*898*	*4*	*886*	---	*-12*
Animal Generic Drug (AGDUFA)	*1*	*293*	*1*	*200*	*1*	*277*	*1*	*297*	---	*20*
Family Smoking Prevention and Tobacco Control Act	*74*	*19,500*	*58*	*11,249*	*76*	*20,668*	*78*	*20,789*	*2*	*121*
Mammography Quality Standards Act (MQSA)	*2*	*238*	*2*	*275*	*2*	*243*	*2*	*248*	---	*5*
Food and Feed Recall	---	*691*	---	---	---	*75*	---	*75*	---	---
Food Reinspection	---	*3,549*	---	---	*2*	*480*	*2*	*480*	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	*277*	*1*	*277*	*1*	---
Third Party Auditor Program					---	---	---	*73*	---	*73*
Outsourcing Facility					*1*	*275*	*1*	*285*	---	*10*
Food Facility Registration and Inspection	---				---	---	*13*	*4,576*	*13*	*4,576*
Food Import	---	---	---	---	---	---	*23*	*5,659*	*23*	*5,659*
International Courier	---	---	---	---	---	---	*1*	*307*	*1*	*307*
Cosmetics	---	---	---	---	---	---	*3*	*1,041*	*3*	*1,041*
Food Contact Substance Notification	---				---	---	*1*	*277*	*1*	*277*
FDA White Oak Consolidation	---	**61,922**	---	**61,603**	---	**47,116**	---	**52,218**	---	**5,102**
Budget Authority	---	***58,044***	---	***58,044***	---	***43,044***	---	***48,044***	---	***5,000***
Prescription Drug (PDUFA)	---	***3,878***	---	***3,559***	---	***4,072***	---	***4,174***	---	***102***

(dollars in thousands)	FY 2014 Final		FY 2014 Actuals		FY 2015 Enacted		FY 2016 President's Budget			
							Request		+/- FY 2015 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Other Rent and Rent Related	---	**116,439**	---	**109,416**	---	**116,406**	---	**136,531**	---	**20,125**
Budget Authority	---	***74,674***	---	***74,674***	---	***72,943***	---	***89,137***	---	***16,194***
User Fees	---	***41,765***	---	***34,742***	---	***43,463***	---	***47,394***	---	***3,931***
Prescription Drug (PDUFA)	---	*26,794*	---	*21,076*	---	*28,134*	---	*28,837*	---	*703*
Medical Device (MDUFA)	---	*3,546*	---	*3,671*	---	*4,027*	---	*4,452*	---	*425*
Generic Drug (GDUFA)	---	*6,598*	---	*6,719*	---	*6,730*	---	*6,898*	---	*168*
Biosimilars (BsUFA)	---	*590*	---	*197*	---	*602*	---	*617*	---	*15*
Animal Drug (ADUFA)	---	*236*	---	*721*	---	*225*	---	*221*	---	*-4*
Animal Generic Drug (AGDUFA)	---	*73*	---	*238*	---	*69*	---	*74*	---	*5*
Family Smoking Prevention and Tobacco Control Act	---	*3,050*	---	*2,120*	---	*3,233*	---	*3,502*	---	*269*
Food and Feed Recall	---	*259*	---	---	---	*43*	---	*43*	---	---
Food Reinspection	---	*619*	---	---	---	*204*	---	*204*	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	*170*	---	*170*	---	---
Third Party Auditor Program					---	---	---	*45*	---	*45*
Outsourcing Facility					---	*26*	---	*26*	---	---
Food Facility Registration and Inspection			---		---	---		*827*	---	*827*
Food Import	---	---	---	---	---	---	---	*689*	---	*689*
International Courier	---	---	---	---	---	---	---	*188*	---	*188*
Cosmetics	---	---	---	---	---	---	---	*535*	---	*535*
Food Contact Substance Notification			---		---	---		*66*	---	*66*
GSA Rental Payments	---	**219,907**	---	**209,372**	---	**228,428**	---	**242,085**	---	**13,657**
Budget Authority	---	***162,076***	---	***162,076***	---	***168,882***	---	***176,683***	---	***7,801***
User Fees	---	***57,831***	---	***47,296***	---	***59,546***	---	***65,402***	---	***5,856***
Prescription Drug (PDUFA)	---	*22,997*	---	*24,548*	---	*24,147*	---	*24,751*	---	*604*
Medical Device (MDUFA)	---	*6,216*	---	*4,265*	---	*7,058*	---	*7,792*	---	*734*
Generic Drug (GDUFA)	---	*14,138*	---	*7,818*	---	*14,421*	---	*14,782*	---	*361*
Biosimilars (BsUFA)	---	*1,033*	---	*220*	---	*1,054*	---	*1,080*	---	*26*
Animal Drug (ADUFA)	---	*1,180*	---	*872*	---	*1,123*	---	*1,107*	---	*-16*
Animal Generic Drug (AGDUFA)	---	*440*	---	*286*	---	*417*	---	*446*	---	*29*
Family Smoking Prevention and Tobacco Control Act	---	*9,974*	---	*9,287*	---	*10,572*	---	*10,592*	---	*20*
Food and Feed Recall	---	*454*	---	---	---	*73*	---	*73*	---	---
Food Reinspection	---	*1,399*	---	---	---	*348*	---	*348*	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	*290*	---	*290*	---	---
Third Party Auditor Program					---	---	---	*77*	---	*77*
Outsourcing Facility					---	*43*	---	*43*	---	---
Food Facility Registration and Inspection			---		---	---		*1,467*	---	*1,467*
Food Import	---	---	---	---	---	---	---	*1,175*	---	*1,175*
International Courier	---	---	---	---	---	---	---	*326*	---	*326*
Cosmetics	---	---	---	---	---	---	---	*937*	---	*937*
Food Contact Substance Notification			---		---	---		*116*	---	*116*
Subtotal	**14,541**	**4,365,988**	**14,500**	**4,254,888**	**15,752**	**4,475,704**	**16,574**	**4,895,415**	**822**	**419,711**
Color Certification	**37**	**7,278**	**36**	**8,241**	**37**	**8,301**	**37**	**9,139**	---	**838**
Export Certification	**19**	**4,604**	**19**	**3,929**	**19**	**4,696**	**19**	**4,696**	---	---
Export Certification (proposed)							---	**4,280**	---	**4,280**
Priority Review Vouchers (PRV) Tropical Disease	---	---	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Pediatric Disease					---	**7,686**		**7,686**	---	---
Food and Drug Safety -- No Year (P.L. 113-6)	---	---	---	**23,610**	---	---	---	---	---	---
Food Safety	---	---	---	18,987	---	---	---	---	---	---
Drug Safety	---	---	---	4,623	---	---	---	---	---	---
Buildings and Facilities (Budget Authority)	---	**8,788**	---	**7,808**	---	**8,788**	---	**8,788**	---	---
Total Program Level	**14,597**	**4,386,658**	**14,555**	**4,298,476**	**15,808**	**4,505,175**	**16,630**	**4,930,004**	**822**	**424,829**
Non-Field Activities	10,027	2,941,285	9,930	2,924,556	10,972	3,055,416	11,455	3,244,661	483	189,245
Field Activities	4,570	1,038,317	4,625	962,111	4,836	1,049,021	5,175	1,241,441	339	192,420
White Oak, Rent Activities, and B&F	---	407,056	---	388,199	---	400,738	---	439,622	---	38,884
Food and Drug Safety -- No Year	---	---	---	23,610	---	---	---	---	---	---

(dollars in thousands)	FY 2014 Final		FY 2014 Actuals		FY 2015 Enacted		FY 2016 President's Budget			
							Request		+/- FY 2015 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
User Fees:										
Current Law										
Prescription Drug (PDUFA)	2,723	760,000	2,772	733,724	3,097	798,000	3,100	826,072	3	28,072
Medical Device (MDUFA)	497	114,833	500	106,942	501	128,282	513	134,475	12	6,193
Generic Drug (GDUFA)	539	305,996	480	226,129	921	312,116	921	320,029	---	7,913
Biosimilars (BsUFA)	24	20,716	---	2,317	72	21,014	72	21,540	---	526
Animal Drug (ADUFA)	91	23,600	87	19,700	91	22,464	91	22,140	---	-324
Animal Generic Drug (AGDUFA)	30	7,328	28	6,159	30	6,944	30	7,429	---	485
Family Smoking Prevention and Tobacco Control Act	714	534,000	650	593,192	849	566,000	1,040	599,000	191	33,000
Indefinite										
Mammography Quality Standards Act (MQSA)	41	19,318	41	15,012	41	19,705	41	20,109	---	404
Color Certification	37	7,278	36	8,241	37	8,301	37	9,139	---	838
Export Certification	19	4,604	19	3,929	19	4,696	19	4,696	---	---
Priority Review Vouchers (PRV) Tropical Disease	---	---	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Pediatric Disease		---	---	---		7,686		7,686	---	---
Food and Feed Recall	---	12,925	---	---	5	1,434	5	1,434	---	---
Food Reinspection	---	15,367	---	---	24	6,414	24	6,414	---	---
Voluntary Qualified Importer Program	---	---	---	---	---	5,300	20	5,300	20	---
Third Party Auditor Program	---	---	---	---	---	---	6	1,400	6	1,400
Outsourcing Facility	---	---	---	---	3	995	3	1,015	---	20
Subtotal, Current Law	**4,715**	**1,825,965**	**4,613**	**1,715,345**	**5,690**	**1,909,351**	**5,922**	**1,987,878**	**232**	**78,527**
Proposed										
Export Certification	---	---	---	---	---	---	---	4,280	---	4,280
Food Facility Registration and Inspection	---	---	---	---	---	---	69	60,120	69	60,120
Food Import	---	---	---	---	---	---	81	103,343	81	103,343
International Courier	---	---	---	---	---	---	21	5,926	21	5,926
Cosmetics	---	---	---	---	---	---	63	19,856	63	19,856
Food Contact Substance Notification	---	---	---	---	---	---	8	5,098	8	5,098
Subtotal, Proposed	**---**	**---**	**---**	**---**	**---**	**---**	**242**	**198,623**	**242**	**198,623**
Total User Fees	**4,715**	**1,825,965**	**4,613**	**1,715,345**	**5,690**	**1,909,351**	**6,164**	**2,186,501**	**474**	**277,150**
Total Budget Authority	**9,882**	**2,560,693**	**9,942**	**2,583,131**	**10,118**	**2,595,824**	**10,466**	**2,743,503**	**348**	**147,679**
Total Program Level	**14,597**	**4,386,658**	**14,555**	**4,298,476**	**15,808**	**4,505,175**	**16,630**	**4,930,004**	**822**	**424,829**

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

** FY 2015 Enacted level is $12.5 million lower than the fee collections estimated in FDA's FY 2015 User Fee Federal Register notices.

*** The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

**** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

***** FTE figures do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR. FY 2015 and FY 2016 estimated FTE levels in the APT have been updated based on FY 2014 actual usage information.

****** Export Certification funding displayed under Proposed User fees reflects FDA's legislative proposal to increase this fee in FY 2016.

MAJOR ACTIVITIES TABLE

Food and Drug Administration
Major Activities
(Dollars in Thousands)

Program	FY 2014 Final								FY 2015 Enacted								FY 2016 President's Budget								FY 2016 Request +/- FY 2015 Enacted							
	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	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Budget Authority:																																
Foods	**3,551**	**882,817**	---	---	---	---	**3,551**	**882,817**	**3,720**	**903,403**	---	---	---	---	**3,720**	**903,403**	**3,977**	**987,328**	---	---	---	---	**3,977**	**987,328**	**257**	**83,925**	---	---	---	---	**257**	**83,925**
Center	925	266,408	---				925	266,408	1,013	279,994					1,013	279,994	1,158	303,994					1,158	303,994	145	24,000	---	---	---	---	145	24,000
Field	2,626	616,409	---				2,626	616,409	2,707	623,409					2,707	623,409	2,819	683,334					2,819	683,334	112	59,925	---	---	---	---	112	59,925
Human Drugs	---	---	**2,023**	**460,354**	**20**	**6,020**	**2,043**	**466,374**	---	---	**2,132**	**476,267**	**20**	**6,020**	**2,152**	**482,287**	---	---	**2,143**	**478,658**	**20**	**6,020**	**2,163**	**484,678**	---	---	**11**	**2,391**	---	---	**11**	**2,391**
Center	---		1,290	333,818	20	6,020	1,310	339,838			1,379	340,060	20	6,020	1,399	346,080			1,387	346,493	20	6,020	1,407	352,513	---	---	8	6,433	---	---	8	6,433
Field	---		733	126,536	---	---	733	126,536			753	136,207	---	---	753	136,207			756	132,165	---	---	756	132,165	---	---	3	-4,042	---	---	3	-4,042
Biologics	---	---	**806**	**208,533**	**9**	**2,395**	**815**	**210,928**	---	---	**828**	**208,987**	**9**	**2,395**	**837**	**211,382**	---	---	**837**	**212,626**	**9**	**2,395**	**846**	**215,021**	---	---	**9**	**3,639**	---	---	**9**	**3,639**
Center	---		595	168,349	9	2,395	604	170,744			608	168,701	9	2,395	617	171,096			615	171,657	9	2,395	624	174,052	---	---	7	2,956	---	---	7	2,956
Field	---		211	40,184	---	---	211	40,184			220	40,286	---	---	220	40,286			222	40,969	---	---	222	40,969	---	---	2	683	---	---	2	683
Animal Drugs and Feeds	**535**	**112,730**	**136**	**28,836**	---	---	**671**	**141,566**	**587**	**112,730**	**148**	**34,847**	---	---	**735**	**147,577**	**618**	**125,305**	**155**	**40,447**	---	---	**773**	**165,752**	**31**	**12,575**	**7**	**5,600**	---	---	**38**	**18,175**
Center	291	61,549	124	26,297	---	---	415	87,846	292	61,549	132	31,956	---	---	424	93,505	304	63,549	139	37,556	---	---	443	101,105	12	2,000	7	5,600	---	---	19	7,600
Field	244	51,181	12	2,539	---	---	256	53,720	295	51,181	16	2,891	---	---	311	54,072	314	61,756	16	2,891	---	---	330	64,647	19	10,575	---	---	---	---	19	10,575
Devices and Radiological Health	---	---	**1,567**	**316,824**	**15**	**4,001**	**1,582**	**320,825**	---	---	**1,605**	**316,824**	**15**	**4,001**	**1,620**	**320,825**	---	---	**1,627**	**323,759**	**15**	**4,001**	**1,642**	**327,760**	---	---	**22**	**6,935**	---	---	**22**	**6,935**
Center	---		1,100	236,344	15	4,001	1,115	240,345			1,121	236,344	15	4,001	1,136	240,345			1,140	242,165	15	4,001	1,155	246,166	---	---	19	5,821	---	---	19	5,821
Field	---		467	80,480	---	---	467	80,480			484	80,480	---	---	484	80,480			487	81,594	---	---	487	81,594	---	---	3	1,114	---	---	3	1,114
National Center for Toxicological Research	**40**	**10,233**	**202**	**52,261**	---	---	**242**	**62,494**	**47**	**10,233**	**240**	**53,098**	---	---	**287**	**63,331**	**47**	**5,900**	**241**	**53,098**	---	---	**288**	**58,998**	---	**-4,333**	**1**	---	---	---	**1**	**-4,333**
FDA Headquarters	**438**	**70,331**	**507**	**81,464**	**33**	**10,312**	**978**	**172,107**	**333**	**73,285**	**401**	**79,765**	**33**	**10,312**	**767**	**173,362**	**337**	**77,783**	**407**	**83,219**	**33**	**10,312**	**777**	**181,314**	**4**	**4,498**	**6**	**3,454**	---	---	**10**	**7,952**
FDA White Oak Consolidation	---			---	---		---	**58,044**			---	---	---	---	---	**43,044**			---	---	---	---	---	**48,044**	---	---	---	---	---	---	---	**5,000**
Other Rent and Rent Related	---	**36,503**	---	**37,235**	---	**936**	---	**74,674**	---	**36,682**	---	**35,325**	---	**936**	---	**72,943**	---	**44,831**	---	**43,370**	---	**936**	---	**89,137**	---	**8,149**	---	**8,045**	---	---	---	**16,194**
GSA Rental Payments	---	**75,341**	---	**85,847**	---	**888**	---	**162,076**	---	**78,145**	---	**89,849**	---	**888**	---	**168,882**	---	**82,789**	---	**93,006**	---	**888**	---	**176,683**	---	**4,644**	---	**3,157**	---	---	---	**7,801**
Food and Drug Safety -- No Year	---				---		---	---	---		---				---	---			---				---	---							---	---
Food Safety								---							---	---							---	---							---	---
Drug Safety								---							---	---							---	---							---	---
SUBTOTAL, BA Salaries and Expenses	**4,564**	**1,187,955**	**5,241**	**1,271,354**	**77**	**24,552**	**9,882**	**2,551,905**	**4,687**	**1,214,478**	**5,354**	**1,294,962**	**77**	**24,552**	**10,118**	**2,587,036**	**4,979**	**1,323,936**	**5,410**	**1,328,183**	**77**	**24,552**	**10,466**	**2,734,715**	**292**	**109,458**	**56**	**33,221**	---	---	**348**	**147,679**
Building and Facilities								**8,788**							---	**8,788**							---	**8,788**	---	---	---	---	---	---	---	---
Total BA	**4,564**	**1,187,955**	**5,241**	**1,271,354**	**77**	**24,552**	**9,882**	**2,560,693**	**4,687**	**1,214,478**	**5,354**	**1,294,962**	**77**	**24,552**	**10,118**	**2,595,824**	**4,979**	**1,323,936**	**5,410**	**1,328,183**	**77**	**24,552**	**10,466**	**2,743,503**	**292**	**109,458**	**56**	**33,221**	---	---	**348**	**147,679**
Total User Fees		**29,559**	**3,964**	**1,255,128**	---		**4,715**	**1,825,965**	**29**	**14,415**	**4,775**	**1,320,635**			**5,690**	**1,909,351**	**279**	**206,197**	**4,808**	**1,372,165**	---		**6,164**	**2,186,501**	**250**	**191,782**	**33**	**51,530**	---	---	**474**	**277,150**
Current Law																																
Prescription Drug (PDUFA)			2,723	760,000			2,723	760,000			3,097	798,000			3,097	798,000			3,100	826,072			3,100	826,072	---	---	3	28,072	---	---	3	28,072
Medical Device (MDUFA)			497	114,833			497	114,833			501	128,282			501	128,282			513	134,475			513	134,475	---	---	12	6,193	---	---	12	6,193
Generic Drug (GDUFA)			539	305,996			539	305,996			921	312,116			921	312,116			921	320,029			921	320,029	---	---	---	7,913	---	---	---	7,913
Biosimilars (BsUFA)			24	20,716			24	20,716			72	21,014			72	21,014			72	21,540			72	21,540	---	---	---	526	---	---	---	526
Animal Drug (ADUFA)			91	23,600			91	23,600			91	22,464			91	22,464			91	22,140			91	22,140	---	---	---	-324	---	---	---	-324
Animal Generic Drug (AGDUFA)			30	7,328			30	7,328			30	6,944			30	6,944			30	7,429			30	7,429	---	---	---	485	---	---	---	485
Family Smoking Prevention and Tobacco Control Act	---						714	534,000							849	566,000							1,040	599,000	---	---	---	---	---	---	191	33,000
Mammography Quality Standards Act (MQSA)			41	19,318			41	19,318			41	19,705			41	19,705			41	20,109			41	20,109	---	---	---	404	---	---	---	404
Color Certification	---						37	7,278							37	8,301							37	9,139	---	---	---	---	---	---	---	838
Export Certification	---	1,267	19	3,337			19	4,604	---	1,267	19	3,429			19	4,696	---	2,003	19	6,973			19	8,976	---	736	---	3,544	---	---	---	4,280
Priority Review Vouchers (PRV) Tropical Disease		---	---	---			---	---	---	---	---	---	---		---	---	---	---	---	---	---		---	---	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Pediatric Disease									---		---	7,686			---	7,686			---	7,686			---	7,686	---	---	---	---	---	---	---	---
Food and Feed Recall	---	12,925					---	12,925	5	1,434					5	1,434	5	1,434					5	1,434	---	---	---	---	---	---	---	---
Food Reinspection		15,367					---	15,367	24	6,414					24	6,414	24	6,414					24	6,414	---	---	---	---	---	---	---	---
Voluntary Qualified Importer Program	---	---	---	---			---	---	---	5,300					---	5,300	20	5,300	---		---		20	5,300	---	---	---	---	---	---	20	---
Third Party Auditor Program							---		---	---					---	---	6	1,400					6	1,400	6	1,400	---	---	---	---	6	1,400
Outsourcing Facility							---		3	995					3	995			3	1,015			3	1,015	---	---	---	20	---	---	---	20
Proposed																																
Food Facility Registration and Inspection							---		---	---					---	---	69	60,120					69	60,120	69	60,120	---	---	---	---	69	60,120
Food Import							---		---	---					---	---	81	103,343					81	103,343	81	103,343	---	---	---	---	81	103,343
International Courier							---		---	---	---	---			---	---	3	1,229	18	4,697			21	5,926	3	1,229	18	4,697	---	---	21	5,926
Cosmetics							---		---	---					---	---	63	19,856					63	19,856	63	19,856	---	---	---	---	63	19,856
Food Contact Substance Notification							---		---	---					---	---	8	5,098					8	5,098	8	5,098	---	---	---	---	8	5,098
Total Program Level	**4,564**	**1,217,514**	**9,205**	**2,526,482**	**77**	**24,552**	**14,597**	**4,386,658**	**4,716**	**1,228,893**	**10,129**	**2,615,597**	**77**	**24,552**	**15,808**	**4,505,175**	**5,258**	**1,530,133**	**10,218**	**2,700,348**	**77**	**24,552**	**16,630**	**4,930,004**	**542**	**301,240**	**89**	**84,751**	---	---	**822**	**424,829**

* Total Budget Authority includes $10 million for the China Initiative. FDA White Oak Consolidation, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification User Fees are not included in Food Safety, Medical Product Safety, and Medical Countermeasures activities.

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

*** FY 2015 Enacted level is $12.5 million lower than the fee collections estimated in FDA's FY 2015 User Fee Federal Register notices.

**** The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

***** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

****** FTE figures do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR. FY 2015 and FY 2016 estimated FTE levels in the APT have been updated based on FY 2014 actual year to date usage information.

******* FY 2016 Medical Product Safety total includes restoration of $1.5 million transferred from FDA to HHS OIG in FY 2015.

********In FY 2016, FDA is proposing an increase of $4.3 million for the export certification program by increasing the statutory maximum for the certification fee.

FY 2015 BUDGET AUTHORITY CROSSWALK

(Dollars in Thousands)	FY 2014 Enacted		Program Changes and FTE Annualization [1]		Increases												Total Increase		Total Changes		FY 2015 Enacted	
					Food Safety		Medical Product Safety															
							Antimicrobial Resistance [2]		Pharmacy Compounding		Drug Inspections		Counterfeit Drugs		Medical Product Safety Sub-Total							
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																						
Foods	**3,650**	**882,817**	**52**	**---**	**18**	**20,586**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**18**	**20,586**	**70**	**20,586**	**3,720**	**903,403**
Center	943	266,408	52	---	18	13,586	---	---						---	---	---	18	13,586	70	13,586	1,013	279,994
Field	2,707	616,409	---	---	---	7,000	---	---						---	---	---	---	7,000	---	7,000	2,707	623,409
Human Drugs	**2,076**	**466,374**	**---**	**---**	**---**	**---**	**---**	**---**	**67**	**9,368**	**---**	**2,000**	**9**	**4,545**	**76**	**15,913**	**76**	**15,913**	**76**	**15,913**	**2,152**	**482,287**
Center	1,361	339,838	---	---	---	---	---	---	37	5,882	---	---	1	360	38	6,242	38	6,242	38	6,242	1,399	346,080
Field	715	126,536	---	---	---	---	---	---	30	3,486	---	2,000	8	4,185	38	9,671	38	9,671	38	9,671	753	136,207
Biologics	**835**	**210,928**	**---**	**---**	**---**	**---**	**---**	**---**	**2**	**454**	**---**	**---**	**---**	**---**	**2**	**454**	**2**	**454**	**2**	**454**	**837**	**211,382**
Center	616	170,744	---	---	---	---	---	---	1	352	---	---	---	---	1	352	1	352	1	352	617	171,096
Field	219	40,184	---	---	---	---	---	---	1	102	---	---	---	---	1	102	1	102	1	102	220	40,286
Animal Drugs and Feeds	**727**	**141,566**	**---**	**---**	**---**	**---**	**1**	**3,977**	**7**	**2,034**	**---**	**---**	**---**	**---**	**8**	**6,011**	**8**	**6,011**	**8**	**6,011**	**735**	**147,577**
Center	417	87,846	---	---	---	---	1	3,977	6	1,682	---	---	---	---	7	5,659	7	5,659	7	5,659	424	93,505
Field	310	53,720	---	---	---	---			1	352			---	---	1	352	1	352	1	352	311	54,072
Devices and Radiological Health	**1,620**	**320,825**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**1,620**	**320,825**
Center	1,136	240,345	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	1,136	240,345
Field	484	80,480	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	484	80,480
National Center for Toxicological Research	**286**	**62,494**	**1**	**837**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**1**	**837**	**287**	**63,331**
FDA Headquarters	**748**	**172,107**	**3**	**-3,449**	**2**	**2,954**	**---**	**---**	**13**	**1,475**	**---**	**---**	**1**	**275**	**14**	**1,750**	**16**	**4,704**	**19**	**1,255**	**767**	**173,362**
FDA White Oak Consolidation		**58,044**		**-15,000**		**---**		**---**		**---**				**---**	**---**	**---**	**---**	**---**	**---**	**-15,000**	**---**	**43,044**
Other Rent and Rent Related		**74,674**		**-2,289**		**179**		**---**		**379**		**---**		**---**	**---**	**379**	**---**	**558**	**---**	**-1,731**	**---**	**72,943**
GSA Rental Payments		**162,076**		**2,712**		**2,804**		**---**		**1,290**		**---**		**---**	**---**	**1,290**	**---**	**4,094**	**---**	**6,806**	**---**	**168,882**
Subtotal, Salaries and Expenses Account	**9,942**	**2,551,905**	**56**	**-17,189**	**20**	**26,523**	**1**	**3,977**	**89**	**15,000**	**---**	**2,000**	**10**	**4,820**	**100**	**25,797**	**120**	**52,320**	**176**	**35,131**	**10,118**	**2,587,036**
Buildings and Facilities Account		**8,788**		**---**										**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**8,788**
Total Budget Authority	**9,942**	**2,560,693**	**56**	**-17,189**	**20**	**26,523**	**1**	**3,977**	**89**	**15,000**	**---**	**2,000**	**10**	**4,820**	**100**	**25,797**	**120**	**52,320**	**176**	**35,131**	**10,118**	**2,595,824**
Non-Field Activities	**5,507**	**1,339,782**	**56**	**-2,612**	**20**	**16,540**	**1**	**3,977**	**57**	**9,391**	**---**	**---**	**2**	**635**	**60**	**14,003**	**80**	**30,543**	**136**	**27,931**	**5,643**	**1,367,713**
Field Activities	**4,435**	**917,329**	**---**	**---**	**---**	**7,000**	**---**	**---**	**32**	**3,940**	**---**	**2,000**	**8**	**4,185**	**40**	**10,125**	**40**	**17,125**	**40**	**17,125**	**4,475**	**934,454**
Rent Activities, B&F, and White Oak	**---**	**303,582**	**---**	**-14,577**	**---**	**2,983**	**---**	**---**	**---**	**1,669**	**---**	**---**	**---**	**---**	**---**	**1,669**	**---**	**4,652**	**---**	**-9,925**	**---**	**293,657**

[1] Includes additional 52 FTE due to Center resource realignment to support FSMA implementation and other mandates, and reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities. In the Major Activities Table: -$2.3 million of ORRR and $2.7 million of GSA Rent are associated with Medical Product Safety.

[2] FY 2015 increase of $997K / 1 FTE in Animal Drugs and Feeds program for antimicrobial resistance re-aligned to medical product safety.

FY 2016 BUDGET AUTHORITY CROSSWALK

(Dollars in Thousands)	FY 2015 Enacted[1]		FTE Annual-ization[2]	Pay Inflation Cost (non-add)	Reductions and Program Changes[3]		Increases																Total Increase		Total Changes		FY 2016 President's Budget	
							Rent and Infrastructure[4]	Food Safety		Medical Product Safety											Medical Product Safety Sub-Total							
										FDASIA Implementation		Combating Antibiotic Resistance Bacteria		Precision Medicine		Compounding		Sunscreen									
	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																											
Foods	**3,720**	**903,403**	**119**	**-6,395**	---	---	---	**138**	**83,925**	---	---	---	---	---	---	---	---	---	---	---	---	**138**	**83,925**	**257**	**83,925**	**3,977**	**987,328**
Center	1,013	279,994	108	-1,868		---	---	37	24,000															145	24,000	1,158	303,994
Field	2,707	623,409	11	-4,527		---	---	101	59,925													101	59,925	112	59,925	2,819	683,334
Human Drugs	**2,152**	**482,287**	**9**	**-3,601**	---	**-4,042**	---	---	---	---	---	**2**	**5,000**	---	---	---	**717**	---	**716**	**2**	**6,433**	**2**	**6,433**	**11**	**2,391**	**2,163**	**484,678**
Center	1,399	346,080	6	-2,341		---	---			---	---	2	5,000	---	---		717		716	2	6,433	2	6,433	8	6,433	1,407	352,513
Field	753	136,207	3	-1,260		-4,042	---			---	---	---	---	---	---		---		---	---	---	---	---	3	-4,042	756	132,165
Biologics	**837**	**211,382**	**4**	**-1,401**	-5	**-1,628**	---	---	---	**4**	**3,035**	**6**	**2,232**	---	---	---	---	---	---	**10**	**5,267**	**10**	**5,267**	**9**	**3,639**	**846**	**215,021**
Center	617	171,096	3	-1,033	-5	-1,206	---			3	1,930	6	2,232	---	---		---		---	9	4,162	9	4,162	7	2,956	624	174,052
Field	220	40,286	1	-368		-422	---			1	1,105	---	---	---	---		---		---	1	1,105	1	1,105	2	683	222	40,969
Animal Drugs and Feeds	**735**	**147,577**	**3**	**-1,230**	---	**-3,000**	---	**28**	**14,075**	---	---	**7**	**7,100**	---	---	---	---	---	---	**7**	**7,100**	**35**	**21,175**	**38**	**18,175**	**773**	**165,752**
Center	424	93,505	2	-710		-3,000	---	10	3,500	---	---	7	7,100	---	---		---		---	7	7,100	17	10,600	19	7,600	443	101,105
Field	311	54,072	1	-520		---	---	18	10,575													18	10,575	19	10,575	330	64,647
Devices and Radiological Health	**1,620**	**320,825**	**7**	**-2,711**	---	**-2,888**	---	---	---	**1**	**1,965**	---	**500**	**14**	**7,358**	---	---	---	---	**15**	**9,823**	**15**	**9,823**	**22**	**6,935**	**1,642**	**327,760**
Center	1,136	240,345	5	-1,901		-2,037	---			---		---	500	14	7,358		---		---	14	7,858	14	7,858	19	5,821	1,155	246,166
Field	484	80,480	2	-810		-851	---			1	1,965	---	---	---	---		---		---	1	1,965	1	1,965	3	1,114	487	81,594
National Center for Toxicological Research	**287**	**63,331**	**1**	-480		**-4,333**	---										---				---	---	---	**1**	**-4,333**	**288**	**58,998**
FDA Headquarters	**767**	**173,362**	**3**	-1,283		**1,500**	---	**3**	**4,498**	---	---	---	---	**4**	**1,954**					**4**	**1,954**	**7**	**6,452**	**10**	**7,952**	**777**	**181,314**
FDA White Oak Consolidation		**43,044**				---	**5,000**										---				---	---	---	---	**5,000**	---	**48,044**
Other Rent and Rent Related		**72,943**				---	**15,653**		**396**		---		---		**145**						---	---	**16,194**	---	**16,194**	---	**89,137**
GSA Rental Payments		**168,882**				---	**5,954**		**1,600**		---		---		**247**						---	---	**7,801**	---	**7,801**	---	**176,683**
Subtotal, Salaries and Expenses Account	**10,118**	**2,587,036**	**146**	**-17,101**	-5	**-14,391**	**26,607**	**169**	**104,494**	**5**	**5,000**	**15**	**14,832**	**18**	**9,704**	---	**717**	---	**716**	**38**	**30,969**	**207**	**162,070**	**348**	**147,679**	**10,466**	**2,734,715**
Buildings and Facilities Account		**8,788**				---	---										---				---	---	---	---	---	---	**8,788**
Total Budget Authority	**10,118**	**2,595,824**	**146**	**-17,101**	-5	**-14,391**	**26,607**	**169**	**104,494**	**5**	**5,000**	**15**	**14,832**	**18**	**9,704**	---	**717**	---	**716**	**38**	**30,969**	**207**	**162,070**	**348**	**147,679**	**10,466**	**2,743,503**
Non-Field Activities	**5,643**	**1,367,713**	**128**	**-9,616**	-5	**-9,076**	---	**50**	**31,998**	**3**	**1,930**	**15**	**14,832**	**18**	**9,312**	---	**717**	---	**716**	**36**	**27,507**	**86**	**59,505**	**209**	**50,429**	**5,852**	**1,418,142**
Field Activities	**4,475**	**934,454**	**18**	**-7,485**	---	**-5,315**	---	**119**	**70,500**	**2**	**3,070**	---	---	---	---	---	---	---	---	**2**	**3,070**	**121**	**73,570**	**139**	**68,255**	**4,614**	**1,002,709**
Rent Activities, B&F, and White Oak	---	**293,657**	---	---	---	---	**26,607**	---	**1,996**	---	---	---	---	---	**392**	---	---	---	---	---	**392**	---	**28,995**	---	**28,995**	---	**322,652**

[1]The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

[2]Includes an additional 104 FTE due to Center resource realignment to support FSMA implementation and other mandates.

[3]Includes restoration of $1.5 million transferred from FDA to HHS OIG in FY 2015.

[4]In the Major Activities Table: $7.6 million of ORRR and $3.0 million of GSA Rent are associated with Food Safety; $7.9 million of ORRR and $2.9 million of GSA Rent are associated with Medical Product Safety. The total FY 2016 budget authority request for Food Safety is $109.5 million; the total FY 2016 budget authority request for Medical Product Safety is $33.2 million.

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,,443,356,000**]**[3] *$4,665,400,000: Provided,* That of the amount provided under this heading, [$798,000,000] $*826,072,000* 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; [$128,282,000] *$134,475,000* 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; [$312,116,000] *$320,029,000* 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; [$21,014,000] *$21,540,000* 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; [$22,464,000] *$22,140,000* 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; [$6,944,000] *$7,429,000* 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; [$566,000,000] *$599,000,000* 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: *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 **[**2015**]** *2016* 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 **[**2015**]** *2016*, including any such fees collected prior to fiscal year **[**2015**]** *2016* but credited for fiscal year **[**2015**]** *2016*, shall be subject to the fiscal year **[**2015**]** *2016* limitations: Provided further, That the Secretary may accept payment during fiscal year **[**2015**]** *2016* of user fees specified under this heading and authorized for fiscal year **[**2016**]** *2017*, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year **[**2016**]** *2017* for which the Secretary accepts payment in fiscal year **[**2015**]** *2016* 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) $903,403,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $1,337,948,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $344,267,000 shall be for the Center for Biologics Evaluation and

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

Research and for related field activities in the Office of Regulatory Affairs; (4) $173,976,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $420,548,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $63,331,000 shall be for the National Center for Toxicological Research; (7) $531,527,000 shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) not to exceed $163,079,000 shall be for Rent and Related activities, of which $47,116,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9) not to exceed $227,674,000 shall be for payments to the General Services Administration for rent; and (10) $277,603,000 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 of the amounts that are made available under this heading for ''other activities'', and that are not derived from user fees, $1,500,000 shall be transferred to and merged with the appropriation for ''Department of Health and Human Services—Office of Inspector General'' for oversight of the programs and operations of the Food and Drug Administration and shall be in addition to funds otherwise made available for oversight of the Food and Drug Administration:**]** *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, priority review user fees authorized by 21 U.S.C. 360n and 360ff, 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), third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1), and third-party auditor authorized by 21 U.S.C. 384d(c)(8), 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 shall assess an increase in export certification user fees otherwise appropriated under this heading, and such fees shall be credited to this account and remain available until expended.

APPROPRIATION 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 and informing industry.
International Courier User Fee	The Administration will propose legislation to allow FDA to collect fees for international couriers. The additional resources are estimated at $5,926,000.
Cosmetic User Fee	The Administration will propose legislation to allow FDA to collect fees for cosmetic safety. The additional resources, estimated at $19,856,000, will allow FDA to establish and maintain a Cosmetic Registration Program.
Food Contact Notification User Fee	The Administration will propose legislation to allow FDA to collect fees for food contact and notification. The additional resources, estimated at $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 $103,343,000 million to support FDA's food safety efforts. The fee will have exemptions for small importers and a maximum charge for large importers.
Export Certification Fee	The Administration will propose legislation to allow FDA to increase the funding cap for the export certification fee from $175 per certification to $600 per certification for an estimated total of $4,280,000. This proposal, and the increased certification fee ceiling it promotes, is necessary to ensure that FDA can efficiently implement the export certification program, while ensuring that other public health programs do not suffer.

In addition, mammography user fees authorized by 42 U.S.C. 263b, export certification fees authorized by 21 U.S.C. 381, priority review user fees authorized by 21 U.S.C. 360n and 360ff, 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), third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1), and third-party auditor authorized by 21 U.S.C. 384d(c)(8), shall be credited to this account, to remain available until expended.	This provision allows collection of the third-party auditor fee.

AMOUNTS AVAILABLE FOR OBLIGATION

(dollars in thousands)	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
General Fund Discretionary Appropriation:			
Appropriation	2,583,131	2,595,824	2,743,503
Total Discretionary Appropriation	**2,583,131**	**2,595,824**	**2,743,503**
Mandatory Appropriation:			
CRADA	2,000	2,000	2,000
Total Mandatory Appropriation	**2,000**	**2,000**	**2,000**
Offsetting Collections:			
Non-Federal Sources:	1,715,345	1,909,351	2,186,501
Total Offsetting Collections	**1,715,345**	**1,909,351**	**2,186,501**
Unobligated Balances Previously Unavailable:			
Sequestered fees from FY 2013	78,691	---	---
Total Unobligated Balances Previously Unavailable	**78,691**	**---**	**---**
Total Obligations	**4,379,167**	**4,507,175**	**4,932,004**

* FY 2015 Enacted level is $12.5 million lower than the fee collections estimated in FDA's FY 2015 User Fee Federal Register notices.

** The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

*** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

SUMMARY OF CHANGES

(dollars in thousands)	Budget Authority	User Fees	Program Level	FTE
FY 2015 Enacted	**2,595,824**	**1,909,351**	**4,505,175**	**15,808**
FY 2016 Program Changes				
Budget Authority Changes				
Reductions and Program Changes	**-14,391**		**-14,391**	
Rent and Infrastructure	26,607		26,607	
Food Safety	104,494		104,494	
FDASIA Implementation	5,000		5,000	
Combating Antibiotic Resistance Bacteria	14,832		14,832	
Precision Medicine	9,704		9,704	
Pharmacy Compounding	717		717	
Sunscreen	716		716	
Total Budget Authority Changes	**147,679**		**147,679**	**348**
User Fee Changes				
Current Law				
Prescription Drug (PDUFA)		28,072	28,072	3
Medical Device (MDUFA)		6,193	6,193	12
Generic Drug (GDUFA)		7,913	7,913	---
Biosimilars (BsUFA)		526	526	---
Animal Drug (ADUFA)		-324	-324	---
Animal Generic Drug (AGDUFA)		485	485	---
Family Smoking Prevention and Tobacco Control Act		33,000	33,000	191
Indefinite				
Mammography Quality Standards Act (MQSA)		404	404	---
Color Certification		838	838	---
Export Certification		---	---	---
Priority Review Vouchers (PRV) Tropical Disease		---	---	---
Priority Review Vouchers (PRV) Pediatric Disease		---	---	---
Food and Feed Recall		---	---	---
Food Reinspection		---	---	---
Voluntary Qualified Importer Program		---	---	20
Third Party Auditor Program		1,400	1,400	6
Outsourcing Facility		20	20	---
Subtotal, Current Law		**78,527**	**78,527**	**232**
Proposed				
Export Certification		4,280	4,280	---
Food Facility Registration and Inspection		60,120	60,120	69
Food Import		103,343	103,343	81
International Courier		5,926	5,926	21
Cosmetics		19,856	19,856	63
Food Contact Substance Notification		5,098	5,098	8
Subtotal, Proposed		**198,623**	**198,623**	**242**
Net Program Changes	**147,679**	**277,150**	**424,829**	**822**
Total FDA Request for FY 2016	**2,743,503**	**2,186,501**	**4,930,004**	**16,630**

* FY 2015 Enacted level is $12.5 million lower than the fee collections estimated in FDA's FY 2015 User Fee Federal Register notices.

** The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

*** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

**** FTE figures do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR. FY 2015 and FY 2016 estimated FTE levels in the APT have been updated based on FY 2014 actual year to date usage information.

*****FY 2016 Reductions and Program Changes includes restoration of $1.5 million transferred from FDA to HHS OIG in FY 2015. The total FY 2016 budget authority request for Food Safety is $109.5 million; the total FY 2016 budget authority request for Medical Product Safety is $33.2 million.

BUDGET AUTHORITY BY ACTIVITY

(dollars in thousands)	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget
Salaries and Expenses Account:			
Foods	**882,814**	**903,403**	**987,328**
Center	266,406	279,994	303,994
Field	616,408	623,409	683,334
Human Drugs	**466,303**	**482,287**	**484,678**
Center	339,773	346,080	352,513
Field	126,530	136,207	132,165
Biologics	**210,912**	**211,382**	**215,021**
Center	170,733	171,096	174,052
Field	40,179	40,286	40,969
Animal Drugs and Feeds	**141,566**	**147,577**	**165,752**
Center	87,845	93,505	101,105
Field	53,721	54,072	64,647
Devices and Radiological Health	**320,815**	**320,825**	**327,760**
Center	240,336	240,345	246,166
Field	80,479	80,480	81,594
National Center for Toxicological Research	**62,488**	**63,331**	**58,998**
FDA Headquarters	**172,021**	**173,362**	**181,314**
FDA White Oak Consolidation	**58,044**	**43,044**	**48,044**
Other Rent and Rent Related	**74,674**	**72,943**	**89,137**
GSA Rental Payments	**162,076**	**168,882**	**176,683**
Subtotal, Salaries and Expenses Account	**2,551,713**	**2,587,036**	**2,734,715**
Food and Drug Safety -- No Year (P.L. 113-6)	**23,610**	---	---
Food Safety	18,987	---	---
Drug Safety	4,623	---	---
Buildings and Facilities Account	**7,808**	**8,788**	**8,788**
Total Budget Authority	**2,583,131**	**2,595,824**	**2,743,503**
FTE	**9,942**	**10,118**	**10,466**

* The FY 2015 Enacted level reflects the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

** In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

*** FTE figures do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR. FY 2015 and FY 2016 estimated FTE levels in the APT have been updated based on FY 2014 actual year to date usage information.

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 2/	4,689,706,000	4,428,900,000	4,443,356,000	4,443,356,000
FY 2016	4,859,743,000			

* Excludes Indefinite user fees.

1/ FY 2009 Appropriation does not include Supplemental Appropriation

2/ The FY 2015 Enacted level requires the transfer of $1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities. In addition to the funding displayed in the table above, the FY 2015 Enacted level includes $25 million in emergency funding for FDA's role in the U.S. Government response to contain, treat, and prevent the spread of Ebola.

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	8,788,000	8,788,000	8,788,000
FY 2016	8,788,000			

FOODS

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Foods	**900,259**	**882,814**	**913,784**	**1,166,636**	**252,852**
Budget Authority	***882,817***	***882,814***	***903,403***	***987,328***	***83,925***
User Fees	***17,442***	---	***10,381***	***179,308***	***168,927***
Center	266,893	266,406	280,480	355,007	74,527
Budget Authority	266,408	266,406	279,994	303,994	24,000
User Fees	485	---	486	51,013	50,527
Food and Feed Recall	*485*		*243*	*243*	---
Voluntary Qualified Importer Program	---	---	*243*	*243*	---
Third Party Auditor Program			---	*64*	*64*
Food Facility Registration and Inspection	---	---	---	*23,279*	*23,279*
Food Import	---	---	---	*9,790*	*9,790*
Cosmetics	---	---	---	*12,755*	*12,755*
Food Contact Substance Notification	---	---	---	*4,639*	*4,639*
Field	633,366	616,408	633,304	811,629	178,325
Budget Authority	616,409	616,408	623,409	683,334	59,925
User Fees	16,957	---	9,895	128,295	118,400
Food and Feed Recall	*9,823*	---	*1,000*	*1,000*	---
Food Reinspection	*7,134*	---	*4,575*	*4,575*	---
Voluntary Qualified Importer Program	---	---	*4,320*	*4,320*	---
Third Party Auditor Program			---	*1,141*	*1,141*
Food Facility Registration and Inspection	---	---	---	*27,376*	*27,376*
Food Import	---	---	---	*84,530*	*84,530*
International Courier	---	---	---	*765*	*765*
Cosmetics	---	---	---	*4,588*	*4,588*
FTE	**3,551**	**3,650**	**3,744**	**4,196**	**452**

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 Amendments Act of 2007; Food and Drug Administration Food Safety 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 comprises the Foods and the Animal Drugs and Feeds Programs, including field activities in the Office of Regulatory Affairs (ORA). The operations of the Foods and Animal Drugs and Feeds Programs are administered by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) respectively, both in collaboration with ORA. CFSAN is responsible for ensuring the safety of the human food supply, dietary supplements, and cosmetics as well as ensuring the proper labeling of foods and cosmetics. 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 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: 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 total in medical costs, lost productivity, and illness-related mortality.[6]

FDA faces unique food safety challenges in the twenty first century. The Food Safety Modernization Act (FSMA) enables FDA to better protect the public health by strengthening the food and feed safety system and empowering FDA to overhaul the existing program, with major new directions, such as:

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

[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).

- shifting food safety from an old, antiquated system of addressing problems after they occur to a new focus on prevention
- creating a federal food safety system that is integrated with state and local efforts rather than duplicating or conflicting with one another
- implementing an entirely new import oversight program that gives importers greater responsibility for assuring the safety of the foods they bring into the U.S.
- increasing domestic and foreign inspections, especially in facilities producing foods at high risk of contamination
- modernizing and streamlining the food importing process to enhance trade in safe food.

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 occur. Furthermore, FSMA gives FDA important new tools to hold imported food and feed to the same standards as domestic food and feed while also directing FDA to build an integrated national food and feed 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, outreach, consumer information, and model codes for food service establishments such as restaurants.

The FVM Strategic Plan also emphasizes the nutrition-related priorities of the Foods Program. Poor diet is a key risk factor which contributes to the high rates of chronic disease, including obesity, in the United States. The Foods Program ensures that nutrition labeling is informative and accurate, and promotes a nutritionally healthy food supply to reduce the hundreds of thousands of deaths each year attributable to poor diet and using the authorities and tools available to FDA.

In addition to the high-priority initiatives identified in the FVM Strategic Plan, the Foods Program conducts many other important activities related to food safety, nutrition, and cosmetics. These include review of infant formula notifications, premarket and postmarket 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 other ongoing regulatory, enforcement, research, communications, education, and outreach activities.

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 identified in the FDA and FVM Strategic Plans.

Enhance Oversight

The FDA Strategic Plan goal of Oversight is the primary goal in which most Foods Program activities are best categorized. As a regulatory and scientific organization responsible for the safety of the nation's foods and cosmetics, much of the Foods Program's mission involves oversight work relating to scientific analysis and support, policy, guidance development, and regulatory research.

FSMA Rules Published

In 2013 and early 2014, FDA proposed seven new foundational 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 new food safety rules on preventive controls for human food and standards for produce safety. In September of 2014, FDA issued four supplemental notices of proposed rulemaking for both of these rules in response to stakeholder input in an effort to make the proposals more flexible and targeted.

The first proposed rule on preventive controls for human food requires 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
- specify what actions will be taken to correct problems that arise
- test products and the food facility's environment, as well as implement certain supplier controls when appropriate (part of the supplemental notice of proposed rulemaking).

The second proposed rule on standards for produce safety would establish enforceable science- and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms. The 2014 supplemental proposals make the criteria for determining the safety of agricultural water for certain uses more flexible and introduced a tiered approach to water testing. FDA is deferring its decision on an appropriate time interval between the application of raw manure and the harvesting of a crop until additional research is conducted, and FDA removed the nine-month interval originally proposed. Also, FDA proposed eliminating the 45-day minimum application interval for composted manure that meets proposed microbial standards and application requirements.

The third and fourth FSMA rules proposed in July 2013 will assure 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 will need to verify that their suppliers meet the same level of public health protection as required of domestic producers. Requirements for verification activities are based primarily on the type of food, nature of the hazard identified, and on who is controlling the hazard. FDA issued a supplemental proposal for this rule in September 2014, which included a comprehensive analysis of potential risks associated with foods and foreign suppliers, and more flexibility for importers in determining appropriate supplier verification measures based on their evaluation of those risks.

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 may 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 published in October 2013, which focused on animal food safety, is discussed in the Animal Drugs and Feeds Program narrative.

The sixth FSMA rule was proposed in December 2013. This rule will require the largest domestic and foreign food businesses take steps to prevent facilities from being the target of intentional attempts to contaminate the food supply. The seventh FSMA rule published in January 2014 requires those who transport food to use sanitary transportation practices.

FSMA Operational Strategy Released

FDA released a FSMA Operational Strategy Document on May 2, 2014. The document highlights how FSMA changes the way FDA approaches food safety and also sets forth the operational strategy for implementing those changes. The operational strategy focuses on how FDA can implement FSMA by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community.

Next, FDA will design methods to promote voluntary industry compliance with the new rules and also establish preventive and public-health-focused inspection and sampling programs to oversee compliance. FDA is also developing enforcement strategies to address situations when producers, processors, distributors, and importers fail to comply voluntarily.

Initiated Import Safety Systems Recognition Pilots

To ensure the safety of imported foods, the Foods Program completed the first pilot with New Zealand for a new tool called systems recognition−previously termed “comparability” in December 2012. This work is critical because 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 set of protections similar 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, whose proximity makes it one of the largest exporters to the United States. A third pilot is underway with Australia.

Improved Pathogen Detection

FDA has established the first national pilot network of whole genome sequencers (WGS), coined the GenomeTrakr, and now has added more than 10,000 whole bacterial genome sequences to a publicly accessible database. FDA has also developed outbreak traceback methodology based on whole bacterial genomes that can distinguish the source of certain outbreaks down to the farm level. The latter has significantly reduced the time necessary to conduct outbreak investigations while greatly enhancing FDA's ability to pinpoint the source of contamination events. It was used for the first time in March 2014 in an official FDA compliance action that led to the closing of a cheese facility responsible for distributing *Listeria monocytogenes* contaminated queso (cheese). In the summer of 2014, WGS data led to the recall of nut butter from a single

manufacturer, after surface samples collected at the facility during a routine assignment matched a very small illness cluster. This action, taken exceptionally early for a foodborne outbreak, likely prevented a larger number of illnesses.

FDA has also developed a new method for the detection of *Salmonella Enteritidis* in shell eggs, reducing the total analysis time from nine days to five days. In addition, a new high throughput molecular serotyping method for pathogenic *E. coli* strains has been developed, reducing the analysis time from days to hours. Single laboratory validations of newly developed methods have been completed for detection of *Salmonella enterica* in oregano, the first assay that can detect *Salmonella* in oregano, and for identifying and serotyping *S. enterica* directly from pre-enrichment broth cultures of leafy greens, which reduces the total analysis time from five days to two days. The development and validation of these new technologies and methods significantly enhances FDA's ability to respond to outbreaks and potentially prevent new outbreaks, by placing faster and more precise bacterial detection tools in the hands of FDA field laboratories.

Launched 2014 FDA Food Safety Challenge

Foodborne illness is estimated to afflict one in six Americans each year and results in billions of dollars in health care costs. In order to target solutions for this wide-reaching problem, FDA announced the 2014 Food Safety Challenge on September 24, 2014. The Challenge utilizes authority granted under The America COMPETES Reauthorization Act of 2010 to offer a $500,000 prize in FDA's first open innovation competition. The challenge asks innovators to submit their ideas for improvements to pathogen detection, specifically for Salmonella in fresh produce. Salmonella is the leading cause of deaths and of hospitalizations related to foodborne illness and is estimated to cause 380 deaths and 19,000 hospitalizations in the United States each year. By collaborating with outside experts and innovators, FDA hopes to identify new technologies and ideas that will ultimately contribute to prevention of foodborne illness and a safer food supply for the American people.

Developed Seafood Product Labeling Online Learning Module

In order to ensure the proper labeling of seafood products offered for sale in the U.S. marketplace, FDA has developed an online learning module for the seafood industry, retailers, state regulators, and anyone else involved in the processing, distribution, sale, or regulation of seafood. The module provides an overview of federal identity labeling requirements for seafood and also lists the specific laws, regulations, guidance documents, and other materials that are pertinent to the proper labeling of seafood.

Stakeholders will be able to better understand FDA's role in ensuring the proper labeling of seafood and get tips for identifying mislabeled seafood, whether it is in the wholesale distribution chain or at the point of retail. The module helps stakeholders properly identify seafood throughout the supply chain while also ensuring that appropriate food safety controls are implemented and consumers are getting the type of seafood they expect for what they are paying.

Encouraged the Safe Production of Dietary Supplements

In FY 2014, FDA completed 482 inspections of dietary supplement firms, domestic and foreign, to implement the requirements of the 2007 final rule describing current Good Manufacturing Practices (cGMPs) for dietary supplements. These cGMP inspections have resulted in 71 warning letters, three regulatory meetings, five injunctions, and three seizures against dietary supplement processors and manufacturers. Regular training sessions are continuing to augment the cadre of investigators with five conducted in FY 2014 and staff is establishing an advanced

course for investigators with FDA's Center of Excellence at the National Center for Natural Products Research (NCNPR), University of Mississippi.

On November 7, 2014, the FDA issued an import alert allowing the agency to detain shipments of dietary supplement and bulk dietary ingredients that contain kratom (*Mitragyna speciosa*). This alert utilized research by NCNPR as well as an evaluation of scientific literature establishing serious concerns regarding the toxicity of kratom. Submission of mandatory premarket safety notifications describing proposed new dietary ingredient (NDIs) in dietary supplement products occurred at a steady pace relative to recent years with 76 submissions. Most (67) resulted in responses objecting to inadequate safety or other problems with the submission. To address this high objection rate, in 2015 FDA intends to publish a revised draft guidance to industry describing expectations for the notification. In addition, FDA published an announcement with preliminary description of an electronic portal (ePortal) for submission of NDI notifications and expects to complete development of the ePortal in FY 2015. FDA continues to review voluntary adverse event reports as well as the 2,745 serious adverse advents, most of which are mandatory submissions from product distributors.

Updating Risk Assessment Capabilities
FDA has completed a review of how the agency evaluates the harmful effects of chemicals in foods, cosmetics, dietary supplements, animal food/feed, and veterinary drugs. FDA Centers, led by CFSAN, will develop a process for updating FDA's Toxicological Principles for the Safety Assessment of Food Ingredients (also called the "Redbook"), so that it reflects current science. Additionally, the centers will jointly develop a process to ensure consistency of methodologies used for safety and risk assessments within and across offices at CFSAN, and between CFSAN and CVM.

Created FDA's "Virtual Deli" Risk-Tool
Listeria monocytogenes is the third leading cause of death from foodborne illness, according to the Centers for Disease Control and Prevention. Proper cooking kills this common bacterium, but ready-to-eat foods, such as those sold in delicatessens are generally not cooked by consumers before being eaten. Once inside the delicatessen, Listeria can spread from object to object, extending its reach. As part of a quantitative risk assessment on these issues, FDA created a "virtual delicatessen," which simulates pathways of Listeria cross contamination in the deli, based on real-world observational studies.

Mathematical models enabled FDA, in partnership with the USDA Food Safety and Inspection Service, to estimate the predicted number of Listeria illnesses that could be prevented if retail delicatessens implemented specific changes in practice. By comparing the predicted results of the virtual interventions, FDA was able to predict which ones would be most effective at preventing Listeria illness from certain representative deli foods. The risk assessment underwent public review and comment before being jointly issued in September 2013. The virtual deli model is available for use by anyone, including the food industry.

Enhanced Food Emergency Response Network Capacity
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. FDA also maintains the FERN Storeroom that provides reagents and supplies to Federal and State laboratories to support analytical activities.

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. In FY 2014, FDA awarded 15 microbiological, 14 chemistry, and five radiochemistry cooperative agreement grants.

Exercised Science Based Compliance 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 that unsafe products do not reach U.S. consumers and requests the firms' shut down of operations.

In FY 2014, there were ten injunctions and two seizures against food and dietary supplement processors and manufacturers. FDA also monitors recalls of food products and ensures the effectiveness of the firm recalls to remove the defective product from commerce. In FY 2014 FDA classified 216 Class I (most serious), 295 Class II, and 43 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 2014, 1,173 such import alert notices were issued. The Foods Program also protects the public by ensuring compliance with FDA procedures designed to keep the public safe from foodborne illnesses caused by adulterated and unsafe foods, sometimes pursuing criminal action under the FD&C Act.

FDA protects the public from impure, adulterated, and misbranded food and acts as an industry-wide deterrent for regulated entities as well as criminal enterprises. For example, in FY 2014 FDA investigated and secured felony convictions against three individuals from a peanut roasting company in Georgia that were knowingly selling adulterated peanut products which resulted in an outbreak of salmonella. In another example, in September 2014 a Texas resident was sentenced for involvement in the sale and distribution of stolen powdered infant formula. FDA's efforts in FY 2014 led to 21 arrests, 22 convictions, and resulted in an excess of $9.6 million in fines and restitutions.

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.

On March 11, 2014, FDA exercised the new authority for the second time by suspending the food facility registration of Roos Foods, Inc., based in Kenton, Delaware. The manufacturer of soft cheeses was linked to an outbreak of *Listeria monocytogenes* that resulted in eight illnesses and one death.

Improved Outbreak Response
The Foods Program and the Coordinated Outbreak Response and Evaluation (CORE) team rapidly detected and responded to major food borne illness outbreaks, including the Cyclospora outbreak from salads and cilantro, and the Hepatitis A outbreak from frozen organic berries.

In preparation for outbreak response, FDA field offices support and provide technical assistance to laboratories awarded International Organization for Standardization (ISO) Cooperative Agreement Program (CAP) grants and laboratories seeking and/or maintaining their accreditation. This program continues to include additional national food/feed testing laboratories, with 23 laboratories joining the program, of which several are making significant progress towards ISO accreditation in a short timeframe. Data generated by the awarded laboratories will be available to inform FDA in its enforcement actions, surveillance, and response to foodborne outbreaks. These ISO accredited laboratories will aid FDA with additional resources and exceptional data to maintain the safety of the food chain.

Created the Manufactured Food Regulatory Program Standards Alliance
To ensure a national integrated food safety system (NIFSS), 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 state and other programs that are implementing these standards. Additionally, FDA's training grants promote consistency in the implementation and application of NIFSS 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.

Published Infant Formula Rule
In June 2014, the Foods Program published a final rule that sets standards for manufacturers to produce safe infant formula that supports healthy growth. Issuance of the final rule provides for greater protection of infants and amends FDA's quality control procedures, requirements about how and when manufacturers must notify FDA about new formulas and changes to formulas, and requirements concerning what records and reports must be established and maintained. The rule establishes current Good Manufacturing Practices and quality factors specifically designed for infant formula, including required testing for contamination from harmful bacteria such as Salmonella. In addition, the final rule helps ensure that infant formula contains all federally required nutrients to support healthy growth, such as protein, fat, and certain vitamins and minerals.

In May 2014, the People's Republic of China implemented a decree requiring registration of any formula powders for infants and young children originating from sources outside of China and intended to be exported into China. The same decree also banned the import of the same products by any unregistered enterprise. FDA worked with other U.S. government agencies, regulatory counterparts in China, and the People's Republic of China Certification and Accreditation Administration (CNCA) to ensure that Chinese concerns are addressed and U.S. manufacturers can continue to export products to China. The U.S. delegation worked extensively, participating in delegation meetings with China and establishing on-site audits of

U.S. manufacturing facilities of the subject commodities. During the on-site audits, FDA provided technical expertise to the CNCA inspection team with respect to U.S. regulations, manufacturing processes, and advanced equipment used in manufacturing infant formulas. CNCA relied upon FDA to provide the required technical assistance and to assure the Chinese government that U.S. regulations would meet or exceed their requirements. At the conclusion of the audit, CNCA granted approval to certain U.S. infant formula manufacturers resulting in a $1 billion trade agreement with the United States. FDA efforts will continue under this initiative to ensure U.S. trade capabilities are minimally impacted.

Launched Food Defense Plan Builder
In December 2013, FDA issued a proposed rule on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" as part of its implementation of the Food Safety Modernization Act (FSMA). The requirements within the proposed rule, if finalized, will require that food facilities develop and implement a food defense plan. In anticipation of the proposed rule, FDA launched the Food Defense Plan Builder, a user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities.

This user-friendly tool harnesses existing FDA tools, guidance, and resources for food defense into one single application. The tool guides users through a series of sections:

- Company Information
- Broad Mitigation Strategies
- Vulnerability Assessments
- Focused Mitigation Strategies
- Emergency Contacts
- Action Plan
- Supporting Documents.

The information collected from each of these sections, automatically compiles a food defense plan for their facility. Since its launch, the Food Defense Plan Builder received excellent reviews from industry and has been downloaded more than 12,000 times by users from all over the world.

Improve and Safeguard Access

The Foods Program has several programmatic aspects that fall within the FDA goal of improving and safeguarding access that largely consist of premarket review activities. The Foods Program has statutory responsibility for review and approval of all petitions for direct food additives in addition to review and approval of all new food contact substances, food contact materials, packaging, antimicrobials, and other indirect food additives. Also included in this category is review of Generally Recognized As Safe (GRAS) ingredients and products of biotechnology relating to food. In FY 2014, the Office of Food Additive Safety further ensured safe access to the food supply by reviewing 7 Food and Color Additive Petitions, 45 GRAS notifications, and 177 premarket notifications for Food Contact Substances.

Published Timely Food and Color Additive and Food Contact Substance Reviews
FDA has the primary legal responsibility for determining the safe use of food additives and color additives. To market a new food additive, color additive or food contact substance (or before using an additive already approved for one use in another manner not yet approved), a

manufacturer or other sponsor must first petition FDA for its approval, a process that is unique to FDA's regulatory mission. In FY 2014, in response to industry submissions, FDA published final rules for five food additive and color additive petitions in the Federal Register and completed review of 115 food contact substances and 45 GRAS (General Recognized As Safe) notifications.

Promote Informed Decisions

The Foods Program is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled. The Nutrition Labeling and Education Act (NLEA) requires most packaged foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. These food labels communicate important nutrition information to consumers and FDA is uniquely responsible for these requirements.

The Foods Program also serves as FDA's lead organization for directing, developing, and coordinating web communications, outreach, and consumer education. It is a resource to all stakeholders in responding to inquiries on topics related to food and feed-regulated products. FDA has statutory responsibility for food safety, which generally covers all domestic and imported food except meat, poultry, and processed egg products (which are under the authority of the U.S. Department of Agriculture). Such outreach is key to ensuring that consumers and food safety partners have the information needed to make informed decisions.

Updated Nutrition Facts Label

On March 3, 2014, the Foods Program published two proposed rules, one on updating the Nutrition and Supplement Facts labels, and one on updating FDA's serving size regulations for conventional foods. The proposal to update the Nutrition and Supplement Facts label reflects new public health and scientific information, including the link between diet and chronic diseases such as obesity and heart disease. The proposal for updating FDA's serving size regulations incorporates new developments including the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and recent consumer research on the use and understanding of the Nutrition Facts label. These proposals also feature a fresh design to highlight key parts of the label such as calories and serving sizes.

Published Final Menu and Vending Machine Labeling Requirements

On December 1, 2014, FDA published two final rules requiring that calorie information be listed on menus and menu boards in chain restaurants, similar retail food establishments, and vending machines. To help consumers understand the significance of the calorie information in the context of a total daily diet, FDA is requiring a succinct statement that says, "2,000 calories a day is used for general nutrition advice, but calorie needs vary" to be included on menus and menu boards. The menu labeling final rule also requires covered establishments to provide, upon consumer request, written nutrition information about total calories, total fat, calories from fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fiber, sugars, and protein.

The vending machine final rule requires operators who own or operate 20 or more vending machines to disclose calorie information for food sold from vending machines, subject to certain exceptions. Providing accurate, clear, and consistent nutrition information—including the calorie content of foods—in restaurants and similar retail food establishments and vending machines, will enable consumers to make informed and healthy dietary choices.

Published Nutrient Content Claims for Omega-3 Fatty Acids and Gluten-free Labeling Rule

The Foods Program regulates certain claims on food labels to provide accurate and useful information to consumers so that they can make healthier diet decisions and reduce the risk of chronic diseases and obesity. In April 2014, FDA published a final rule revoking nutrient content claims for certain omega-3 fatty acids that had been submitted as nutrient content claim notifications under 403(r)(2)(H) of the Federal Food, Drug, and Cosmetic Act. 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 suffer from celiac disease. Because the rule provides a clear definition of the term, consumers with celiac disease will know what to expect when they see "gluten-free" on a food or supplement label; packaged food products labeled as "gluten-free" must, among other things, contain less than 20 parts per million of the protein. Companies have one year to comply with the new "gluten-free" labeling regulations, and all products that bear the "gluten-free" label after August 5, 2014, must be in full compliance with the rule.

Developed Seafood Product Labeling Online Learning Module

In order to ensure the proper labeling of seafood products offered for sale in the U.S. marketplace, FDA has developed an online learning module for the seafood industry, retailers, state regulators, and anyone else involved in the processing, distribution, sale, or regulation of seafood. The module provides an overview of federal identity labeling requirements for seafood and also lists the specific laws, regulations, guidance documents, and other materials that are pertinent to the proper labeling of seafood.

Stakeholders will be able to better understand FDA's role in ensuring the proper labeling of seafood and get tips for identifying mislabeled seafood, whether it is in the wholesale distribution chain or at the point of retail. The module helps stakeholders properly identify seafood throughout the supply chain while also ensuring that appropriate food safety controls are implemented and consumers are getting the type of seafood they expect for what they are paying.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2012 Actual	$866,920,000	$866,920,000	$0
FY 2013 Actual	$796,638,000	$796,638,000	$0
FY 2014 Actual	$882,814,000	$882,814,000	$0
FY 2015 Enacted	$913,784,000	$903,403,000	$10,381,000
FY 2016 Request	$1,166,636,000	$987,328,000	$179,308,000

BUDGET REQUEST

The FY 2016 Budget Request for the Foods Program is $ 1,166,636,000. This amount is $252,852,000 above the FY 2015 Enacted level. Budget authority resources account for an increase of $83,925,000, and user fee resources account for an increase of $168,927,000. The Center for Food Safety and Applied Nutrition amount in this request is $355,007,000. The

Office of Regulatory Affairs amount is $811,629,000. The source of funding for this request is $987,328,000 in budget authority and $179,308,000 in user fees.

In FY 2016 the Foods Program will carry 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. FDA's greatest new funding need is to have the resources necessary to make the U.S. food supply safer. A cascade of foodborne illnesses in the mid-2000s highlighted the weaknesses in the current food safety program. Thousands of Americans were stricken from contaminated spinach, peanuts, peppers, seafood, eggs, and other foods, all part of an estimated 48 million annual illnesses from foodborne disease. The economic losses to industry, farmers and the public are enormous, estimated at over $75 billion per year. 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. In addition to implementing FSMA, examples of additional FY 2016 Foods Program priorities within the base include:

- integrating best practices and science-based preventive controls standards to achieve high rate of domestic and international industry compliance across the farm-to-table continuum
- providing consumers information that is useful and accurate for safe handling of food products
- modernizing inspections by developing more targeted, risk-based and efficient inspection and compliance models
- enhancing the safety of dietary supplements and food additives
- improving quick and accurate detection and response to foodborne outbreaks by advancing the use of whole genome sequencing to track outbreaks and contamination through the GenomeTrakr network of state and federal laboratories.

BUDGET AUTHORITY

Food Safety: +$83.9 million

Inspection Modernization and Training: +$21.7 million
Center: +$3.0 million / Field: +$18.7 million

FDA inspectors are trained to inspect food manufacturers using a compliance model focused on finding evidence of hazards. The new food safety paradigm will be focused on preventing food contamination through a system-based approach, and ensuring consistency among all inspections. This new paradigm involves a major reorientation and retraining of more than 2000 FDA inspectors, compliance officers, and other staff involved in food safety activities in fundamentally different approaches to food safety inspection and compliance. Thousands of state inspectors and related enforcement personnel also will need training.

To accomplish this in time, training efforts must begin well in advance of the effective date of the new standards. For example, determination of core competencies for inspectors and assessment of each inspector's level of needed training began in 2014, with trainers trained and training materials completed in 2015. Training will need to begin early in 2016 if inspectors are to be competent to begin inspections by the time the new rules begin to take effect in mid-2016. The training program will be comprised of several training models encompassing a variety of education and training needs directly and indirectly tied to the FSMA authorities and transitions.

Examples include:

- enlarging and strengthening FDA's internal and external training infrastructure with a variety of training models -- on-line, webinar, face-to-face, job aids, soft skill communications
- recruiting and training instructors at various levels of regulated industry, trade organizations, academia, and industry
- scheduling and delivering training sessions over the next two or more years for FDA internal and external stakeholders.

FDA will move toward more targeted, risk-based, and efficient inspection models, which will require better data about facilities, new IT systems to identify and track risk, and methods for assessing and tracking inspection efficiency and inspector competency. Additional equipment will enable field staff to complete all required electronic submissions on-site, expediting the overall inspection process. These systems need to be in place at the time inspections begin in 2016.

National Integrated Food Safety System: +$25.8 million
Center: +$2.0 million / Field: +$23.8 million

The states are projected to conduct over half of the facility inspections required by FSMA. However, FDA has received complaints that the states are not well prepared to do so and often conduct inspections using different standards and methodologies than FDA inspectors use, and often with inadequate information−for example, without knowledge that a facility was recently inspected by FDA.

Building state capacity to coordinate effectively with FDA is a central FSMA tenet, but to be successful in aligning state programs with FDA's new inspection and compliance approach, the states will need:

- inspector training and certification programs
- information sharing capacity with FDA and other states
- state laboratory coordination.

Engaging thousands of state, tribal, and territorial personnel and ensuring that state and Federal standards are consistent will be an enormous undertaking; but without it industry could experience inconsistent and costly regulatory oversight. FDA's efforts to strengthen state coordination will be carried out mostly via FDA grants to 40 or more states.

The new standards will be in place in August 2015. A high-quality information exchange with state, local, territory, and tribal agencies is currently underway to support their compliance with the Manufactured Food Regulatory Program Standards.

In addition, the Foods Program will expand its current proficiency testing program to better target food safety and food defense concerns in support of the FSMA mandate for laboratory accreditation. The expansion of the testing program will help ensure that inspectors, investigators, and analysts meet national standards. FDA will evaluate and implement new methods, validation manuals, training, fit-for-purpose method extension, and new instruments in order to build lab capacity for the NIFSS.

Education and Technical Assistance for Industry: +$10.0 million
Center: +$10.0 million

The shift toward preventing food and feed contamination directed by FSMA creates a need among many farmers and processors – and especially small businesses – for technical assistance to facilitate their implementation of the new standards.

The new standards are to be finalized beginning in the 4th quarter of FY 2015 and continuing through the middle of FY 2016. FDA has a strategy for implementation and enforcement that recognizes the special needs of small entities covered by these rules and the major changes in practices that these rules will require for all covered entities. This strategy will take one to four years for full implementation. During that time, hundreds of thousands of entities covered by these rules will need education and technical assistance in order to ensure compliance with the new standards, ultimately resulting in a safer food supply and a reduction in illness and hospitalizations due to food borne illness. More specifically, more than 36,000 fruit and vegetable producers could be subject to the proposed produce safety rule, and more than 40,000 food and feed facilities to the proposed preventive controls rule. These firms are expected to seek training, advice, and technical assistance from FDA to fully understand and comply with the new requirements. Further, many additional farms and facilities that are subject to modified requirements or exemptions are expected to seek assistance. FDA lacks the resources to provide the necessary assistance, and believes that it should expend substantial financial resources to help industry.

Technical assistance for industry, especially small and medium-sized firms will include materials, such as small business guides, sample food safety plans, webinars, technical workshops, help-desk support, educational inspections, and many other similar activities. Efforts are already underway to develop content. Once finalized, resources are needed to get the information and knowledge in the hands of the hundreds of thousands of entities involved, with FDA working with them to ensure compliance and the ultimate public health benefits and health care cost reduction objectives. FDA employees and collaborative partners – including States, Federal Agencies, and public-private-academic entities such as the Produce Safety Alliance and the Preventive Controls Alliance – will carry out the dissemination, education, and assistance efforts. In fact, 80 percent of the requested resources will be used to provide financial support to state and private sector entities. Without these resources, industry will be unable to meet the requirements of new regulations and the movement toward safer food and feed production will be markedly delayed.

Technical Staffing and Guidance Development: $4.0 million
Center: +$4.0 million

FSMA directs FDA to undertake a very complex and challenging effort to produce the rules and guidelines under which the food industry will ensure safe food and feed production and FDA and State investigators will inspect. Those new standards must have a strong basis in science, be the product of the best technical expertise available, and be the result of continuous discussion with the affected industry, farmers, and other stakeholders. Approximately half of the funds for this activity would be used to recruit knowledgeable experts at FDA who can ensure that the new prevention standards and guidelines are based on the best science and intimate knowledge of industry practices. These experts are also essential to support FDA's compliance force in properly overseeing implementation of the new standards. For example, additional experts in

agricultural produce production will be needed to assure that proper guidances and technical assistance are provided for the many different types of fruits and vegetables that are grown or imported in the United States. These experts will be responsible for providing the scientific input to future amendments to safety standards and guidance, and they will be responsible for much of the scientific content of educational programs and industry guidance that must be developed. The remaining half would be devoted to collaboration with industry, academia, and state extension services to ensure that their concerns are heard, that their advice is solicited and utilized, and that the rules and their implementation are the most cost-effective solutions achievable. This funding is urgent because the rule and guidance development are underway, key elements must be completed on a court-ordered timeline, and staffing for technical assistance must be ramped up in 2016 to help industry comply with the requirements in the final rules (in particular for farms and small businesses).

Import Safety – Foreign Supplier Verification Program (FSVP) Implementation: +$22.4 million

Center: +$5.0 million / Field: +$17.4 million

The Foods Program will implement the Foreign Supplier Verification Program (FSVP). FSVP will require importers to verify that food imported into the United States has been produced consistent with U.S. food safety standards, that it offers the same level of protection as FDA's preventive controls requirements and produce safety standards, and that it is not otherwise adulterated or misbranded with respect to food allergen labeling. This shift presents an enormous challenge for both FDA and food importers, given that there were approximately 88,000 consignees receiving food shipments last year.

To be successful, FSVP will require a substantial regulatory development process, staffing and training within FDA to enforce the regulation, and extensive training and technical assistance for importers. The food and feed industry has expressed significant concern that FDA's ability to screen food and feed imports is an impediment to the smooth flow of trade, and that without the means to make FSVP implementation successful, FDA's efforts might become a barrier to trade. FDA receives thousands of inquiries each year from importers regarding operations at ports of entry, to which it cannot adequately respond; and a poorly implemented FSVP regulation could aggravate that problem.

FSVP implementation will require not only training of over 400 FDA investigative and compliance personnel, but also outreach and technical assistance to importers who have not previously had legal obligations under the FD&C Act and are unaccustomed to FDA regulation. With the first compliance date for this rule coming in early 2017, internal training, and technical assistance to industry must occur in 2016. This effort includes training FDA's investigative and compliance personnel and developing and delivering technical assistance. Compliance with FSVP is essential to ensure the continued importation of food products. An importer's failure to comply with FSVP may result in denial of entry of the food products. Therefore, failure by the importers to be properly trained and educated to meet FSVP standards could result in unnecessary and harmful impacts to their businesses.

USER FEES

Current Law User Fees: +$1.2 million

Third Party Auditor Program User Fee: +$1.2 million
Center: +$0.1 million / Field: +$1.1 million

The Food Safety Modernization Act directed FDA to establish a program to accredit entities to conduct food safety audits and to issue certifications for foreign food facilities to ensure compliance with United States safety standards. This program will optimize federal resources by allowing FDA to leverage third-party auditors to enhance the assurance of the safety of food and animal feed products imported and facilitates the movement of regulated products in international trade in a more efficient way. In FY 2016, FDA will begin collecting user fees in support of this program. The final regulation is scheduled to be finalized in 2015

Proposed User Fees: +$167.8 million

Proposed Food Import Fee: +$94.3 million
Center: +$9.8 million / Field: +$84.5 million

The Foods Program request for the proposed Food Import Fee is $94,300,000, a $43,100,000 decrease from the amount requested in past years. The decrease in the proposed user fee results from a shift of activities being requested in budget authority due to the urgency for support of the Foreign Supplier Verification Program (FSVP) and to conduct import verification inspections to meet FSMA requirements. Revenue from the proposed Food Import Fee would enable FDA to modernize its import oversight program in ways that would facilitate the entry of safe food.

The volume of imported food has increased enormously over the past 20 years, going from fewer than 200,000 line-entries in the early 1990s to an estimated 12 million in 2013. A cascade of contaminated food incidents in recent years, such as melamine in pet food, bacterial contamination of fresh fruits and vegetables, and illegal antibiotics in seafood, has resulted in public distrust of imported food and a belief that the Federal government is not taking adequate steps to ensure imported food safety.

Congress has repeatedly criticized FDA for inadequate border screening of food, noting that less than 1.7 percent of imported food entries, and less than 1.2 percent of imported feed, are physically examined.

The fundamental tenet of the FSMA import provisions is to design an import control strategy that does not solely depend on FDA reviews at the ports of entry but where such reviews are the final step in a comprehensive system of safeguards for improving the safety of the U.S. food supply, with importers responsible for far greater safety assurance responsibilities.

These resources will benefit foreign food producers, U.S. food importers, and the general public. For importers in particular, the fee will result in an improved import program resulting in greater efficiency and predictability for their businesses. The improvements to the import process will not only facilitate the entry of safe products but also improve public health by enabling FDA to focus its attention on higher risk products. The ultimate result will be improved confidence in the safety of food from abroad, thus encouraging future trade opportunities in food.

Importer Support
To improve the safety of imported food, FDA will establish new systems to prevent the import of unsafe foods earlier in the process rather than detaining a product at the border. Additional funds

will support the establishment of a "Help Desk" that would assure importers of an available, responsive communications system to help address their concerns and answer their questions about the status of their shipments.

Port-of-Entry Streamlining
Food importers are increasingly complaining that FDA's current import screening process is hindering their ability to trade competitively. These funds will help develop and maintain improved risk analytics and IT systems that will allow FDA to target the highest risk imports, thus resulting in fewer detentions and less delay for lower-risk entries. This will include better integration with U.S. Customs and Border Protection (CP) IT systems, as importers have urged, and continuous improvement of FDA's import screening system (PREDICT).

These systems will decrease reliance on paper notices and improve FDA's ability to exchange information electronically with industry during the import review process. These funds will also be used to expand the use of analytical tools deployed on-site for faster screening and better targeting of high-risk samples going to traditional laboratories for lengthy analysis. These tools will include technology such as hand-held scanners and small, portable on-site testing capability.

Resources will be invested in the implementation of a Quality Management System across all ports designed to improve uniformity and efficiency of the import decision process. The facilitation of continuous process improvements across all ports of entry will allow FDA to develop measures for quality service and manage import operations to those measures, resulting in greater uniformity and predictability across all FDA ports. A formal assessment will establish baseline measurements against which FDA and importers can evaluate improvements in import business operations as the user fee program is implemented.

Increased Border Staffing
Additionally, these funds will increase FDA border coverage and extend hours of operations at high-priority locations. The result will be fewer instances when FDA investigators are not available to process an entry and will make FDA's response timelier.

Proposed Food Facility Registration and Inspection Fee: +$50.7 million
Center: +$23.3 million / Field: +$27.4 million

Revenue from the proposed Food Facility and Registration Fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models and information technology to improve targeting and risk-based efficiency of inspection. This investment will complement the investment in inspection modernization and training that can be achieved with the budget authority request and ensue that modernization is fully achieved on a timely basis.

The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide. With this investment, FDA will be better able to make sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply.

The resources allocated to planning and response will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge. 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. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts.

Proposed Cosmetics Safety User Fee: +$17.4 million
Center: +$12.8 million / Field: +$4.6 million

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 postmarket 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 Food Contact Substances Notification User Fee: +$4.6 million
Center: +$4.6 million

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 International Courier User Fee: +$0.8 million
Field: +$0.8 million

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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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 2014: 100% 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 2014: 623 enrolled Target: 584 enrolled (Target Exceeded)	638	653	+15
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2013: 13.82 cases/100,000 CY 2013 Target: 11.7 cases/100,000 (Target Not Met)	11.0 cases/ 100,000	10.6 cases/ 100,000	-0.4
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2013: 1.15 cases/100,000 CY 2013 Target: 1.04 cases/100,000 (Target Not Met)	0.95 cases/ 100,000	0.89 cases/ 100,000	-0.06

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2013: 0.26 cases/100,000 CY 2013 Target: 0.28 cases/100, (Target Exceeded)	0.27 cases/ 100,000	0.26 cases/ 100,000	-0.01
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2013: 15.19 cases/100,000 CY 2013 Target: 14.2 cases/100,000 (Target Not Met)	13.6 cases/ 100,000	13.2 cases/ 100,000	-0.4
212409: Reducing foodborne illness in the population. By December 31, 2015, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 1.9 cases per 100,000. (*Outcome*)	CY 2013: 2.58 cases/100,000 Target: 2.3 cases/100,000 (Target Not Met)	1.9 cases/ 100,000	1.9 cases/ 100,000	maintain
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2014: 4 working days Target: 4 working days (Target Met)	4 working days	3 working days	-1 day
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 2014: 8 assessments completed Target: 10 (Target Not Met)	8	8	maintain
214201: Number of prior notice import security reviews. *(Output)*	FY 2014: 82,821 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2014: 183,224 Target: 160,158 (Target Exceeded)	160,000	160,000	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
214203: Number of Filer Evaluations. (Output)	FY 2014: 1,247 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2014: 9,817 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2014: 12 labs Target: 13 labs (Target Not 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 2014: 44% Target: 33% of approximate inventory every three years based on 19,500 firms (Target Exceeded)	67%	100%	+33%
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2014: 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.

Food Additive and Color Additive Petition Review

FDA conducts an extensive review as part of its Food Additive and Color Additive Petition review process, which includes a Chemistry, Toxicology and Environmental evaluation. The current measure requires FDA to complete review and action on the safety evaluation of direct and indirect food and color additive petitions within 360 days of receipt. FDA exceeded the FY 2014 target of 80 percent by reviewing and completing 100 percent of the petitions received within 360 days of receipt, an improvement over the already strong FY 2013 performance of 92 percent completed within the same timeframe.

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 Retail 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. The FY 2014 target for enrollment of State, local and tribal agencies in the Retail Program Standards was far exceeded. Awareness of the value of the using the Retail Program Standards to drive program improvement continues to

grow, particularly among local health departments. In addition, more retail food regulatory programs are recognizing that FDA cooperative agreement funds are available to jurisdictions that enroll in the Retail Program Standards and commit to achieving key milestones. The FY 2015 and FY 2016 targets reflect increases in the number of enrollees by 15 above the previous year's actual number of enrollees.

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.

Pathogen Detection
FDA microbiologists are evaluating and integrating commercially available instrumentation into its microbiological testing workflow that is vastly improving the ability of FDA to more quickly and effectively detect and characterize foodborne pathogens such as Salmonella directly from the food supply. Improvements in sample throughput, along with the high degree of sensitivity and specificity built into new pathogen detection technologies, will dramatically improve FDA's foodborne response and traceback capabilities. When fully deployed, technologies such as next-generation whole-genome sequencing (WGS) and others will reduce the time to conduct these analyses from 14 days originally to just a few days. One updated technology which provides highly accurate and rapid Salmonella serotype results for FDA, known as the flow cytometry/fluorescence platform, has been validated extensively and is now deployed in nearly all FDA field laboratories, as well as in CFSAN and CVM laboratories. In FY 2014 and FY 2015 upcoming, FDA has and will meet the target of reducing the average number of days to serotype priority pathogens in foods to four days. The proposed target for FY 2016 is three days, continuing the critically important downward trend in analytical return times.

Systems Recognition
Systems recognition provides objective criteria and a robust process for determining whether a foreign country's food safety systems provide a level of assurance whereby FDA can confidently leverage the work conducted by food safety authorities in that country to determine if it provides a similar set of protections to that of FDA. Systems recognition, once fully implemented, will allow FDA to focus inspection and resources where most needed. In FY 2015, the program will begin the transition process from the pilot stage to full implementation. Because significant resources will be redirected towards improving existing processes during this transition, no new country assessments will be scheduled until the program has reached the stage of full implementation. At the completion of the implementation phase, FDA will be able to fully operationalize Systems Recognition in its internal operations and, thus, enhance its risk-based approaches to resource utilization.

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. 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. As FY 2014 represents the completion of the first year in the new three-year cycle, ORA has made significant progress towards this requirement having accomplished inspections of 44 percent of the high-risk domestic inventory. FY 2016 will mark the completion of the next three year cycle for 100 percent coverage of the high-risk inventory.

Laboratory Accreditation Corrective Actions
Appropriate corrective actions have been initiated to address not meeting the measure. We anticipate meeting this measure in FY 2015.

Increased Laboratory Surge Capacity
A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially adulterated 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 inherent risk, outbreaks, 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 2014 FDA met or exceeded inspection targets for foods, as well as animal drugs and feeds facilities.

PROGRAM ACTIVITY DATA

Foods Program Activity Data

CFSAN Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Food and Color Additive Petitions			
Petitions Filed [1]	5	7	7
Petitions Reviewed [2]	7	7	7
Premarket Notifications for Food Contact Substances			
Notifications Received	156	114	114
Notifications Reviewed [3]	117	100	100
Infant Formula Notifications			
Notifications Received [4]	27	40	40
Notifications Reviewed [5]	27	40	40
FDA Review Time	90 days	90 days	90 days
New Dietary Ingredient Notifications			
Notifications Received [6]	39	75	75
Notifications Reviewed [7]	39	75	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 due to 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] 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.

[7] 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 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,133***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,032	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk**
Imported and Domestic Cheese Program Inspections	285		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	334		
Domestic Fish & Fishery Products (HACCP) Inspections	970		
Import (Seafood Program Including HACCP) Inspections	214		
Juice HACCP Inspection Program (HACCP)	159		
Interstate Travel Sanitation (ITS) Inspections	872		
Domestic Field Exams/Tests	2,280	3,945	3,945
Domestic Laboratory Samples Analyzed	11,350	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,339***	***1,200***	***1,200***
All Foreign Inspections	1,339	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***8,472***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	183,224	160,200	160,200
Import Laboratory Samples Analyzed	24,540	35,300	35,300
Import Physical Exam Subtotal	**207,764**	**195,500**	**195,500**
Import Line Decisions	12,180,223	13,033,779	13,874,509
Percent of Import Lines Physically Examined	1.71%	1.50%	1.41%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	82,821	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,667***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***91***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,615	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	948	1,104	1,104
State Contract Juice HACCP	94	103	103
State Contract LACF	110	68	68
State Partnership Inspections	94	273	273
State Contract Foods Funding	$13,564,985	$14,514,534	$15,530,551
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$21,876,992	$23,408,381	$25,046,968
Total State & Annual FERN Funding	**$35,441,977**	**$37,922,915**	**$40,577,519**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS [2]	***18,230***	***20,496***	***20,496***

[1] The FY 2014 actual unique count of foreign inspections includes 139 OIP inspections (65 for China, 67 for India, & 7 for Latin America).

[2] The Actual count of establishment inspections conducted in FY 2014 was less than projected due to the loss of approximately one month of activity during the government shutdown in October of 2013. Efforts were made to minimize the impact as much as possible. In addition, FDA completed 8,607 high risk inspections, which are a subset of total establishment inspections.

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***103***	***100***	***100***
Domestic Inspections	103	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***4***	***0***	***0***
Foreign Inspections	4	0	0
IMPORTS			
Import Field Exams/Tests	6,809	1,600	1,600
Import Laboratory Samples Analyzed	448	500	500
Import Physical Exam Subtotal	**7,257**	**2,100**	**2,100**
Import Line Decisions	2,596,057	2,611,156	2,704,653
Percent of Import Lines Physically Examined	0.28%	0.08%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***107***	***100***	***100***

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HUMAN DRUGS

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Human Drugs	**1,289,304**	**1,210,709**	**1,338,599**	**1,371,580**	**32,981**
Budget Authority	***466,374***	***466,303***	***482,287***	***484,678***	***2,391***
User Fees	***822,930***	***744,406***	***856,312***	***886,902***	***30,590***
Center	1,097,515	1,062,552	1,135,258	1,169,906	*34,648*
Budget Authority	339,838	339,773	346,080	352,513	*6,433*
User Fees	757,677	722,779	789,178	817,393	28,215
Prescription Drug (PDUFA)	*534,526*	*536,041*	*561,252*	*583,688*	*22,436*
Generic Drug (GDUFA)	*207,475*	*185,066*	*211,625*	*216,996*	*5,371*
Biosimilars (BsUFA)	*15,676*	*1,672*	*15,900*	*16,298*	*398*
Outsourcing Facility			*401*	*411*	*10*
Field	191,789	148,157	203,341	201,674	*-1,667*
Budget Authority	126,536	126,530	136,207	132,165	*-4,042*
User Fees	65,253	21,627	67,134	69,509	*2,375*
Prescription Drug (PDUFA)	*10,908*	*6,109*	*11,453*	*11,910*	*457*
Generic Drug (GDUFA)	*53,023*	*15,518*	*54,083*	*55,456*	*1,373*
Biosimilars (BsUFA)	*1,322*	---	*1,348*	*1,382*	*34*
Outsourcing Facility			*250*	*250*	---
International Courier	---	---	---	*511*	*511*
FTE	**4,648**	**4,639**	**5,503**	**5,516**	**13**

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; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Best Pharmaceuticals for Children Act (BPCA) of 2002; Freedom of Information Act (FOIA) as amended in 2002 (5 U.S.C. § 552); Pediatric Research Equity Act (PREA) of 2003; Project Bioshield Act of 2004 (21 U.S.C. 360bbb-3); Food and Drug Administration Amendments Act (FDAAA) of 2007; Public Health Service Act of 2010 (42 U.S.C. 262); Protecting Patients and Affordable Care Act of 2010; Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA); Drug Quality and Security Act (2013); Sunscreen Innovation Act (2014); Adding Ebola to the FDA Priority Review Voucher Program Act (2014)

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 components of FDA's Human Drugs Program, which operates with funding from budget authority 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.

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

Improve and Safeguard Access

Within this Goal area, the Human Drugs Program addresses the FDA Strategic Priorities on Regulatory Science, Globalization, Safety and Quality, and Smart Regulation.

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.

During 2014, the Human Drugs Program effectively employed a variety of regulatory tools including FDA's expedited development and review programs – fast track, priority review, accelerated approval, and new breakthrough therapy designation. Early and repeated communications with sponsors have also been helpful in expediting these products to market.

FDA is working to increase the speed and efficiency in several areas in the clinical trial phase of drug development. FDA's efforts include:

- accepting flexible clinical development designs;
- meeting frequently and working closely with industry sponsors throughout the development process to plan efficient clinical trial programs and agree on needed data; and
- helping create clinical trial networks and "master protocols," where appropriate, to greatly reduce the cost of conducting clinical trials and reduce the time needed to carry them out.

FDA's recent accomplishments include implementing several components of the Food and Drug Safety and Innovation Act of 2012 (FDASIA). Accomplishments include publishing the Strategic Plan for Preventing and Mitigating Drug Shortages[7] as well as issuing the final rule extending FDA's authority to administratively detain products that are believed to be adulterated or misbranded. Additionally, two user fee programs were implemented - 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).

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

[7] http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf

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 2014, FDA successfully surpassed the performance goal to hire and train at least 50 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.

During FY 2014, FDA produced two additional draft guidances related to the BsUFA program. The first draft guidance, "Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product" was published in May 2014, as one in a series to implement the Biologics Price Competition and Innovation Act (BPCI). The second draft guidance, "Reference Product Exclusivity for Biological Products, Filed Under Section 351(a) of the Public Health Service Act," was published in August 2014.

During FY 2014, FDA collaborated with Health and Human Services partners to respond to the Ebola Virus Disease outbreak in West Africa by contributing to policy development, providing feedback on proposals for clinical trials, working with medical product sponsors to expedite the review of Investigational New Drug Applications (INDs), and working to uphold product quality and counterfeit product monitoring and enforcement. FDA worked to provide expanded access (including emergency requests) to potential Ebola therapeutics that are currently unapproved. Additionally, FDA has provided regulatory guidance for potential therapeutics development programs and delivered feedback for potential Ebola therapeutics to international public health partners and regulatory bodies.

Opioids are powerful medications that can help manage pain when prescribed for the right condition and when used properly. But when physicians prescribe these medications to patients who should not receive them, or when these medications are used improperly or for recreational purposes, they can cause serious harm, including overdose and death. FDA continues to encourage the development of opioid products with abuse-deterrent properties and believes that these products have promise to help reduce prescription drug abuse. At the same time, FDA remains committed to ensuring that patients with pain have appropriate access to opioid analgesics.

In October 2014, FDA hosted a public meeting to discuss the development, assessment, and regulation of abuse-deterrent opioid medications. The meeting focused on scientific and technical issues related to the development and in vitro assessment of these products, as well as FDA's approach towards assessing the benefits and risks of all opioid medications, including those with abuse-deterrent properties.

Enhance Oversight

Within this Goal area, the Human Drugs Program addresses the FDA Strategic Priorities on Globalization, Safety and Quality, and Smart Regulation.

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 from inspections

and examines 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 currently available to consumers. FDA aims to identify and communicate risks associated with approved drugs. The ongoing post market safety activities allow FDA to discover risks associated with drug products that could not have been discovered during premarket review. The goal of safety activities is 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. In response to the FDAAA requirement, FDA launched 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. This includes access to large quantities of data that enhance 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 2014, the Human Drugs Program expanded surveillance to 178 million patients, which is a 19 percent increase of 29 million patients from FY 2013. To date, the Sentinel Initiative has contributed to several safety communications and labeling changes to better inform patients and providers about safe use of drugs and vaccines.

In November 2013, President Obama signed into law the Drug Quality and Security Act (DQSA), Public Law 113-54, which provides FDA with additional responsibilities to oversee compounding activities. During fiscal year 2014, FDA continued to conduct inspections of compounding facilities, including outsourcing facilities, issued numerous warning letters, initiated several enforcement actions, and continued to develop the framework to implement the new law. Since the law was passed in November 2013, FDA has issued numerous policy documents to implement both section 503A, as amended by the DQSA, to remove uncertainty regarding its validity, as well as the new section 503B. FDA continues to work on numerous additional rules and guidances. In addition, FDA has announced the membership of a Pharmacy Compounding Advisory Committee which will provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B.

Title II of the DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Ten years after enactment, the system will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. FDA has published several draft guidances to support implementation of the Drug Supply Chain Security Act and is continuing to implement the law and further enhance the safety of the drug supply chain.

Promote Informed Decisions

Within this Goal area, the Human Drugs Program addresses the FDA Strategic Priority on Safety and Quality.

FDA is responsible for protecting the public health by assuring prescription drug information that healthcare professionals and consumers receive is truthful, balanced, and accurate. This is

accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information directed to both healthcare professionals and consumers.

Strengthen Organizational Excellence

Within this Goal area, the Human Drugs Program addresses the FDA Strategic Priority on Stewardship.

The Human Drugs Program supports FDA's objective to recruit, develop, retain, and strategically manage a world-class workforce, improving the overall operation and effectiveness of FDA. Specifically, the Center for Drug Evaluation and Research (CDER) employs a lean management approach to streamline operations in order to meet public health responsibilities and uphold CDER's public health mission with limited resources. CDER analyzes business operations and processes to maximize business modernization to accomplish as much as possible within budget constraints.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$1,210,709,000	$466,303,000	$744,406,000
FY 2015 Enacted	$1,338,599,000	$482,287,000	$856,312,000
FY 2016 Request	$1,371,580,000	$484,678,000	$886,902,000

BUDGET REQUEST

The FY 2016 Budget Request is $1,371,580,000, of which $484,678,000 is budget authority and $886,902,000 is user fees. This amount is $32,981,000 more than the FY 2015 Enacted. The FY 2016 Budget provides a net budget authority increase of $2,391,000. This includes $4,042,000 in reductions to targeted, lower priority enforcement activities. In addition, user fees increase by $30,590,000.

The FY 2016 Budget will allow the Human Drugs Program to uphold its public health mission of ensuring that prescription, generic, and OTC drugs are safe and effective. FDA will continue to review new prescription, generic, and biosimilar biological drug products and continue activities to ensure product safety and efficacy throughout the drug lifecycle. FDA will also continue its efforts related to opioids with abuse-deterrent properties. FDA is committed to making progress on setting and applying appropriate regulatory incentives and expectations regarding opioids with abuse-deterrent properties.

FDA will continue inspections and enforcement activities related to compounded drugs, policy development activities, and stakeholder outreach. The FY 2016 budget will also support FDA's ability to uphold the integrity of the drug supply chain. FDA will continue to establish the regulatory framework to support the implementation of the Drug Supply Chain Security Act by conducting public meetings, drafting proposed rules, and drafting guidance documents.

The FY 2016 budget will support FDA's efforts to minimize public health risks associated with counterfeit and substandard drugs. FDA is educating consumers and the health care community about the risks of, and minimizing exposure to, counterfeit and substandard drug products in addition to implementing regulatory and enforcement tools to improve the security of the drug supply chain.

BUDGET AUTHORITY

Medical Product Safety: +$6.4 million

Combating Antibiotic Resistant Bacteria: +$5.0 million
Center: +$5.0 million

Antibiotic resistance is poised to worsen due to the selective pressure from the use of existing antibacterial drugs, coinciding with a marked decline in innovative antibacterial drug development. Patients and clinicians are increasingly confronting infections caused by pathogens resistant to many or all antibacterial drugs in both the inpatient and outpatient settings. Antibacterial products face high development costs, particularly for late-stage clinical trials, but additional factors can complicate conduct of clinical trials for antibacterial drugs. For example, patients with serious infections are likely to be acutely ill and in need of urgent therapy, which can preclude efficient consent and timely trial enrollment procedures. In addition, many patients with serious drug-resistant infections have significant comorbidities that may render them less likely to meet inclusion criteria, thus precluding study enrollment.

Advancing the science of clinical trials for antibacterial drugs can have an impact in facilitating, as well as stimulating, development of needed, new therapies. The requested funds will support CDER's efforts to streamline clinical trial protocols, continue endpoint development, develop novel clinical trial designs, and facilitate the establishment of a clinical trial network as a part of the National Strategy for Combating Antibiotic Resistant Bacteria. Important to this work will be engaging stakeholders in the area of antibacterial drug development. In addition, sustained funding would allow CDER to explore pharmacological strategies in drug development to prevent the emergence of resistance to new antibacterial drugs and continue refining ways to increase efficiencies of and knowledge gained from clinical trials.

Compounding: +$0.7 million
Center: +$0.7 million

FDA will continue implementation of the DQSA through inspections and enforcement, policy development and implementation, and state collaboration and coordination. FDA will continue to support case management for inspections of human drug compounding pharmacies and outsourcing facilities 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 taking action, as appropriate. FDA will continue conducting for-cause inspections in response to adverse event reports, product quality complaints, and state requests.

The requested resources will also support development 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.

Sunscreen: +$0.7 million
Center: +$0.7 million

The Sunscreen Innovation Act was established to provide a more efficient review process for the approval of over-the-counter (OTC) sunscreen active ingredients while maintaining strict safety standards. The Sunscreen Innovation Act allows any person to submit a request to FDA for determination of whether a nonprescription sunscreen active ingredient can be generally recognized as safe and effective.

The requested funds will support the collaboration within CDER and across FDA as necessary in the evaluation of OTC sunscreen products. Activities related to reviewing the validity and outcome of new pharmacology and toxicology data, conducting searches of public literature and data, and writing summaries of relevant pharmacology and toxicology data will provide important support in the review process. The funds will enhance CDER's ability to complete timely reviews of filed requests and determine the safety and efficacy of the sunscreen active ingredient or combination of ingredients.

USER FEES

Current Law User Fees: +$30.1 million

Center: +$28.2 million / Field: $1.9 million

The Human Drugs Program request includes an increase of $30.1 million for current law user fees, which will allow FDA to fulfill its mission of protecting the public health, treating and curing diseases, and accelerating innovation in the industry.

Proposed User Fees: +$0.5 million

Proposed International Courier User Fee: +$0.5 million
Field: +$0.5 million

Millions of shipments of medical product 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 Human Drugs Program's performance measures focus on premarket and post market activities, generic drug review actions, and drug safety 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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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)*	FY 2013: 93% Target: 90% (Target Exceeded)	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)*	FY 2013: 100% Target: 90% (Target Exceeded)	90%	90%	maintain
223212: Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt. *(Output)*	FY 2013: 97% Target: 90% (Target Exceeded)	90%	90%	maintain
223213: Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt. *(Output)*	FY 2013: 88% Target: 90% (Target Not Met)	90%	90%	maintain
223205: The total number of actions taken on abbreviated new drug applications in a fiscal year *(Output)*	FY 2014: 1,521 Target: 1,350 (Target Exceeded)	N/A	N/A	N/A

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
223215: Review and act on original Abbreviated New Drug Application (ANDA) submissions within the established time frame. *(Output)*	N/A New Goal	60% within 15 months	75% within 15 months	+15%
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2014: 918 Target: 750 (Target Exceeded)	750	750	maintain
292202: Number of people for whom FDA is able to evaluate product safety through miniature Sentinel pilots. *(Outcome)*	FY 2013: 178 million Target: 150 million (Target Exceeded)	180 million	185 million	+5%

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

Review Goals

The New Drug Review performance measures focus on ensuring that the public stakeholders, and industry are accessible to safe and effective new treatments as quickly as possible. 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.

CDER has included a new performance measure for the generic drug review to align to the GDUFA commitments and process enhancements resulting from the GDUFA program. 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. For this reason, the generic drug review goal that was included prior to GDUFA has been replaced with the new measure reflected above. In FY 2014, FDA exceeded the historical target of actions taken on abbreviated new drug applications and achieved 1,521 actions.

Sentinel

The Sentinel program provides essential public health benefits by providing an evaluation tool to medical scientists that allows the FDA to monitor targeted post market safety of medical products available to consumers. The Sentinel program evaluates drug safety issues that may require regulatory action. In FY 2014, FDA exceeded the target and expanded surveillance to 178 million patients, which is a 19 percent increase of 29 million patients from FY 2013.

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 inherent risk, outbreaks, 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 2014 FDA met or exceeded inspection targets for human drugs facilities.

PROGRAM ACTIVITY DATA

Human Drugs Program Activity Data (PAD)

CDER Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
New Drug Review			
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	121	121	121
Efficacy Supplements	177	177	177
Manufacturing Supplements	1,564	1,564	1,564
Commercial INDs (Drugs and Biologics) with Activity	6,443	6,443	6,443
Sponsor Requests: IND-Phase Formal Meetings	2,106	2,106	2,106
Sponsor Requests: Review of Special Study Protocols	194	194	194
Submissions of Promotional Materials	84,654	85,000	85,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	35	35	35
Reviews: Standard NDA/BLA	140	140	140
Approvals: Priority NDA/BLA	31	31	31
Approvals: Standard NDA/BLA	88	88	88
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	13	13	13
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	17	17	17
Median time from Receipt to Approval: Priority NDA/BLAs (in months)	8	8	8
Median Time from Receipt to Approval: Standard NDA/BLAs (in months)	11	11	11
Reviews: NDA Supplementals	3,251	3,251	3,251
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	4,633	4,864	5,107
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	109	109	109
Receipts: IND/IDE Amendments (Biologics Only)	20,362	20,362	20,362
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	14	14	14
Approvals: PLA/BLA	11	11	11
Reviews: License Supplement (PLA/ELA/BLA)	349	349	349
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	1,545	1,000	1,000
Outputs – Reviews/Approvals			
Actions – ANDA	1,521	1,550	1,600
Approval Actions - ANDA (both Tentative and Full Approvals)	480	550	600
Median Review Time from ANDA Receipt to Approval (months)	42	42	42
Actions - ANDA Supplementals (Labeling and Manufacturing)	7,630	7,500	7,400
Over-the-Counter Drug Review			
OTC Monographs Under Development*	25	25	25
OTC Monographs Published*	1	5	3
*Category includes Proposed Rules and Final Rules			
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	11	10	10
New Written Requests Issued	16	15	15
Pediatric Exclusivity Determinations made	6	8	10
Post Exclusivity Safety Report	9	9	9
Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	1,317,813	1,595,380	1,872,947
Electronic Submissions: % of Total Adverse Drug Reaction Reports	91%	95%	99%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	94%	94%	99%
Submissions: Drug Quality Reports	13,193	15,400	18,434
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	4,107	4,518	4,970
Number of drugs with Risk Communications	413	250	275
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	36	42	45
Number of FOI Requests	3,143	2,600	2,600
Number of FOI Requests Processed	3,224	2,650	2,650
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	102	97	97
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	181	172	172
Number of Citizen Petitions Completed [1] (excluding suitability petitions and OTC monograph-related petitions)	106	106	106

[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 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,869***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	161	171	171
Pre-Approval Inspections (ANDA)	140	216	216
Bioresearch Monitoring Program Inspections	635	563	563
Drug Processing (GMP) Program Inspections	780	591	591
Compressed Medical Gas Manufacturers Inspections	218	295	295
Adverse Drug Events Project Inspections	90	120	120
OTC Monograph Project and Health Fraud Project Inspections	60	79	79
Compounding Inspections[1]	92	130	130
Domestic Laboratory Samples Analyzed	1,320	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***993***	***999***	***999***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	168	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	116	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	200	255	255
Foreign Drug Processing (GMP) Program Inspections	757	843	843
Foreign Adverse Drug Events Project Inspections	8	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,862***	***2,855***	***2,855***
IMPORTS			
Import Field Exams/Tests	7,314	7,200	7,200
Import Laboratory Samples Analyzed	353	490	490
Import Physical Exam Subtotal	**7,667**	**7,690**	**7,690**
Import Line Decisions	641,908	643,990	672,765
Percent of Import Lines Physically Examined	1.19%	1.19%	1.14%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS [3]	***0***	***0***	***0***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	0	0	0
State Partnership Inspections: GMP Inspections	0	0	0
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,862***	***2,855***	***2,855***

[1] The number of compounding inspections includes inspections of compounding pharmacies and outsourcing facilities under sections 503A and 503B respectively.

[2] The FY 2014 actual unique count of foreign inspections includes 102 OIP inspections (36 for China, 62 for India and 4 for Latin America).

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

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT[8]

	FY 2014 Actual	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Program Level[9]	$24,745,165	$23,598,688	$23,598,688	0
Orphan Product Development Grants[10]	$14,035,060	$14,035,060	$14,035,060	0
Pediatric Device Consortia Grants[11]	$3,000,000	$3,000,000	$3,000,000	0
Program Administration[12, 13]	$7,710,105	$6,563,628	$6,563,628	0

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, Sections, 510, 620 and 908.

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 prevention, diagnosis, and/or treatment of rare diseases or conditions. There are an estimated 7,000 rare diseases, with a public health impact that affects more than 25 million Americans and

[8] 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.

[9] Assumes approximately 50 percent of non-grant budget from user fees in FY 2015

[10] Orphan Product Grants are part of the aggregate amount of budget authority contained in the CDER budget line item of the All Purpose Tables.

[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 2014 actual includes $2,175,000 in supplemental funds for OPD grants and $300,000 for PDC grants; FY 2015 and FY 2016 include a supplemental of $1,200,000 to support Orphan Product Grants.

many millions more of family members in the United States. Between 85 and 90 percent of these cases are serious or life-threatening.

Improve and Safeguard Access

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' strategic goal to advance scientific knowledge and innovation. Further, OOPD activities support FDA's strategic goal to improve access to FDA regulated products that benefit health by enhancing the process of developing promising new products into safe, effective, and accessible treatments for rare disease patients. OOPD programs facilitate product development through collaboration with private, public, and academic entities.

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.

Over 600 clinical trials funded by the Orphan Products Grants Program have been used to bring more than 55 orphan products to marketing approval for serious or life threatening orphan indications. OOPD Grants Program has funded approximately 10 percent of orphan product approvals. In FY 2014, OOPD funded 15 new grants (out of 99 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. 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.

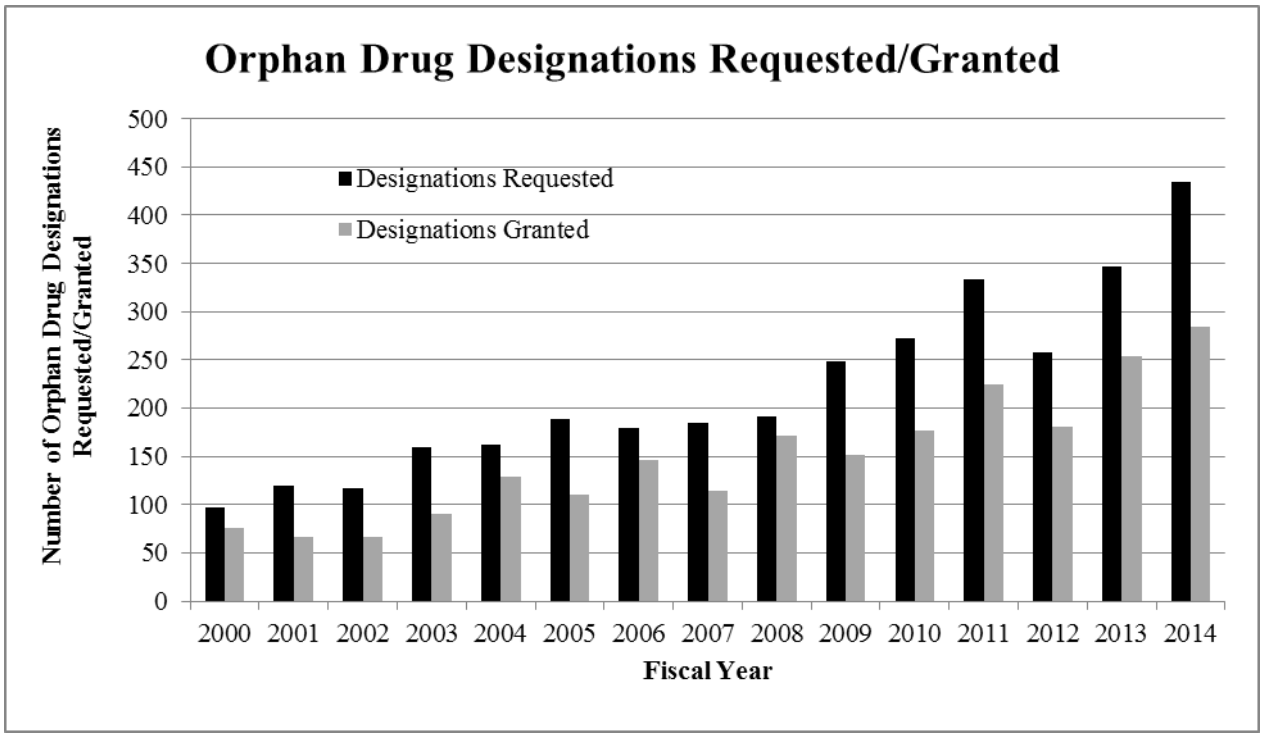
Orphan Drug Designation Activity

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 3,200 orphan drug designations OOPD issued since 1983, over 490 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 2014, OOPD received a record 434 new applications for orphan drug designation reflecting a 30%

increase over the previous FY. These included potential treatments for many kinds of rare cancers, sickle cell disease, and Ebola. OOPD designated a record 285 orphan drugs in FY 2014. FDA approved 45 orphan designated drugs for marketing in FY 2014.

The number of requests for orphan designation has more than tripled since 2000. Not only are the requests rapidly increasing, but the complexity of the science associated with these orphan drugs is increasing due to advances in pharmacogenomics and personalized medicine. In FY 2014, 33.3 percent of all the new molecular entities that FDA approved were orphan designated drugs and biologics.



Rare Pediatric Disease Priority Review Voucher Designation

FDASIA added Section 529 to the FD&C Act to encourage development of new drug and biological products ("drugs") for the prevention and treatment of qualifying rare pediatric diseases. This legislation created the Rare Pediatric Disease Priority Review Voucher (PRV) program wherein the sponsor of an approved drug to prevent or treat a rare pediatric disease may receive a voucher for a priority review of a subsequent drug.

Sponsors who are interested in receiving a rare pediatric disease priority review voucher may first request a "rare pediatric disease" designation through OOPD. While such designation is not required to receive a voucher, requesting this in advance may expedite a sponsor's future request for a priority review voucher. In FY 2014, OOPD received 14 rare pediatric disease designation requests and 2 consults from submitted marketing applications for rare pediatric disease determinations. Of these, OOPD determined that 5 met the definition of a "rare pediatric disease." One rare pediatric disease voucher was also issued. By legislative mandate, the program will sunset one year after the third voucher has issued and a GAO study conducted.

Humanitarian Use Device Designation Activity
The HUD program to encourage the development of devices for rare diseases was created by the Safe Medical Devices Act and is 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, 62 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, eleven 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 2014, OOPD received 17 new HUD applications and designated 7 devices. An additional five devices were designated based on HUD applications originally submitted in prior years for a total of 12 HUD devices designated in FY 2014. In FY 2014, four devices received an HDE approval from CDRH and three 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. 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, the consortia are funded in this program are based out of Boston, Philadelphia, District of Columbia, Atlanta, Ann Arbor, Los Angeles, and San Francisco.

Since the Program's inception in 2009, a total of $17.9 million have been awarded to the consortia over six years. Collectively, the consortia have supported the development of more than 440 potential pediatric devices, many of which are in the early stages of development. The success of the consortia has also leveraged more than $32 million additional funding dollars to support pediatric device development research.

Communication
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 pediatric device needs and orphan drug shortages
- providing web-based rare disease and orphan product resources and information to various stakeholders such as industry, the patient community, advocacy groups, and international regulatory agencies

In FY 2014**,** OOPD participated in 71 individual industry outreach meetings. In addition, OOPD received more than 63 invitations to speak and participate at orphan product stakeholder meetings and conferences to discuss different rare disease issues. OOPD made presentations and participated in 42 of these meetings both nationally and internationally, 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 2014 include conducting training courses for researchers and reviewers, 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 2012 Actual	$23,636,200	$23,636,200	$0
FY 2013 Actual	$23,139,897	$23,139,897	$0
FY 2014 Actual	$24,745,165	$24,745,165	$0
FY 2015 Enacted	$23,598,688	$23,598,688	$0
FY 2016 Request	$23,598,688	$23,598,688	$0

BUDGET REQUEST

The FY 2016 Budget Request for the Office of Orphan Products Development is $23,598,688 in budget authority and user fees, which is the same as the FY 2015 Enacted.

PROGRAM ACTIVITY DATA

Office of Orphan Products Development			
Program Workload and Outputs	**FY 2014 Actual**	**FY 2015 Estimate**	**FY 2016 Estimate**
Grants Program			
New Orphan Product Grants Awarded	14	8	8
Total Pediatric Consortia Grants (New and Continuations)	7	7	7
Orphan Drug Request, Designations, and Market Approvals			
New Designation Requests	434	348	348
Designations	285	233	233
FDA Marketing Approvals	45	34	34
HUD Requests and Designations			
New Designation Requests	17	25	25
Designations	12	14	14

BIOLOGICS

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Biologics	**337,543**	**321,064**	**344,267**	**350,457**	**6,190**
Budget Authority	***210,928***	***210,912***	***211,382***	***215,021***	***3,639***
User Fees	***126,615***	***110,152***	***132,885***	***135,436***	***2,551***
Center	292,586	278,091	298,979	307,254	*8,275*
Budget Authority	170,744	170,733	171,096	174,052	*2,956*
User Fees	121,842	107,358	127,883	133,202	*5,319*
Prescription Drug (PDUFA)	*109,993*	*96,253*	*115,493*	*120,107*	*4,614*
Medical Device (MDUFA)	*10,301*	*10,211*	*10,549*	*11,208*	*659*
Generic Drug (GDUFA)	*774*	*671*	*1,052*	*1,078*	*26*
Biosimilars (BsUFA)	*774*	*223*	*789*	*809*	*20*
Field	44,957	42,973	45,288	43,203	*-2,085*
Budget Authority	40,184	40,179	40,286	40,969	*683*
User Fees	4,773	2,794	5,002	2,234	*-2,768*
Prescription Drug (PDUFA)	*4,581*	*2,618*	*4,810*	*2,022*	*-2,788*
Medical Device (MDUFA)	*192*	*176*	*192*	*212*	*20*
FTE	**1,302**	**1,319**	**1,326**	**1,337**	**11**

Authorizing 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 (FDAAA); Patient Protection and Affordable Care Act of 2010; Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA); and Drug Quality and Security Act of 2013.

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Biologics Control Act, passed in 1902, established the Biologics Program in the Department of Treasury's Hygienic Laboratory, which 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 program, comprises the FDA Biologics Program.

FDA's Biologics Program is responsible for protecting and enhancing public health by ensuring the safety, purity, potency and effectiveness of biological products − for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries − including:

- vaccines and allergenic products
- blood and blood products
- certain cells and tissues
- gene therapies.

FDA regulates complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science. FDA is responsible for the evaluation of the safety and effectiveness of biological products and determines whether a product can be approved based on an evaluation of scientific data. Some cells and tissues for transplantation are regulated solely under section 361 of the Public Health Service (PHS) Act, with a focus on prevention of contamination of the tissues and spread of communicable disease.

FDA works with other Federal agencies, foreign governments and their national regulatory authorities, and international organizations such as the World Health Organization (WHO). FDA also protects the public against the threat of emerging infectious diseases, neglected tropical diseases, and potential bioterrorism agents.

Major accomplishments for the Biologics program include the following:

- FDA contributed to global policy development in response to the Ebola outbreak in West Africa by providing scientific and regulatory advice to sponsors, and rapidly evaluated investigational new drug (IND) applications for biological products to treat patients
- Under the accelerated approval regulations, FDA approved TRUMENBA, a Meningococcal Group B Vaccine that was designated as a breakthrough therapy
- FDA approved noteworthy biological products such as ALPROLIX, RUCONEST, ELOCTATE, and OBIZUR for treatment of patients with blood disorders; and ORALAIR, GRASTEK, and RAGWITEK, the first three sublingual allergen extracts to be approved in the United States
- FDA provided essential support to the Department of Justice (DOJ), leading to conviction and sentencing of individuals responsible for introducing misbranded and unapproved new drugs (stem cells) into interstate commerce.

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

Improve and Safeguard Access

Within this Goal area, the Biologics Program addresses the following FDA Strategic Priorities: Safety and Quality, Regulatory Science, Globalization and Smart Regulation. FDA is responsible for regulating a diverse range of products, from new and innovative vaccines and allergenics to novel cellular and gene therapies.

To improve access to biological products, FDA uses all available tools, including regulatory science, to effectively evaluate products and improve predictability, consistency, transparency, and efficiency of the review process. Activities include increasing preparedness to address public health threats, approving new biological products to treat and prevent diseases, supporting expedited regulatory pathways, facilitating biological product development and improving global public health through international collaboration.

Increasing Preparedness to Address Threats as a Result of Bioterrorism, Pandemic and Emerging Infectious Diseases

To help speed development and production programs for Ebola vaccines, FDA is providing scientific and regulatory advice to the regulated industry and U.S. government agencies that support medical product development, including the National Institute of Allergy and Infectious Diseases (NIAID) and, the Biomedical Advanced Research and Development Authority (BARDA) within, the U.S. Department of Health and Human Services (HHS), and the U.S.

Department of Defense (DOD). Between September and December 2014, the FDA Biologics Program expeditiously reviewed IND applications for numerous investigational Ebola vaccines, allowing for the initiation of studies in humans.

FDA also is collaborating with WHO and several of our international regulatory counterparts, including the European Medicines Agency and Health Canada, to exchange information about investigational products for Ebola. These efforts support regulatory collaboration to harmonize and accelerate the development of these and other biological products.

On December 12, 2014, FDA convened a public workshop in collaboration with the NIH/NIAID, DOD, the Centers for Disease Control and Prevention (CDC), and BARDA to discuss the Ebola virus and vaccine immunology to inform future clinical, scientific, and regulatory decision-making related to vaccines against Ebola.

On April 3 and 4, 2014, FDA convened a public workshop in collaboration with the NIH/NIAID to engage scientific experts to review data on existing dengue human infection models; discuss each model's advantages, risks and limitations; evaluate their possible role in advancing the development of vaccines for dengue; and discuss appropriate avenues for further research.

On February 28, 2014, FDA's Vaccines and Related Biological Products Advisory Committee met to select the influenza viruses for the composition of the trivalent and quadrivalent formulations for the influenza vaccine for the 2014-2015 U.S. influenza season. During this meeting, the advisory committee reviewed and evaluated the surveillance data related to epidemiology and antigenic characteristics of recent influenza isolates, serological responses to 2013-2014 vaccines, and the availability of candidate strains and reagents.

There are currently 14 FDA-approved seasonal influenza vaccines for the United States, including 4 quadrivalent vaccines and 10 trivalent vaccines for seasonal influenza and 2 (H5N1) FDA-approved vaccines for the National Stockpile.

Supporting Expedited Regulatory Pathways for Product Review

FDA grants designation of breakthrough therapies per Section 902 of FDASIA. FDA collaborated with the CDC to ensure a prompt response to the meningococcal B outbreak on U.S. college campuses. In spring 2014, Pfizer and Novartis publicly acknowledged receiving breakthrough therapy designation for the development of meningitis B vaccines. On October 29, 2014, under the accelerated approval regulatory pathway, FDA approved TRUMENBA, a meningococcal group B vaccine. Accelerated approval allows FDA to approve products for serious or life-threatening diseases based on a surrogate endpoint that is reasonably likely to predict clinical benefit, reducing the time it takes for needed medical products to become available to the public.

In October 2014, FDA participated in the 21st Century Cures roundtable on vaccines in Research Triangle Park, North Carolina. Roundtable participants included representatives from the Department of Health and Human Services, other HHS agencies, industry, academia, patient advocacy groups, and members of Congress.

In May 2014, FDA issued the final 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.[14]

In April 2014, FDA issued draft guidance, "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," which will help patients have more timely access to these medical devices by expediting their development, assessment and review.

Approving New Biological Products

In addition to the aforementioned work on Ebola and approvals for influenza and TRUMENBA for meningitis B, the Biologics Program reviewed and approved an array of biological products to treat and prevent diseases.

In December 2014, FDA approved the Intercept Blood System for platelets, the first pathogen reduction system to treat single donor apheresis platelets. The system is for use by blood establishments that collect and manufacture blood and blood components to prepare pathogen reduced platelets for transfusion to reduce the risk of transfusion-transmitted infections. The Intercept System for platelets has been shown to reduce the number of a broad range of viruses, bacteria and other pathogens that may contaminate platelets, an important advancement in improving platelet safety. That same month, FDA approved the Intercept Blood System for the preparation of plasma to reduce the risk of transfusion-transmitted infections.

Also, in December 2014, FDA approved Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV), five more HPV types than Gardasil. Overall, Gardasil 9 has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers, providing broader protection against HPV-related cancers.

In October 2014, FDA approved Geenius™ HIV 1/2 Supplemental Assay, the first FDA approved rapid supplemental diagnostic test. This assay is for use as an aid in diagnosis of infection with HIV-1 and HIV-2. It is intended for use as an additional more specific test, for use with fingerstick whole blood, venous whole blood, serum, or plasma samples, to confirm the presence of and differentiate between antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by diagnostic screening procedures.

In October 2014, FDA approved OBIZUR, Antihemophilic Factor (Recombinant), Porcine Sequence, under the orphan drug designation, and was reviewed under the Priority Review schedule of the PDUFA V program. This approval is for the treatment of bleeding episodes in patients with acquired hemophilia A (AHA). Currently, OBIZUR is licensed only in the U.S. and will address an unmet medical need for a Coagulation Factor VIII based product to treat AHA.

In September 2014, FDA approved HyQvia, Immune Globulin Infusion 10 percent (Human) with Recombinant Human Hyaluronidase, for the treatment of patients with primary humoral

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

immune deficiency. The product, administered subcutaneously, will offer greater convenience to patients by reducing the frequency of required infusions from weekly to monthly.

In July 2014, FDA approved RUCONEST, the first recombinant C1-Esterase Inhibitor product for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). RUCONEST received orphan designation because it is intended to treat a rare disease or condition. This drug is also intended to restore the level of functional C1-esterase inhibitor in a patient's plasma, thereby treating the acute attack of swelling, which has the potential to be fatal. RUCONEST contains human C1-Esterase Inhibitor that is expressed in the milk of genetically modified rabbits.

In June 2014, FDA approved ELOCTATE, Antihemophilic Factor (Recombinant), Fc fusion protein, for use in adults and children who have Hemophilia A, and is the first Hemophilia A treatment designed to require less frequent injections.

In May 2014, FDA approved the Immucor PreciseType Human Erythrocyte Antigen (HEA) Molecular BeadChip Test, the first FDA-approved molecular assay used in transfusion medicine to assist in determining blood compatibility. The assay can be used to determine donor and patient non-ABO/non-RhD red blood cell types in the United States.

FDA also approved allergenic products, which are non-user fee biological products. There are currently three types of allergenic products licensed for use: allergen extracts, allergen patch tests and antigen skin tests. In April 2014, FDA approved ORALAIR and GRASTEK, the first sublingual allergen extracts for the treatment of allergic rhinitis with or without conjunctivitis induced by certain grass pollens. FDA also approved RAGWITEK, the first sublingual allergen extract for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis in adults.

Facilitating Biological Product Development

In December 2014, FDA issued a draft guidance entitled, "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance provides human cells, tissues, and cellular and tissue-based product (HCT/P) manufacturers, healthcare providers, and FDA staff, with draft recommendations for meeting the criterion under Title 21 of the Code of Federal Regulations (CFR) Part 1271, specifically the 21 CFR 1271.10(a)(1) criterion of minimal manipulation. The interpretation of the minimal manipulation criterion and definitions of related key terms has been of considerable interest to industry stakeholders since the criterion and definitions were first proposed during FDA's rulemaking on HCT/Ps. It is anticipated that this guidance, when finalized, will improve stakeholders' understanding of the definitions of minimal manipulation in 21 CFR 1271.3(f), and how to apply the regulatory criterion in 21 CFR 1271.10(a)(1) to their HCT/Ps.[15]

In October 2014, FDA issued a draft guidance entitled, "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Draft

[15] In December 2014, FDA also issued a draft guidance entitled "Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance." FDA has recently received numerous inquiries regarding HCT/Ps manufactured from adipose tissue. When finalized, this guidance, currently addressed to sponsors, clinicians, and other establishments that manufacture and use HCT/Ps from adipose tissue, will provide FDA's current thinking with respect to regulatory considerations for adipose tissue.

Guidance for Industry." This draft guidance is intended for tissue establishments and healthcare professionals and discusses one of the exceptions for establishments from the requirements in 21 CFR Part 1271.

On September 22-23, 2014, FDA, NIH, CDC, WHO, and the Bill and Melinda Gates Foundation held a Public Workshop entitled, "Translational and Regulatory Science of Polio Vaccines and Antivirals," in Bethesda, MD. The purpose of the workshop was to review polio eradication and planning for the future including development of new prophylactic and therapeutic tools.

In July 2014, FDA issued the draft guidance for industry entitled "Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products." This draft guidance provides industry with recommendations on how to conduct shedding studies and what data to collect for virus or bacteria-based gene therapy products and oncolytic viruses or bacteria during preclinical and clinical development.

On June 19-20, 2014, in partnership with NIAID, FDA co-sponsored a workshop on solutions to address common barriers to vaccine development. Participants discussed novel approaches to vaccine antigen selection, scientific issues regarding induction of vaccine memory, and correlates of protection.

On March 31, 2014, FDA held a workshop to inform stakeholders on current efforts to standardize the clinical development of cellular therapies and regenerative medicine products, and the role federal Agencies play in standards development. The workshop also provided opportunities to discuss future standards development and explore ways to minimize redundancy and maximize collaboration among stakeholders.

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

FDA has participated in various meetings with WHO to facilitate regulatory capacity building of national regulatory authorities in developing countries.

Throughout 2014, FDA made key contributions to ongoing negotiations within the International Conference on Harmonization (ICH) to form a new legal identity, with the goal of creating a more open organizational model, introducing greater transparency, and securing financial soundness and parity across the participating bodies via a new funding model. Specific contributions were made to an ICH Statutes Task Force to craft a legal instrument to govern the new legal entity in addition to the ongoing core contributions of experts to ICH guidelines under development.

In August 2014, FDA participated in the WHO International Conference of Drug Regulatory Authorities to help identify and promote best practices in drug regulation. Additionally, FDA participated in a pre-meeting with industry and regulators to discuss strategies to assure the quality and safety of biosimilar products.

In May 2014, FDA announced the Mutual Reliance Initiative, with the European Union, to enhance pharmaceutical quality through international collaboration, and further the goal of ensuring that the public has access to quality pharmaceuticals. FDA is collaborating with our colleagues in European institutions and member states to build upon existing relationships with the European Medicines Agency and member states of the European Union, the European Commission, and the European Parliament.

On March 31 - April 1, 2014, FDA participated in its annual bilateral meeting with the European Commission and the European Medicines Agency in London to share updates and programmatic information on the regulation of vaccines, therapeutics, and blood products as well as to strategize regarding future collaborations of mutual interest.

Throughout 2014, the Biologics Program participated with the European Medicines Agency in multiple regularly scheduled, standing virtual meetings of experts ("Clusters") across a range of topic areas (oncology, vaccines, blood products, cell and gene therapies, biosimilars, pharmacovigilance, good clinical practice, and pediatric medicines). The "cluster" discussions included information exchanges on a multitude of topic areas under our mutual confidentiality commitments. Many of the "cluster" discussions now include regulatory counterparts from Canada and Japan.

In March 2014, FDA held the jointly sponsored 17th US-Japan Cellular and Gene Therapy Conference to exchange ideas on cutting edge areas of biomedical research and to enhance opportunities for collaborations among scientists from Japan and the US.

Enhance Oversight

Within this Goal area, the Biologics Program addresses the following FDA Strategic Priorities: Safety and Quality, Regulatory Science, Globalization and Smart Regulation. FDA's oversight of production, manufacturing, and the global supply chain, and surveillance of postmarket product use plays a critical role in assuring the safety of FDA-regulated products. In addition, regulatory oversight has enabled FDA to develop standards, reduce risks in the manufacturing, production, and distribution of FDA-regulated products, strengthen the detection and surveillance of potential problems, and improve the response to identified and emerging problems with FDA-regulated products. Activities related to enhanced oversight include, providing outreach on good manufacturing practices and enhancing the surveillance of biological products.

Providing Outreach to the Blood Industry

In December 2014, the FDA issued a draft guidance entitled "Bacterial Detection Testing by Blood and Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion."

On November 13, 2014, the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) met to consider the deferral of men who have had sex with another man (MSM) since 1977 as blood donors. The Committee agreed that the completed HHS MSM Blood Donor Deferral Studies, along with other additional studies and data, provide the ACBTSA with sufficient information to support a change from the current MSM deferral policy. The Committee recommended a one year deferral period and that a surveillance system to monitor the safety of the blood supply is needed prior to implementation of this change.

FDA brought the issue of the use of recency tests for HIV infection as a tool to monitor blood safety if a change to the MSM donor deferral is made to the Blood Products Advisory Committee for discussion and advice on December 2, 2014.

In September 2014, FDA participated in the development of the WHO guidance entitled "Use of convalescent whole blood or plasma collected from patients recovered from Ebola virus disease Empirical treatment during outbreaks."

In August 2014, FDA issued a final guidance entitled, "Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis." The recommendations in the guidance apply to blood establishments that collect Whole Blood or blood components, including Source Plasma.

In January 2014, FDA held a public workshop in partnership with NIH's National Heart, Lung and Blood Institute and the Plasma Protein Therapeutics Association entitled, "Strategies to Address Hemolytic Complications of Immune Globulin Infusions." The goals of the workshop were to identify and discuss potential risk mitigation strategies for immune globulin infusion-associated hemolysis, including improved identification of patients at high risk for hemolysis; changes in product specifications, tests, or test methods; and modifications to manufacturing to lower product risk. Additionally, this workshop allowed for discussions on outstanding research questions related to patient risk and product characteristics.

Enhancing the Surveillance of Biological Products

On July 18, 2014, FDA issued a draft guidance for industry entitled, "Providing Submissions in Electronic Format – Postmarketing Safety Reports for Vaccines." This guidance was issued in association with the rulemaking discussed directly below. This draft guidance will provide recommendations pertaining to the electronic submission of postmarketing safety reports for licensed human vaccines to the Vaccine Adverse Event Reporting System.

In June 2014, FDA issued the final rule "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements," requiring the electronic submission of mandatory postmarketing safety reports for human drug and biological products along with a companion guidance. Receiving all mandatory postmarket safety reports in electronic format will help FDA more rapidly review postmarket safety reports, identify emerging safety problems, and disseminate safety information. This action is also a key element in harmonizing FDA's postmarket safety reporting regulations with international standards for the electronic submission of safety information.

In May 2014, using PRISM – the Post Licensure Rapid Immunization Safety Monitoring System – FDA completed the first large scale safety evaluation of multiple vaccines classes including:

- trivalent influenza vaccines (TIV)
- 13-valent pneumococcal conjugate vaccine
- diphtheria, tetanus, and acellular pertussis containing vaccines.

Results showed no statistically significant association between TIVs and increased risk of febrile seizures in children ages 6 – 59 months. Based on these findings, FDA did not change the Prescribing Information for influenza vaccines.

PRISM studies continued to evaluate venous thromboembolism and Gardasil – a human papillomavirus vaccine – and Kawasaki Disease and Prevnar 13 – a pneumococcal conjugate vaccine – and is also assessing the feasibility of addressing pregnancy and birth outcomes after the use of influenza vaccines.

In September 2014, FDA continued its routine 'rapid cycle' safety surveillance for Guillain-Barre Syndrome (GBS) after influenza vaccine for the 2014-2015 season using data from the Centers for Medicaid and Medicare.

FDA continued development of the Blood Safety Continuous Active-Surveillance Network (BloodSCAN) to create an active pharmacovigilance system for blood and blood products by continuing a protocol-based evaluation of thromboembolic events and Immune Globulin Products. FDA also initiated a new partnership with Hospital Corporation of America to enable safety assessments of intravenously administered medical products in the hospital setting, where the majority of blood and blood-derived products are administered.

In tandem with the aforementioned licensure of Gardasil 9, FDA initiated the first protocol-based study designed to mine the electronic healthcare data in Sentinel and to detect serious and unexpected adverse events after vaccination for this new vaccine.

FDA developed the CBER Product Shortage database, which is mapped to be consistent with the CDER Drug Shortage database for reporting to Congress as mandated under FDASIA Title X. CBER has responded to 12 potential shortages in FY 2014, with one confirmed shortage.

In FY 2014, Team Biologics continued to conduct highly complex inspections of foreign and domestic biological drug product manufacturers, including but not limited to manufacturers of medically necessary vaccines and immune globulin products, to ensure compliance with current Good Manufacturing Practice (cGMP) and identify and document violations of these regulations. As a result of documented violations of the FD&C Act and the PHS Act, FDA issued four Warning Letters to biological drug manufacturers

In April 2010, the Office of Criminal Investigations initiated an investigation of a medical facility for selling illegal stem cell therapies to patients. The treatment protocol consisted of supplements, vaccines, and stem cell therapy in treating amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS) and Parkinson's disease. The facility falsely represented to patients that the treatment protocol had been reviewed by the FDA and was effective in the treatment of ALS, MS, and Parkinson's disease. As of May 2014, the individuals responsible were convicted and sentenced for their roles in a conspiracy to introduce misbranded and unapproved new drugs into interstate commerce.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$321,064,000	$210,912,000	$110,152,000
FY 2015 Enacted	$344,267,000	$211,382,000	$132,885,000
FY 2016 Request	$350,457,000	$215,021,000	$135,436,000

BUDGET REQUEST

The FY 2016 Budget Request is $350,457,000, of which $215,021,000 is budget authority and $135,436,000 is user fees. This amount is $6,190,000 more than the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $3,639,000. This amount includes $1,628,000 in reductions to targeted, lower priority compliance, inspection, outreach, and training activities. In addition, user fees increase by $2,551,000.

The FY 2016 Budget will enable FDA to advance the public health through innovative regulation that promotes the safety, effectiveness, and timely delivery of biological products to patients. In FY 2016, FDA's strategic goals and priorities 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.

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.

FDA 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.

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

BUDGET AUTHORITY

Medical Product Safety: +$5.3 million

Combatting Antibiotic Resistant Bacteria: +$2.2 million
Center: +$2.2 million

With this funding the Biologics Program will facilitate the development of better diagnostics, therapeutics, and vaccines for the management of antimicrobial resistant organisms as a part of the National Strategy for Combating Antibiotic Resistant Bacteria. This request will support animal model development to support vaccine and antimicrobial drug development for high priority bacterial pathogens such as *Staphylococcus aureus, Mycobacterium tuberculosis* (TB), *Klebsiella pneumonia*, and *Clostridium difficile.* The timeframe for achieving success in developing these new animal models would be two to five years.

FDASIA Implementation – Unique Facility Identifier: +$1.1 million
Field: +$1.1 million

Domestic and foreign drug manufacturers are required to register annually with the FDA and each registration, as mandated by FDASIA, must include a Unique Facility Identifier (UFI). With this funding increase, FDA will be able to support electronic registration and integration of the UFI into FDA's IT systems that support ORA's medical product related regulatory work, including ORA's Official Establishment Inventory (OEI).

FDASIA Implementation – Electronic Biological Product Application Submission: +$1.9 million

Center: +$1.9 million

FDA will use the requested funding to implement Section 1136 "Electronic submission of application" of FDASIA which requires application submissions in an electronic format specified by FDA, beginning no earlier than 24 months after FDA issues a final guidance specifying an electronic submission format. Draft guidance was issued in February 2014. FDA is requesting resources for the infrastructure to process electronic New Drug Application, Abbreviated New Drug Application, Biologic License Application, and Investigational New Drug submissions for biological products and resources to implement the guidance, once it is finalized. FDA regulates a number of important biologic products that are not covered by user fees; this request to implement electronic biological product application submission supports these non-user fee biological products.

USER FEES

Current Law User Fees: +$2.6 million

Center: +$5.3 million / Field: -$2.8 million

The Biologics Program request includes an increase of $2.6 million for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry.

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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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)*	FY 2013: 100% Target 90% (Target Exceeded)	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)*	FY 2013: 100% Target 90% (Target Exceeded)	90%	90%	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
233209: Review and act on standard non-NME original NDA submissions within 10 months of receipt. *(Output)*	FY 2013: NA (No submissions received)	90%	90%	maintain
233210: Review and act on priority non-NME original NDA submissions within 6 months of receipt. *(Output)*	FY 2013: NA (No submissions received)	90%	90%	maintain
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. *(Output)*	FY 2013: 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 2013: 99% Target: 90% (Target Exceeded)	90%	90%	maintain
233211: Review and act on new non-user fee, non-blood product applications within 12 months of receipt. *(Output)*	FY 2013: 63% (Historical Actual)	60%	60%	maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. *(Output)*	FY 2014: Continued evaluation of 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.	Evaluate new methods to characterize influenza vaccines.	NA

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2014: 1,026 Target: 1,000 (Target Exceeded)	900	900	maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2014: 650 Target: 570 (Target Exceeded)	570	570	maintain

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

Review Performance Measures
FDA continues to exceed PDUFA and non-user fee blood bank and source plasma review measures. Performance results for FY 2014 will not be available until the review of the applications for the FY 2014 cohort is complete, typically sometime within the next fiscal year. The non-New Molecular Entities (NME) performance goals are important because the PDUFA V agreement requires FDA to report on the review performance for non-NME and NME product applications separately. In cohort years where no non-NME applications were submitted by industry, we've indicated that by saying NA for the actual data. For additional information on the PDUFA approvals, see the "Approving New Biological Products" section listed above in the program narrative.

In 2014, a performance measure to: review and act on new non-user fee, non-blood product applications within 12 months of receipt was added to better align with FDA strategic priorities and represent CBER's non-user fee workload.

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

FDA is evaluating three new methods for determining influenza vaccine potency; initial results show feasibility of all three and further evaluation is continuing.

In FY 2014, FDA met the target to continue evaluation of new methods to produce high-yield influenza vaccine reference strains. Activities to meet this target include the following items.

FDA continued evaluation and standardization of multiple assays, such as total viral protein yield and HA antigen by HPLC-based analysis. In addition, FDA included a new technology, Virus Counter platform, to quantify the virus particles in the virus preparation.

FDA developed a H7N9 influenza vaccine candidate virus. The vaccine candidate virus was optimized by introduction of targeted mutations in the viral genome to increase its protein yield, measured using the methods described above.

Decrease in Domestic Blood Bank Inventory for Inspection

The number of blood banks in the United States has decreased over the last several years due to significant changes in the industry, driven by less transfusions and the associated decrease in the amounts of stored blood, as well as consolidations and firms going out of business. FDA historically inspects 50 percent of the blood bank inventory each year to meet the statutory requirement to inspect each firm once every two years. With fewer firms to inspect, FDA is reducing the FY 2015 and 2016 target levels to 900 respectively to reflect the new inventory level.

PROGRAM ACTIVITY DATA

Biologics Program Activity Data (PAD)

CBER Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Original Biologics License Applications (BLA)			
Workload [1]	24	24	24
Total Decisions [2]	34	34	34
Approved	18	18	18
BLA Efficacy Supplements			
Workload [1]	38	38	38
Total Decisions [2]	21	21	21
Approved	18	18	18
BLA Manufacturing Supplements			
Workload [1]	985	985	985
Total Decisions [2]	1,160	1,160	1,160
Approved	978	978	978
BLA Labeling Supplements			
Workload [1]	221	221	221
Total Decisions [2]	237	237	237
Approved	217	217	217
Original New Drug Application (NDA)			
Workload [1]	1	1	1
Total Decisions [2]	0	0	0
Approved	0	0	0
NDA Efficacy Supplements			
Workload [1]	0	0	0
Total Decisions [2]	1	1	1
Approved	1	1	1
NDA Manufacturing Supplements			
Workload [1]	27	27	27
Total Decisions [2]	44	44	44
Approved	29	29	29
NDA Labeling Supplements			
Workload [1]	4	4	4
Total Decisions [2]	10	10	10
Approved	9	9	9
Original Abbreviated New Drug Application			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0
ANDA Efficacy Supplements			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0
ANDA Manufacturing Supplements			
Workload [1]	2	2	2
Total Decisions [2]	6	6	6
Approved	5	5	5
ANDA Labeling Supplements			
Workload [1]	1	1	1
Total Decisions [2]	2	2	2
Approved	2	2	2
Device 510Ks			
Workload [1]	57	57	57
Total Decisions [2]	86	86	86
Final Decision - SE	38	38	38

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,929***	***2,047***	***2,047***
Bioresearch Monitoring Program Inspections	95	100	100
Blood Bank Inspections	994	1,060	1,060
Source Plasma Inspections	167	194	194
Pre-License, Pre-Market Inspections	18	7	7
GMP Inspections	32	28	28
GMP (Device) Inspections	4	7	7
Human Tissue Inspections	650	661	661
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***68***	***47***	***47***
Bioresearch Monitoring Program Inspections	25	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	7	8	8
Pre-License, Pre-market Inspections	11	2	2
GMP Inspections (Biologics & Device)	23	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,997***	***2,094***	***2,094***
IMPORTS			
Import Field Exams/Tests	49	45	45
Import Line Decisions	82,710	96,091	109,202
Percent of Import Lines Physically Examined	0.06%	0.05%	0.04%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,997***	***2,094***	***2,094***

ANIMAL DRUGS AND FEEDS

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Animal Drugs and Feed	**173,207**	**164,313**	**174,783**	**197,192**	**22,409**
Budget Authority	***141,566***	***141,566***	***147,577***	***165,752***	***18,175***
User Fees	***31,641***	***22,747***	***27,206***	***31,440***	***4,234***
Center	115,461	110,546	119,314	130,103	*10,789*
Budget Authority	87,846	87,845	93,505	101,105	*7,600*
User Fees	27,615	22,701	25,809	28,998	*3,189*
Animal Drug (ADUFA)	*20,768*	*17,281*	*19,814*	*19,527*	*-287*
Animal Generic Drug (AGDUFA)	*6,302*	*5,420*	*5,995*	*6,414*	*419*
Food and Feed Recall	*545*		---	---	---
Food Facility Registration and Inspection	---	---	---	*1,557*	*1,557*
Food Import	---	---	---	*1,500*	*1,500*
Field	57,746	53,767	55,469	67,089	*11,620*
Budget Authority	53,720	53,721	54,072	64,647	*10,575*
User Fees	4,026	46	1,397	2,442	*1,045*
Animal Drug (ADUFA)	*472*	*31*	*404*	*399*	*-5*
Animal Generic Drug (AGDUFA)	*220*	*15*	*186*	*198*	*12*
Food and Feed Recall	*668*	---	---	---	---
Food Reinspection	*2,666*	---	*807*	*807*	---
Food Facility Registration and Inspection	---	---	---	*1,038*	*1,038*
FTE	**787**	**837**	**854**	**906**	**52**

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 devices and the safety and effectiveness of animal drugs. The FVM Program comprises the Animal Drugs and Feeds and the Foods Programs, including field activities in the Office of Regulatory Affairs (ORA). The operations of 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 Applied Nutrition (CFSAN) respectively, both in

collaboration with ORA. CVM is responsible for ensuring the safety and effectiveness of animal drugs as well as ensuring the safety of animal feeds. The Office of Foods and Veterinary Medicine provides leadership and strategic direction to the FVM Program.

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 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 feeds 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 (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 FVM Program Strategic Plan[16] 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 FVM Strategic Plan goals of standards setting, compliance, risk assessment and regulatory science, nutrition and food labeling, response, and animal drug safety.

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 appropriate use of approved drugs
- providing scientific research solutions that ensure the safety of the animal-derived food and health products
- putting measures in place to minimize the illegal sale of compounded and unapproved drugs
- 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, such as milk, that are harvested or produced 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. The efforts of the Animal Drugs and Feeds Program 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.

[16] The strategic plan can be found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf.

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 has many recent major accomplishments. These accomplishments include the finalization of Guidance for Industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals…" (December 2013). This guidance implemented a plan to help phase out the use of medically important antimicrobials in food-producing animals.

Other major accomplishments are the extensive work on the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" proposed rule 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).

The following selected accomplishments demonstrate how the Animal Drugs and Feeds Program has carried out its regulatory and public health responsibilities within the context of current priorities.[17]

Improve and Safeguard Access

The Animal Drugs and Feeds Program is responsible for regulating drugs and feed for over 100 million companion animals, plus millions of poultry, cattle, swine, and minor animal species. The Animal Drugs and Feeds Program's premarket responsibilities include ensuring the product review process is as effective and efficient as possible, and working collaboratively with partners in the private sector, public sector, and academia to facilitate product development. Within this goal area, the Animal Drugs and Feeds Program addresses the following FDA Strategic Priorities: Safety and Quality, Regulatory Science, and Globalization.

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.

FDA exceeded all performance goals and completed the review and action on 99.8 percent of original New Animal Drug Applications (NADAs) and other ADUFA sentinel submissions within timeframes specified by ADUFA for applications reviewed in FY 2013. 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 2013.

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

FDA also championed industry's adoption and use of the CVM Electronic Submission Tool, eSubmitter, for premarket review launched in FY 2011. As a result, electronic submissions rose from 17 percent to 63 percent by the end of FY 2014. Because all paper submissions from the industry are scanned, FDA has electronic access to 100 percent of submissions, reviews, and responses. Electronic submission eliminates the need for paper and reduces printing and mailing costs for industry. eSubmitter provides a structured online system and is a more efficient and effective drug approval process than with paper submissions.

On July 31, 2014, FDA issued a draft Guidance for Industry #218 "Cell-Based Products for Animal Use" describing FDA's current thinking on cell-based products for animal use that meet the definition of a new animal drug. The draft guidance is directed at facilities and individuals manufacturing and marketing such products for animal use. A cell-based product – including an animal stem cell-based product – that is intended to diagnose, cure, mitigate, treat, or prevent disease in animals or is intended to affect the structure or function of the animal generally meets the definition of a new animal drug. Cell-based products that meet the definition of a new animal drug are subject to the same statutory and regulatory requirements as other new animal drugs and require an approved or conditionally approved new animal drug application (NADA) or index listing to be legally marketed.

Animal Drug Inspections

FDA's field force conducts preapproval inspections to support the review of premarket applications for pioneer and generic animal drugs. In addition to aiding the preapproval process, bioresearch monitoring (BiMo) inspections of study facilities, clinical investigators, or sponsors, or contract research organizations are conducted to help assure the integrity of scientific testing and the reliability of test data submitted to FDA.

Once animal drug products are available on the market, the field continues oversight by inspecting manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application and to ensure manufactured products are free from contaminants. 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.

Minor Use Minor Species

FDA reviews conditional drug approvals, designation requests, and index requests to increase the number of safe and effective new animal drug products available for minor animal species and uncommon diseases in major animal species. Furthermore, FDA administers a grant program to support the development of these new drugs. Through FY 2014, FDA granted 125 drug designations. Recent new drug designations include those related to aquaculture and cancer treatments for dogs. FDA has a total of six animal drugs on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species. In many cases, minor species drug products are intended for uses that cannot reasonably go through the standard drug approval process. These drugs are often intended for use in species too rare or varied to be used in traditional safety and efficacy studies.

International Activities

The Animal Drugs and Feeds Program engages in numerous international partnerships that promote and protect animals, as well as the humans who are exposed to them, and develop

harmonized product standards and conformity assessment procedures. FDA partners with the European Food Safety Authority (EFSA) on the Animal Feed Cluster, which allows feed safety experts from both FDA and EFSA to discuss issues of joint interest such as reviews of safety assessments of various animal feed ingredients. FDA is a major participant in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In FY 2013, FDA chaired the VICH Steering Committee meeting and Outreach Forum meeting in Washington, D.C., and continued providing critical leadership in FY 2014, serving on the VICH Steering Committee and chairing a workgroup to develop a strategy for international training directed to developing countries.

The Animal Drugs and Feeds Program also has a strong partnership with Health Canada through the U.S.-Canada Regulatory Cooperation Council (RCC), a council that works to reduce unnecessary regulatory differences. The Veterinary Drug Initiative (VDI), a part of the RCC that enhances the premarket evaluation of veterinary drugs, encourages the U.S. and Canada to seek greater alignment in regulatory approaches to:

- remove duplicative requirements
- reduce costs
- work towards more timely access to animal drug products.

The cornerstone of the RCC action plan to advance regulatory cooperation was the simultaneous review by regulators in FDA and Health 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. In FY 2014, FDA and VDD approved BRAVECTO, the first oral flea and tick medication that lasts up to 12 weeks. Collaborative review on additional pilot drugs is ongoing. Moreover, with the onset of the FSMA, deliberative efforts were made to expand the class of medicines to include both food and non-food animals. The Animal Drugs and Feeds Program participated in many sponsor meetings with RCC on products under simultaneous review, continuing to promote the concurrent availability of drugs. 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.

Enhance Oversight

The Animal Drugs and Feeds Program protects public and animal health by ensuring that animal drugs and feed including medicated feeds are safe and effective and that food from treated animals is safe to eat. To accomplish this goal, the Animal Drugs and Feeds Program provides critical oversight of production, manufacturing, and the global supply chain for regulated products. The Program also provides surveillance of post market product use and assures the safety of FDA regulated products. Within this goal area, the Animal Drugs and Feeds Program addresses the following FDA Strategic Priorities: Safety and Quality, and Regulatory Science.

Preventive Controls for Animal Food

In October 2013, the Animal Drugs and Feeds Program published the FSMA proposed rule on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals." The purpose of the proposed rule is to establish requirements for current good manufacturing practices and preventive controls for the manufacturing, processing, packing, and holding of food for animals. This rule is one of FDA's set of foundational rulemakings to implement the modern prevention-focused food safety mandate granted to FDA

under FSMA. FDA reviewed more than 2,100 comments received and, in response to stakeholder input, proposed changes to sections of the proposed rule for public comment in September 2014. FDA also held three public meetings and over a dozen webinars in FY 2014 to obtain stakeholder and industry input to ensure that the final rule is practical, flexible, and effective.

Intentional Adulteration

The Animal Drugs and Feeds Program played a key role in drafting the proposed FSMA rule "Forced Mitigation Strategies to Protect Food Against Intentional Adulteration," published in December 2013. In addition, FDA held three public meetings in FY 2014 to obtain critical stakeholder input on the proposed rule. Efforts to protect against acts of intentional adulteration require a different approach than that used for non-intentional adulteration of food and feed products. This proposed rule would help address this important issue and protect the public from potentially catastrophic results including illness and death.

In some instances where intentional misbranding or adulteration occurs, FDA action will necessitate criminal investigations and measures. In April 2014, the field's Office of Criminal Investigations (OCI) charged a South Carolina couple in relation to operating a website selling illegally imported pet medications and pesticides. Two of the veterinarian drugs being sold over the website were being sold without valid veterinarian prescriptions. One of the owners pled to charges including wire fraud, trafficking in counterfeit goods and service, smuggling, selling unregistered pesticides, and introducing misbranded drugs into interstate commerce.

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 the authority 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.

Before the passage of FSMA, FDA was able to detain a food product only with credible evidence that the product presented a threat of serious adverse health consequences or death to humans or animals. Training grants have been awarded to state and local food safety partners to ensure consistent implementation and application of the national integrated food safety system and FSMA training requirements related to setting standards and administering training and education programs to state, local, territorial, and tribal food safety officials. For example, a course in animal production from the medicated feed and food safety perspective was created to address proper use of medicated feeds and avoidance of cross contamination in feed mills. Also, several manuals were developed for the training and education programs regarding production animal management and nutrition for beef and dairy cattle and swine.

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 "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based 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.

Adverse Drug Review

The Animal Drugs and Feeds Program reviews approximately 83,000 Adverse Drug Experience (ADE) reports annually and is the largest animal drug ADE database in the world, with over 500,000 entries. Over the past few 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 percent 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 premarket and postmarket approval animal drug work. The efforts to increase the functionality and utilization of this Pharmacovigilance database have improved animal drug safety.

In December 2014, FDA issued final guidance #214, "*Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data*." The guidance provides recommendations to help animal drug manufacturers create a single electronic adverse event message that can be used by multiple regulatory authorities. The need for drug manufacturers and regulatory bodies to exchange and send information on a worldwide scope is essential to monitoring potential health risks and ensuring drug safety. GFI #214 supports the FDA's work with the Veterinary International Conference on Harmonization (VICH), an international program aimed at harmonizing technical requirements for veterinary product regulation. The guidance is the FDA's version of VICH Guideline (GL) 35 and provides a standardized format to allow for electronic exchange of information between stakeholders.

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. Thus, PREDICT enhances the prevention for entry of adulterated, misbranded, or otherwise violative goods and expedites the entry of non-violative goods.

Vet-LIRN

The Animal Drugs and Feeds Program offers 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 FDA with investigations into potential problems with animal feeds, including pet foods, and animal drugs.

Since 2007, FDA has been actively investigating the cause of illnesses reported in pets which may be associated with the consumption of 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. In FY 2014, FDA continued its investigation of pet illnesses. 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 1,000 tests on pet jerky treat products. FDA also continues to conduct consumer complaint follow-ups, inspections, and sample collections and analyses. Moreover, FDA continues to publish periodic reports on its progress in the investigation.

In FY 2014, FDA collaborated with the Centers for Disease Control and Prevention (CDC) on a study of cases reported of sick dogs compared with "controls" – dogs that have not been ill. The goal of the study was to compare the foods eaten by the sick dogs (cases) to those eaten by the dogs that did not get sick (controls), in order to determine whether jerky pet treat exposure is associated with illness. Data collected during this investigation will allow federal investigators to better understand what is making pets sick. A manuscript of study results and analysis is currently being prepared for publication in a peer-reviewed scientific journal and the data will be made public once published.

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 assisted with more targeted inspections in FY 2014.

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 firm's potential shut down of operations. FDA issued 114 warning letters in FY 2014 as a result of field recommendations for regulatory action based on violative inspection findings. 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. In FY 2014, FDA classified 16 Class I (most serious), 32 Class II, and 13 Class III recalls of regulated animal products.

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. Following the fungal meningitis outbreak in 2012 and the enactment of the Drug Quality and Security Act (DQSA) in 2013, products from compounding pharmacies and outsourcing facilities continue to be a crucial area of concern. In March 2014, sample collections by the field indicated that a compounded equestrian drug contributed to the euthanasia and death of two thoroughbred horses in Kentucky and two in Florida. Therefore FDA continues to increase activities and focus in these areas.

In FY 2015, FDA expanded its Animal and Veterinary compliance and enforcement webpage to include a page dedicated to: Inspections, Recalls, and Other Actions with Respect to Firms that

Engage in Animal Drug Compounding.[18] 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 human and animal health. FDA is revising Compliance Policy Guide (CPG) section 608.400 entitled "Compounding of Drugs for Use in Animals" to ensure that FDA's enforcement policy regarding the compounding of drugs intended for use in animals is consistent, to the extent practicable, with its enforcement policy regarding the compounding of drugs intended for use in humans. FDA is planning on publishing the updated CPG in FY 2015 for public comment.

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.

In December 2013, FDA released final Guidance for Industry (GFI) #213 on removing production claims for medically important antimicrobials as well as the proposed rule revising the Veterinary Feed Directive which brings remaining therapeutic claims for these products under veterinary oversight. FDA asked affected sponsors to notify FDA in writing within three months of their intent to engage with FDA as defined in GFI #213. All 26 affected sponsors, holding 283 affected applications, confirmed in writing their intent to engage with FDA as defined in GFI #213 and have given FDA consent to make their names public. While GFI #213 specified a three-year timeframe (until December 2016) for drug sponsors to complete the recommended changes to their antimicrobial products, some sponsors have already begun to implement them.

To enhance 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. The Animal Drugs and Feeds Program analyzed the comments received, and have made changes to the tables. These additional tables categorize active ingredients sold by medical importance, dosage form, marketing status, and indication. The comment period for this *Federal Register* Notice closed in November 2013. FDA analyzed the comments and incorporated the proposed tables into the 2012 sales and distribution data, which published in October 2014.

The Animal Drugs and Feeds Program monitors antimicrobial resistance among enteric bacteria using new collaborative approaches for the National Antimicrobial Resistance Monitoring System (NARMS) that are statistically representative, scientifically sound, and support FDA regulatory activities. Because NARMS data have played key roles in recent regulatory activities, the program must continue to re-evaluate its sampling approach to assure that the data being generated can withstand scrutiny from both a scientific and regulatory perspective. In FY 2014,

[18] The webpage can be accessed at: http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/ucm417562.htm

FDA published the NARMS 2011 Executive Report[19] showing both increasing and decreasing antimicrobial resistance trends. The annual NARMS Executive Report focuses on resistance to antibiotics that are considered important in human medicine as well as multidrug resistance (described as resistance to three or more classes of antibiotics).

Through an interagency agreement with FDA, the USDA's 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. FDA also worked with the USDA's Agriculture Research Service (ARS) to develop a new consortium of ARS research centers and select universities to collect and test on-farm samples 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.

Research Studies related to Antibiotic Resistance and Salmonella

FDA provides scientific research solutions that ensure the 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. Methods to measure antibiotic levels in distillers grains, along with techniques to assess the effect of these drugs on bacteria, will allow FDA to determine if residues remaining from the fermentation process are at a concentration that can lead to the development of 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 detection methods should be valuable tools in routine testing and quantification of *Salmonella* in regulatory samples. In FY 2013, FDA released a new Compliance Policy Guide (CPG) entitled "*Salmonella* in Food for Animals" 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.

Nanotechnology

The Animal Drugs and Feeds Program is an integral partner in FDA's regulation of nanotechnology products. Nanotechnology is an emerging technology that allows scientists to create, explore, and manipulate materials on a scale measured in nanometers – billionths of a meter or particles so small that they cannot be seen with a regular microscope. Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.

In June 2014, FDA issued a draft guidance addressing the use of nanotechnology in food for animals. This guidance was released in conjunction with final guidance documents on the use of nanotechnology in foods, in cosmetics, and an FDA-wide guidance outlining overarching consideration for all FDA-regulated products. The draft guidance on the use of nanotechnology in food for animals addresses the legal framework for ingredients in food for animals and includes recommendations for submitting a Food Additive Petition (FAP) for a nanomaterial

[19] The NARMS 2011 Executive Report can be found at: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM407962.pdf

animal food ingredient. FDA posted the draft guidance for public comment through September 2014. FDA is analyzing the comments received.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$164,313,000	$141,566,000	$22,747,000
FY 2015 Enacted	$174,783,000	$147,577,000	$27,206,000
FY 2016 Request	$197,192,000	$165,752,000	$31,440,000

BUDGET REQUEST

The FY 2016 Budget Request for the Animal Drugs and Feeds Program is $197,192,000, of which $165,752,000 is budget authority and $31,440,00 is user fees. This amount is $22,409,000 more than the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $18,175,000. This amount includes $3,000,000 in reductions to targeted, lower priority surveillance, compliance, enforcement, and research activities. In addition, user fees increase by $4,234,000.

The FY 2016 Budget 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, and not compromise human health. In order to achieve this, the Animal Drugs and Feeds Program has prioritized the activities of greatest public health importance to maintain support for FDA core mission goals, to enhance oversight of FDA-regulated products and improve access to FDA-regulated products that benefit health. These activities include approval of marketed animal drug products, monitoring the safety of animal devices and the safety and effectiveness of animal drugs on the market, approving feed additives, and ensuring food for animals is safe.

At this funding level, the Animal Drugs and Feeds Program will approve safe and effective products for animals in the pre-approval process. The funding level 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. FDA will also conduct preapproval inspections in support of the animal drug review process.

In addition, the Animal Drugs and Feeds Program will continue important postmarket efforts to protect human and animal health. These efforts include reviewing Adverse Drug Experience reports which provide the ability to data mine, an important tool to analyze data in large complex databases with the goal of discovering unexpected occurrences of adverse event signals, for use in both pre and postmarket approval animal drug work. The Animal Drugs and Feeds Program

will continue investigating pet illnesses and enforce compliance actions in support of ensuring safe and effective products.

The Animal Drugs and Feeds Program will continue to address the source and magnitude of antimicrobial resistance in the food supply including making necessary enhancements to the National Antimicrobial Resistance Monitoring System (NARMS). Enhancements will improve 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 human and animal health.

The following proposed increases in the FY 2016 Budget Request support mission critical program activities and Presidential, HHS, and FDA public health priorities including the Food Safety initiative and Combating Antibiotic Resistant Bacteria.

BUDGET AUTHORITY

Food Safety: +$14.1 million

The Food Safety Modernization Act (FSMA) aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination of the food supply to preventing it. The law applies to human food as well as food for animals, including pets. Along with other FDA partners, the Animal Drugs and Feeds Program is working to create a modern, prevention-focused, science- and risk-based food and feed safety system.

Inspection Modernization and Training: +$3.3 million
Field: +$3.3 million

In FY 2016, the Animal Drugs and Feeds Program will:

- invest in inspection modernization and training of FDA investigators to focus on preventing food contamination
- develop and administer preventive, control-based inspection training to FDA and other federal, state, local, tribal, and territorial regulatory and public health partners.

National Integrated Food Safety System: +$6.2 million
Center: +$2.0 million / Field: +$4.2 million

In FY 2016, the Animal Drugs and Feeds Program will:

- invest in the capacity of state, local, tribal, and territorial regulatory and public health partners to strengthen coordination and consistency nationwide, improve information sharing capacity between FDA and states, and bolster state laboratory coordination
- set animal feed regulatory standards, establish training and education programs for state and local food safety partners and improve rapid response and recovery efforts by integrating the capabilities of federal, state and local partners
- modify existing surveillance infrastructure to provide a platform for ongoing high priority pathogen detection in the food supply
- partner with the CDC, USDA, and other FDA Centers to develop rapid strain typing methods for rapid response to foodborne outbreaks.

Education and Technical Assistance for Industry: +$1.5 million
Center: +$1.5 million

In FY 2016, the Animal Drugs and Feeds Program will develop guidance and conduct targeted education, training, and outreach to support implementation of the FSMA preventive control safety standards.

Import Safety – Foreign Supplier Verification Program (FSVP) Implementation: +$3.1 million
Field: +$3.1 million

The Animal Drugs and Feeds Program will support the implementation of the Foreign Supplier Verification Program (FSVP), which would require importers to perform certain risk-based activities to verify that food and feed imported into the U.S. has been produced in a manner that is consistent with U.S. safety standards. More specifically, the importer will be required to ensure that the imported food and feed is produced in compliance with processes and procedures that offer the same level of protection as FDA's preventive controls requirements and produce safety standards, and is not otherwise adulterated or misbranded with respect to food allergen labeling.

To be successful, FSVP will require a substantial regulatory development process, staffing and training within FDA to enforce the regulation, and extensive training and technical assistance for importers. The food and feed industry has expressed significant concern that FDA's ability to screen food and feed imports is currently an impediment to the smooth flow of trade, and that without the means to make FSVP implementation successful, FDA's efforts might become a barrier to trade. Already, FDA receives thousands of inquiries each year from importers regarding operations at port of entries, to which it cannot adequately respond, and a poorly implemented FSVP regulation may expand that problem.

FSVP implementation will require not only training of over 400 FDA investigative and compliance personnel, but also outreach and technical assistance to importers who have not previously had legal obligations under the FD&C Act and are unaccustomed to FDA regulation. With the first compliance date for this rule coming in early 2017, internal training, and technical assistance to industry must occur in 2016, including training FDA's investigative and compliance personnel and developing and delivering technical assistance.

Compliance with FSVP is essential to ensure the continued importation of food and feed products. An importer's failure to comply with FSVP may result in denial of entry of the food and feed products. Therefore, failure by the importers to be properly trained and educated to meet FSVP standards could result in unnecessary and harmful impacts to their businesses.

Medical Product Safety: +$7.1 million

Combating Antibiotic Resistant Bacteria: +$7.1 million
Center: +$7.1 million

With this funding increase, the Animal Drugs and Feeds Program will assess and measure the impact of Guidance for Industry (GFI) #213 and the Veterinary Feed Directive (VFD) guidance over time as a part of the National Strategy for Combating Antibiotic Resistant Bacteria.

This effort supports the continued work to address public health safety concerns associated with antimicrobial drug use in animals and the related development of antimicrobial resistant bacteria.

Bacteria and other microorganisms that cause infections are remarkably resilient and can develop ways to survive drugs meant to kill or weaken them. Emergence of resistant bacterial pathogens has been attributed to the increased use of antimicrobials in both food producing animals and humans.

FDA will develop a system, with input from public and industry stakeholders, for monitoring antimicrobial drug use in food-producing animals through the periodic collection of nationally-representative on-farm data on antimicrobial-use practices and resistance. FDA will implement a VFD compliance program and provide guidance and training to support the VFD guidance implementation. FDA will also issue videos to the public to inform and educate in the area of antimicrobial resistance.

USER FEES

Current Law User Fees: +$0.139 million

Center: +$0.132 million / Field: +$0.007 million

The Animal Drugs and Feeds Program request includes an increase of $0.139 million for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry.

Proposed User Fees: +$4.1 million

Proposed Food Import Fee: +$1.5 million
Center: +$1.5 million

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. FSMA provisions create new obligations for food and feed importers to have a risk-based foreign supplier verification program in place to ensure that their suppliers produce food and feed in compliance with processes and procedures that offer the same level of protection as FDA's preventive controls requirements and produce safety standards, and is not otherwise adulterated or misbranded with respect to food allergen labeling.

The Animal Drugs and Feeds Program will conduct the following activities with this user fee:

- establish new systems earlier in the process to prevent the import of unsafe feeds
- conduct outreach with international public health agencies to further international cooperation to ensure a safe feed supply
- develop and implement the International Comparability Assessment Tool (ICAT) for animal feed to evaluate the feed safety systems of foreign countries.

Proposed Food Facility Registration and Inspection Fee: +$2.6 million
Center: +$1.6 million / Field: +$1.0 million

Revenue from the proposed Food Facility and Registration Fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models and information technology to improve targeting and risk-based efficiency of inspection. This investment will complement the investment in

inspection modernization and training that can be achieved with the budget authority request and ensue that modernization is fully achieved on a timely basis.

The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide. With this investment, FDA will be better able to make sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. FDA will provide funding to federal, state, local, territorial, and tribal regulatory and public health partners in the form of grants or cooperative agreements, contracts, or inter-agency agreements between federal agencies. FDA will improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws and regulations.

In addition, this user fee will allow FDA to implement preventive controls in feed processing facilities through the support, implementation, and enforcement of preventive controls in feed processing facilities. FDA will be able to train more than 215 ORA 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 to assist the states in the implementation of the Animal Feed Regulatory Program Standards (AFRPS), as well as provide support and coordinate with the states as FDA moves towards establishing 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, and lab coordination for detection and response, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2013: 99.8% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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 2013: 100% w/in 270 days Target: 90% w/in 270 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 2014: 286 Target: 250 (Target Exceeded)	250	250	maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2014: 537 Target: 500 (Target Exceeded)	500	500	maintain
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2014: 64% w/in 15 working days Target: 60% w/in 15 working days (Target Exceeded)	60% w/in 15 working days	50% w/in 15 working days	-10%
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 2014: 36 Target: 26 (Target Exceeded)	36	36	maintain

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

New Animal Drug Application Review

For the tenth year in a row, CVM exceeded the ADUFA performance goals and, for the fifth year in a row, the AGDUFA performance goals. CVM completed review and action on 99.8 percent of original NADAs as well as other ADUFA sentinel submissions within the timeframes

specified during FY 2013. CVM also completed review and action on 100 percent of original ANADAs as well as other AGDUFA sentinel submissions within the time frames specified in FY 2013.

CVM Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
FDA provides cooperative agreements to veterinary diagnostic laboratories to further FDA's response capacity. The cooperative agreements are designed to enable the analyses of animal diagnostic samples and animal food/drug products during CVM investigations of consumer complaints or in the event that laboratory surge capacity is needed by FDA for analyses of potential microbiological or chemical contamination. While FDA's Office of Regulatory Affairs (ORA) is the primary inspection and analysis component of FDA, the Vet-LIRN program adds a component that is outside of ORA's usual investigations and testing programs, the examination of veterinary diagnostic samples. Examination of such samples facilitates early detection of animal food/drug adulteration or contamination.

These efforts can contribute to overall food safety as animal food events could signal potential issues in the human food system. These cooperative agreements facilitate methods standardization, training, and proficiency testing of the partner laboratories. Such activities strengthen the overall food safety system by developing increased capacity and capabilities to detect adulteration which could affect animals raised for human consumption or companion animals consuming ingredients used in both animal and human food products.

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 inherent risk, outbreaks, 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 2014 FDA met or exceeded inspection targets for animal drugs and feeds facilities.

PROGRAM ACTIVITY DATA

Animal Drugs & Feeds Program Activity Data (PAD)

CVM Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
New Animal Drug Applications (NADAs) [1]			
Received	18	14	14
Completed	14	13	14
Approved	12	13	13
Pending [2]	4	5	5
New Animal Drug Application Supplements [1, 3]			
Received	474	470	470
Completed	455	465	475
Approved	390	360	360
Pending [2]	118	123	118
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	31	29	29
Completed	35	25	30
Approved	18	6	6
Pending [2]	17	21	20
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	221	195	195
Completed	229	185	201
Approved	162	120	120
Pending [2]	104	114	108
Investigational New Animal Drug (INAD) Files [4]			
Received	2,782	2,995	2,995
Completed	2,853	2,913	3,000
Pending [2]	331	413	408
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	497	350	350
Completed	476	350	350
Pending [2]	87	87	87
Food (Animal) Additive Petitions Completed	72	65	65
Investigational Food Additive Petitions Completed	132	175	175
Adverse Drug Event (ADE) [5]			
ADE Reports Received	86,851	80,000	80,000
Post-Approval ADE Data Reviews	140	100	100

[1] Includes originals applications and reactivations. If the application is not approvable, the sponsor may submit additional information until FDA is able to approve the application.

[2] Reflects submissions received during the fiscal year that still require review.

[3] A supplemental application is a sponsor request to change the conditions of the existing approval. Supplemental applications can be significant (such as a new species or indication), or routine (such as product manufacturing changes). The estimates do not include invited labeling change supplement applications because it is not possible to accurately project sponsor or CVM requests for this type of application.

[4] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including requests for interstate shipment of an unapproved drug for study, protocls, technical sections, data sets, meeting requests, memos of conference, and other information.

[5] 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 2014 Actual			FY 2015 Estimate			FY 2016 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	***1,677***	***230***	***1,465***	***1,792***	***299***	***1,524***	***1,792***	***299***	***1,524***
Pre-Approval /BIMO Inspections	38	38	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	192	192	0	222	222	0	222	222	0
BSE Inspections	1,248	0	1,248	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	15	0	15	25	0	25	25	0	25
Illegal Residue Program Inspections	490	0	490	473	0	473	473	0	473
Feed Manufacturing Program Inspections	161	0	161	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,507	13	1,494	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***78***	***71***	***7***	***76***	***69***	***6***	***76***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	26	26	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	64	64	0	33	33	0	33	33	0
Foreign Feed Inspections	7	0	7	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	***1,755***	***301***	***1,472***	***1,868***	***368***	***1,530***	***1,868***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	3,910	237	3,673	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	694	1	693	750	2	748	750	2	748
Import Physical Exam Subtotal	**4,604**	**238**	**4,366**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	391,388			455,140			505,859		
Percent of Import Lines Physically Examined	1.18%			0.96%			0.86%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***5,031***	***0***	***5,031***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [1]	***4***	***0***	***4***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***415***	***0***	***415***	***600***	***0***	***600***	***600***	***0***	***600***
State Contract Inspections: BSE	4,603	0	4,603	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	646	0	646	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	246	0	246	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	5	0	5	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	415	0	415	600	0	600	600	0	600
State Contract Animal Drugs/Feeds Funding	2,765,193	0	2,765,193	2,958,757	0	$2,958,757	3,165,870	0	$3,165,870
BSE Cooperative Agreement Funding	2,315,621	0	2,315,621	2,246,156	0	$2,246,156	2,178,772	0	$2,178,772
State Contract Tissue Residue Funding	553,409	0	553,409	590,025	0	$590,025	631,326	0	$631,326
Total State Funding	**$5,634,223**	**$0**	**$5,634,223**	**$5,794,938**	**$0**	**$5,794,938**	**$5,975,968**	**$0**	**$5,975,968**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***6,790***	***301***	***6,507***	***6,913***	***368***	***6,575***	***6,913***	***368***	***6,575***

[1] 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.

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DEVICES AND RADIOLOGICAL HEALTH

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Devices and Radiological Health	**427,998**	**417,583**	**440,010**	**456,148**	**16,138**
Budget Authority	***320,825***	***320,815***	***320,825***	***327,760***	***6,935***
User Fees	***107,173***	***96,768***	***119,185***	***128,388***	***9,203***
Center	332,528	325,537	344,278	354,965	10,687
Budget Authority	240,345	240,336	240,345	246,166	5,821
User Fees	92,183	85,201	103,933	108,799	4,866
Medical Device (MDUFA)	*86,180*	*80,251*	*97,810*	*102,550*	*4,740*
Mammography Quality Standards Act (MQSA)	*6,003*	*4,950*	*6,123*	*6,249*	*126*
Field	95,470	92,046	95,732	101,183	5,451
Budget Authority	80,480	80,479	80,480	81,594	1,114
User Fees	14,990	11,567	15,252	19,589	4,337
Medical Device (MDUFA)	*1,913*	*1,780*	*1,913*	*2,148*	*235*
Mammography Quality Standards Act (MQSA)	*13,077*	*9,787*	*13,339*	*13,612*	*273*
International Courier	---	---	---	*3,829*	*3,829*
FTE	**2,045**	**2,087**	**2,086**	**2,135**	**49**

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 Devices 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. US postmarket 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:

- meeting or exceeding all FY 2014 MDUFA III performance goals for 510(k) submissions and Premarket Approval (PMA) applications
- established the Global Unique Device Identification Database (GUDID), an information system that serves as a public reference for every device with a unique device identifier
- decreased the number of Investigational Device Exemptions (IDEs) studies requiring more than two cycles to reach full approval by 31 percent, from FY 2013, and decreased the overall median time to full IDE approval by 52 percent.

The following selected accomplishments demonstrate the Devices Program's delivery of its regulatory and public health responsibilities within the context of current priorities.[20]

Improve and Safeguard Access

The Devices Program is committed to flexible, smart regulation, and to working with industry and the clinical community to ensure that innovative new medical devices that demonstrate a reasonable assurance of safety and effectiveness are available for U.S. patients. Each year, the Devices Program evaluates the safety and effectiveness of new devices and approves or clears thousands of products for market. Recent first-of-a-kind device approvals and clearances include:

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

- a test that helps to determine if certain critically ill hospitalized patients are at risk of developing moderate to severe acute kidney injury within 12 hours of the test
- a prosthetic arm system that performs multiple, simultaneous powered movements by translating electrical signals received from a patient's muscles close to where the prosthesis is attached.
- an externally worn system that delivers insulin and continuously measures glucose levels, automatically stopping insulin delivery at a level set by the user.

By increasing the predictability, consistency, and transparency of the medical device premarket program, the Devices Program works to improve access of new treatments and diagnostic tests to U.S. patients and stimulate investment in and development of promising new technologies to meet public health needs. As a result, millions of U.S. patient benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

Within this FDA Goal area, the Devices Program supports Smart Regulation through efforts including the Clinical Trail Enterprise, Balancing Data Collection, and Laboratory Developed Tests. At the same time, Regulatory Science is supported by the Women's Health and Safety and Quality through efforts including the FDA Safety and Innovation Act and the Quality Management (QM) Framework.

Clinical Trial Enterprise

The Devices Program committed to improving U.S. patient access to new devices by strengthening and streamlining the clinical trial enterprise. As part of its 2014 – 2015 strategic priorities, the Devices Program established a premarket clinical trials program responsible for the oversight and performance of Investigational Device Exemptions (IDEs) and the policies that contribute to the timely initiation and successful execution of device clinical trials. The Devices Program also formalized the incorporation of our benefit-risk framework into the IDE process and established a process to reduce the number of multi-cycle IDEs.

The Devices Program also published several final guidances to help streamline the clinical trial enterprise. On October 1, 2013, FDA published "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies," which outlines the development and review of IDE applications for early feasibility studies of significant risk devices. On November 7, 2013, FDA published "Design Considerations for Pivotal Clinical Investigations for Medical Devices," which describes specific study designs, principles, and techniques for sustaining the quality of clinical studies. On August 19, 2014, FDA published "FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations," which outlines more flexible options for approvals that allow clinical studies to begin sooner, while ensuring patient protections.

In FY 2014 the Devices Program achieved substantial improvements as a result of efforts to streamline the IDE process. The number of IDE studies requiring more than two cycles to reach full approval decreased by 31 percent from FY 2013. FDA decreased the overall median time to full IDE approval by 52 percent. In addition, a teleconference was offered to occur within ten business days for 100 percent of disapproved IDEs during the last quarter of FY 2014. Overall, since this program started, the Devices Program has missed this goal only once.

Making it easier to start clinical studies in the United States, while assuring patient protections, can result in device makers choosing to bring their innovate technologies and treatments to U.S. patients first in the world.

Balancing Data Collection

A key determinant of early U.S. patient access to high-quality, safe, and effective devices is how much premarket data device developers must provide to the FDA. By shifting some premarket data needs to the postmarket setting, FDA can improve U.S. patient access to high-quality, safe, and effective medical devices of public health importance.

In 2014, FDA took several actions toward striking the right balance between premarket and postmarket data collection. FDA conducted a retrospective review of over 50 percent of all PMA device types to determine whether or not to shift some premarket data requirements to the postmarket setting or to down classify device types in light of our current understanding of the technology. On April 23, 2014, FDA issued draft guidance entitled "Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions" proposing the Expedited Access Program (EAP) for high-risk medical devices. On April 23, 2014, FDA also issued draft guidance entitled "Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval" outlining when data that might otherwise be collected premarket can be collected postmarket instead.

Striking the right balance between premarket and postmarket data collection can facilitate timely patient access to important new technology, without undermining patient safety, and reflects a total life cycle approach to understanding the benefit-risk profile of medical devices. More information is available on FDA's website.[21]

Ebola Epidemic

The Ebola epidemic is an unprecedented global health and security crisis that has taken thousands of lives. That's why in FY 2014, the Devices Program worked to expedite the development and availability of medical devices and diagnostic tests to help address the Ebola epidemic as quickly as possible. The Devices Program held over 100 collaborative meetings, workshops, and presentations with stakeholders on Ebola product study designs, data requirements and Emergency Use Authorizations (EUAs). As a result of these efforts, the Devices Program authorized use for over six diagnostic tests for Ebola virus, including tests from the Department of Defense (DOD), the Centers for Disease Control and Prevention (CDC) and two commercial companies. More information is available on FDA's website.[22]

[21] Available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm393882.htm

[22] Available at http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm

FDA Safety and Innovation Act
While moving forward with addressing public health emergencies and 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.[23]

MDUFA III Independent Assessment
As part of MDUFA III, FDA agreed to participate with the medical device industry in an independent assessment of our device review process. A third party consulting firm assessed the Devices Program's review process, management systems, IT infrastructure, reviewer training programs and staff turnover. The Final Report on Findings and Recommendations, released in June 2014, affirms that FDA is on a path to meet many of the challenges that were flagged in the months leading up to the enactment of MDUFA III, including sponsor communication, IT infrastructure, reviewer training, reviewer attrition, and submission quality. As committed to under MDUFA III, in December, 2014, the Devices Program released a Plan for Action to implement the high priority recommendations. More information is available on FDA's website.[24]

510(k) eSubmissions Pilot Program
In FY 2014, FDA announced the availability of the 510(k) eSubmissions Pilot program that offers a new route for applicants to construct and submit 510(k) submissions electronically. The e-Submitter user interface was designed to guide the sponsor through a step by step process of constructing and submitting a 510(k) submission. Built into the software are a number of features that ensure appropriate regulatory submission standards and recommendations are met or considered. Once finalized, the 510(k) eSubmission program may decrease the time industry spends creating and submitting 510(k)s and the time FDA spends reviewing them. More information is available on FDA's website.[25]

510(k) Program Final Guidance
In addition to streamlining the 510(k) submission process, on July 28, 2014, FDA released final guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)s]." This guidance clarifies each of the critical decision points FDA uses during the 510(k) review process, specifies information manufacturers should include in submissions, and explains when clinical data may be required. The guidance also includes an easy to follow decision-making flow chart to help manufactures through the application process. FDA is committed to bringing early patient access to high quality, safe and effective

[23] Available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/default.htm

[24] Available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM426392.pdf

[25] Available at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm392818.htm

devices speeding by increasing the predictability, consistency, and transparency of our 510(k) Program. More information is available on FDA's website.[26]

Quality Management (QM) framework

In FY 2014, the Devices Program announced the Quality Management (QM) framework as part of our effort to address the independent assessment recommendations. 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. More information is available on FDA's website.[27]

Laboratory Developed Tests (LDTs)

On October 3, 2014, FDA issued a draft oversight framework for Laboratory Developed Tests (LDTs) intended to close well known regulatory gaps and provide clarity regarding the proposed enforcement for LDTs that pose the greatest risk to patients. LDTs are in vitro diagnostic tests that are designed, manufactured, and used within a single laboratory. Many LDTs are used to diagnose common diseases, conditions, and to guide therapy. Like conventional in vitro diagnostics, some LDTs may present significant health risks to patients if the results that they generate are not accurate, while others present a much lower risk.

FDA believes the tailored framework proposed would strike the right balance by providing a risk-based, focused approach to the oversight of those LDTs that pose greater risk to patients, and that would phase in review for this subset of LDTs over time. FDA intends to continue to exercise enforcement discretion for many LDTs – including those that are low risk, for rare diseases, and for unmet medical needs. The proposed framework would incentivize innovation and support the advancement of personalized medicine by assuring that patients and their physicians can rely on LDTs for making major medical decisions. More information is available on FDA's website.[28]

Cybersecurity in Medical Devices

The need for effective cybersecurity to ensure medical device functionality and safety has become more important with the increasing use of wireless, internet and network- connected devices. To that end, on October 1, 2014, FDA released final guidance entitled "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." This guidance recommends that manufacturers consider cybersecurity risks as part of the design of a medical device and submit documentation about the risks identified and controls in place to mitigate those risks. By carefully considering possible cybersecurity risks while designing

[26] Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf

[27] Available at: http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhqualitymanagementprogram/ucm384569.pdf

[28] Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm

medical devices, and having a plan to manage system or software updates, manufacturers can reduce the vulnerability in their medical devices. More information is available on FDA's website.[29]

Women's Health

On August 22, 2014, CDRH published final guidance entitled, "Evaluation of Sex-Specific Data in Medical Device Clinical Studies." It was written in response to the fact that certain medical devices may yield different responses in women than men, yet women are under-represented in some medical device studies. This has led to less information for women regarding the risks and benefits of using these devices. The primary intent of the guidance is to improve the quality and consistency of available data regarding the performance of medical devices in both genders by encouraging appropriate enrollment by gender in clinical studies of devices, and that data from such studies is appropriately analyzed by gender. More information is available on FDA's website.[30]

Experiential Learning Program

To help reviewers understand the challenges of technology development, manufacturing, and use, and become informed about specific current and emerging technologies, the Devices Program implemented the Experiential Learning Program. The program provides reviewers with real-world training experiences through visits to manufacturers, research facilities, and health care facilities. In FY 2014, over 320 staff participated in 33 visits at 27 external sites. The ELP General Training component was also added to enhance staff understand of the challenges faced throughout device development, testing, manufacturing, and clinical use. More information is available on FDA's website.[31]

Enhance Oversight

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. At the same time, the Devices Program monitors postmarket performance including adverse events, respond quickly to identify and limit potential public health problems, and collaborates with industry to improve the quality of medical devices for U.S. patients.

In FY 2013 the Devices Program 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. As of June 30, 2014, FDA classified and issued 48 Class I, 891 Class II, and 34 Class III device recall events. OCI made 35 device related arrests and secured 29 device related convictions.

[29] Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
[30] Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM283707.pdf
[31] Available at: http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm

Within this FDA Goal area, the Devices Program supports Smart Regulation through efforts including the National Medical Device Postmarket Surveillance Plan and Unique Device Identification. At the same time, Globalization is supported by The Medical Device Single Audit Program and Safety and Quality by efforts including the Case for Quality Initiative and the Mammography Quality Standards Act Program.

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. In FY 2014, the Devices Program reviewed 95 percent of all death MDRs within 5 business days of the submission, enabling rapid identification of device issues and failures that help to minimize widespread consequences on public health. To expedite the report processing and reduce the burden of data entry on the FDA, manufacturers, and importers, FDA published the eMDR final rule in February 2014 requiring all medical device manufacturers to submit their reports electronically, rather than in paper form.

Medical Product Safety Network

The Medical Product Safety Network (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. In FY 2014, there have been 38 recalls and 44 manufacturer actions directly influenced by MedSun reports. More information is available on FDA's website.32

National Medical Device Postmarket Surveillance Plan

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 that can quickly identify new safety problems, capture real world experience with device use in near real time, and facilitate device approval or clearance. In FY 2014, FDA worked to implement the following as part of its postmarket strategy:

- developed new methods for evidence generation, synthesis, and appraisal
- promoted the development of external device registries including the National Breast Implant Registry and the International Consortium of Cardiovascular Registries
- established the Global Unique Device Identification Database (GUDID) to facilitate incorporation of UDI into electronic health information.

In FY 2014 the multi-stakeholder Planning Board was established to identify the policies, procedures, and models necessary to create a sustainable, integrated medical device postmarket surveillance system. The over 20 member board is composed of representatives from the medical device industry, professional societies, patient and consumer groups, third-party

[32] Available at http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm

payers, hospitals, and other important stakeholders. More information is available on FDA's website.[33]

Registry-Based Surveillance

Registries play a unique role in modernizing medical device surveillance because they can provide a cost effective method to gain detailed information about patients, procedures, and devices not routinely collected by electronic health records, administrative or claims data. In FY 2014, to enhance postmarket surveillance efforts and reduce regulatory burdens on industry, the Devices Program implemented registry-based surveillance of transcatheter valve therapy (TVT) devices using a multi-stakeholder TVT Registry. The TVT Registry is a benchmark tool developed to track patient safety and real-world outcomes involving transcatheter aortic valve replacement, a minimally invasive surgical procedure to repair a damaged valve in the heart. The first expanded indication for an approved TVT device was approved in FY 2014, based solely on the data collected postmarket in the registry.

Unique Device Identification

On September 24, 2013, the Devices Program 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. When fully implemented, the label of most devices will include a unique device identifier in human and machine-readable form. The Devices Program also established the Global Unique Device Identification Database (GUDID), an information system that serves as a public reference for every device with a unique device identifier. By November 2014, there were over 30,000 records published in GUDID, empowering stakeholders with access to non-confidential device information.

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. More information is available on FDA's website.[34]

Signal Management Program

The Devices Program established the Signal Management Program (SMP) to provide processes and procedures to consistently evaluate and advance mitigation strategies for safety signals identified for medical devices on the U.S. market. A safety signal is data that suggests a potential association between a medical device and an adverse event or set of events of public health concern. As part of SMP, the Devices Program implemented Signal Review Teams focused on high priority clinical product areas including General Hospital, Surgery, and Neurology devices. In FY 2014, SMP has evaluated over 35 safety signals that have resulted in

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

[34] Available at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/default.htm

actions including device recalls, device labeling changes and public communications to help limit and address device safety issues before they have widespread impacts on public health.

Case for Quality Initiative
Through the Case for Quality, the FDA is working with stakeholders to foster medical device quality by identifying and promoting practices that result in high-quality devices and adapting regulatory approaches to align with those practices. As part of the initiative, in FY 2014 FDA launched a pilot program focused on specific operations, design considerations, and controls to improve the quality of implantable devices that use batteries. These factors have been linked to FDA's inspectional approach and quality manufacturing requirements, allowing FDA and industry to collaborate more closely on medical device quality during site inspections. FDA aims to reduce the risk of patient harm by helping the medical device manufacturing sector deploy quality-related design and production practices to improve the safety of U.S. manufactured devices. More information is available on FDA's website.[35]

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 to American patients. Instead of an FDA inspection and the regulatory consequences that may follow, participating manufacturers are afforded the opportunity to voluntarily correct identified deficiencies if they meet VCIP program criteria. Firms that participate in the VCIP program must demonstrate the ability to define problems, analyze root causes, create appropriate corrective actions, and verify that the actions taken were effective. Through the VCIP program, FDA aims to improve medical device quality by promoting voluntary compliance of firms that have self-identified compliance deficiencies. More information is available on FDA's website.[36]

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 inspections. The MDSAP framework allows a single regulatory audit of a medical device manufacturer to satisfy the needs of multiple regulatory jurisdictions including Australia, Brazil, Canada, and the United States. To leverage limited inspection resources, In FY 2014 the MDSAP Pilot study was launched authorizing third-party auditing organizations (AOs) to conduct independent MDSAP audits under a single, shared uniform regulatory standard. In FY 2015, the Devices Program plans to accept MDSAP Pilot audit reports as a substitute for certain routine inspections, enabling a cost savings method to eliminate duplicate inspections with participating international partners. More information is available on FDA's website.[37]

Mammography Quality Standards Act Program
As part of the Mammography Quality Standards Act (MQSA) Program, FDA and its state contract partners, annually inspect over 8,700 certified mammography facilities in the United

[35] Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm
[36] Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378183.htm
[37] Available at: http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

States to ensure compliance with national quality standards for mammography. MQSA certified facilities provide nearly 39 million mammography procedures annually in the United States. In FY 2014, over 99 percent of domestic mammography facilities had no serious violations of the law, and less than one percent of facilities were cited with the most serious Level I violations. As a result of these efforts, millions of American women who receive their annual mammograms can be confident that they are receiving reliable breast images that can lead to early detection of disease and improved treatment. More information is available on FDA's website.[38]

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$417,583,000	$320,815,000	$96,768,000
FY 2015 Enacted	$440,010,000	$320,825,000	$119,185,000
FY 2016 Request	$456,148,000	$327,760,000	$128,388,000

BUDGET REQUEST

The FY 2016 Budget Request for the Devices Program is $456,148,000, of which $327,760,000 is budget authority and $128,388,000 is user fees. This amount is an increase of $16,138,000 above the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $6,935,000. This amount includes $2,888,000 in reductions to targeted, lower priority compliance, inspection, outreach, and training activities. In addition, user fees increase by $9,203,000.

The FY 2016 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 2016 Budget includes an increase in the Devices Program MDUFA III user fees by $4,975,000. This increase allows the Devices Program to continue to build a solid reviewer base to meet the increasingly rigorous MDUFA III performance goals, as approved by Congress under FDASIA. The Devices Program has met or exceeded all FY 2014 MDUFA III performance goals for 510(k) submissions and Premarket Approval (PMA) applications, which demonstrates FDA's continued commitment to increase the efficiency with which medical devices are developed and made available to U.S. patients.

The FY 2016 Budget Request 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

[38] Available at http://www.fda.gov/radiation-emittingproducts/mammographyqualitystandardsactandprogram/default.htm

the protection and growth of the nation's medical device industry, which is made up of over 60 percent small businesses, including:

- 400,000 American jobs[39]
- 17,500 U.S. manufacturing establishments[40]
- three percent of total annual spending by U.S. consumers[41]
- $54.5 billion in U.S. exports and growing, positive trade surplus.[42]

The FY 2016 Budget Request enables the Devices Program to continue to ensure patients in the United States have access to high-quality, safe, and effective medical devices of public health importance – first in the world. Our vision also sees the United States as the world's leader in regulatory science, medical device innovation, and manufacturing; establishing a robust postmarket surveillance system; assuring that devices on the market remain safe, effective, and high quality; and providing consumers, patients, caregivers, and providers the information they need to make well-informed decisions. The FY 2016 Budget Request enables the Devices Program to move our vision forward and help medical device developers choose the U.S. as the country of first choice for their technologies and treatments to improve public health.

BUDGET AUTHORITY

Medical Product Safety: +$9.8 million

FDASIA Implementation – Unique Device Identifier: +$2.0 million
Field: +$2.0 million

The increased funding will be used to continue the implementation of a Unique Device Identifier (UDI) system. UDI will help provide a consistent, standardized, unambiguous way to identify medical devices. It will provide the ability to quickly and efficiently identify marketed devices when recalled which will improve the accuracy and specificity of adverse event reports. Implementation of a UDI would allow FDA to search large databases to potentially allow FDA to know more precisely the rate at which a medical device is failing and which patients have devices prone to malfunctions.

Combating Antibiotic Resistance Bacteria: +$0.5 million
Center: +$0.5 million

As part of the National Strategy for Combating Antibiotic Resistant Bacteria, FDA plans to leverage an existing genome sequence repository to drive breakthrough research on antibiotic resistant bacteria. Industry will be able to use FDA validated data from this repository to develop new molecular and genome based diagnostic tests and advance the rapid detection and control of resistant bacteria. As a result, FDA will help strengthen national capacities to detect,

[39] Medical device industry employment estimated using 2012 data from the U.S. Bureau of Census and Dunn & Bradstreet (D & B) Inc.
[40] Medical device industry establishments estimated using 2012 data from CDRH Registration and Listing and U.S. Bureau of Census.
[41] Annual consumer spending estimated using 2012 data from Dunn & Bradstreet, including sales from primary and secondary medical device manufacturers.

[42] 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.

analyze, report, and characterize antibiotic resistance while spurring the development of breakthrough diagnostic tests to help control the spread of antibiotic resistance in the United States.

Precision Medicine: +$7.4 million
Center: +$7.4 million

Rapid developments in genomics have created the possibility for precision diagnostics and therapeutics that can diminish the duration and severity of illness, shorten product development timelines, and improve treatment success rates for U.S. patients. Despite extraordinary advances in technology and understanding of disease processes, the development of precision medicine and its translation into clinical practice pose a number of scientific and regulatory challenges that block the promise of a new era of personalized treatment options.

In FY 2016, FDA will build the infrastructure and acquire expert scientists and clinicians necessary to advance the regulatory science and accelerated premarket evaluation of these new technologies. Funding this initiative permits FDA to keep pace with rapid scientific advancements, bridge developments in genomics to modern clinical practice, and speed the development and evaluation of precision diagnostics and therapeutics for U.S. patients. This funding will also allow FDA to provide increased scientific and review expertise to sustain the accelerated premarket evaluation of these new technologies overtime, ensuring the U.S. leads the world in precision medicine products.

FDA will work to develop next generation sequencing (NGS) standards that, when met, would provide assurance the tests being performed are valid. Analytical validity refers to how well the test measures what it is supposed to measure, whereas clinical validity looks at how well the test predicts who has or does not have a disease or condition for which it is being tested. Such standards will help:

- define the technical metrics of NGS data quality and test performance
- support development of new technology and analysis methods and provide guidelines for quality systems that laboratories must have in place to perform NGS tests
- provide current best practices for quality assurance and control in NGS sequencing, and specify requirements for proficiency testing.

FDA will also advance the development and use of high quality curated databases to provide information on genetic variants and their link to disease, permitting a better understanding of whether or not there is a link between genetic variants, particular diseases, and the strength of those links. For example, ClinGen is a National Institutes of Health (NIH) effort to evaluate research data and the data from the hundreds of thousands of clinical genetics tests being performed each year to determine which variants are most relevant to patient care. Through this initiative, FDA will leverage databases, including ClinGen, to help determine whether the data curated can be used to support clinical validity for NGS tests.

FDA's advancement of precision medicine will help reduce the burden of disease by targeting prevention and treatment more effectively. These efforts reduce healthcare costs by improving our ability to quickly and reliably select effective therapy for patients while minimizing costs associated with ineffective treatments and avoidable adverse events.

USER FEES

Current Law User Fees: +$5.4 million

Center: +$4.9 million / Field: +$0.5 million

Proposed User Fees: +$3.8 million

Proposed International Courier User Fee: +$3.8 million
Field: +$3.8 million

Millions of shipments of medical product 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 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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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	90% in 180 days	+10%

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
253204: Percentage of 180 day PMA supplements reviewed and decided upon within 180 days. *(Outcome)*	FY 2012: 95% in 180 days and 96% in 210 days Target: 85% in 180 days and 95% in 210 days (Target Exceeded)	90% in 180 days	95% in 180 days	+5%
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)	95% in 90 days	95% in 90 days	maintain
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2014: 322 Target: 300 (Target Exceeded)	300	300	maintain
252203: Percent of total received Code Blue MDRs reviewed within 72 hours during the year. *(Output)*	FY 2014: 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 2014: 42% Target: 60% (Target Not Met)	60%	60%	maintain
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (*Output)*	FY 2014: 94% (Historical Actual)	85%	85%	maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2014: 1,976 Target: 1,600 (Target Exceeded)	1,600	1,600	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
252101: Number of technical analyses of postmarket device problems and performance. *(Output)*	FY 2014: 46 Target: 131 (Target Not Met)	50	50	maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. *(Output)*	FY 2014: 2,260 Target: 1,300 (Target Exceeded)	2,000	2,000	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 2014: 99.6% 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 2014, 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 November 18, 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.

Mammography Quality Standards Act (MQSA)
MQSA certified facilities provide over 39,000,000 mammography procedures annually in the United States. As a result of the MQSA program, over 86 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.

Technical Analyses of Postmarket Device Problems

FDA conducts technical analyses of postmarket device problems as well as technical reviews of new applications. In FY 2014, the number of technical reviews of new applications was greater than expected. The higher demand for premarket consultations resulted in far exceeding the premarket technical review goal, and missing the postmarket analyses goal. As this trend is expected to continue, the FY 2015 and 2016 targets for both goals have been adjusted to meet this new workload balance

PROGRAM ACTIVITY DATA

Devices and Radiological Health Program Activity Data (PAD)

CDRH Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1]	31	30	30
Total Decisions [2]	24	20	20
Approved [3]	12	14	14
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	10	10	10
Total Decisions [2]	12	10	10
Approved	9	6	6
Modular PMAs			
Workload	64	60	60
Actions [4]	44	50	50
180-day PMA Supplements			
Workload	178	180	180
Total Decisions [5]	161	170	170
Approved	129	140	140
Real Time PMA Supplements			
Workload	336	310	310
Total Decisions [6]	306	300	300
Approved	289	270	270
510(k) Premarket Notifications			
Workload	3,765	4,000	4,000
Total Decisions [7] (SE & NSE)	3,263	3,300	3,300
Cleared [9] (SE)	3,148	3,100	3,100
Humanitarian Device Exemptions (HDE)			
Workload	3	6	6
Total Decisions [2]	12	5	5
Approved	4	3	3
Investigational Device Exemptions (IDE)			
Workload	248	240	240
Total Decisions [8]	256	240	240
Approved	124	140	160
Investigational Device Exemption Supplements			
Workload	1,755	1,800	1,800
Closures [10]	1,761	1,800	1,800
Pre-Submissions			
Workload	1,857	1,900	1,900
Closures [11]	1,862	1,900	1,900
Standards			
Total Standards Recognized for Application Review	1,057	1,125	1,200
Medical Device Reports (MDRs) [12]			
Reports Received	1,255,054	1,606,500	2,056,000
Analysis Consults [13]	1,105	1,270	1,460

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

[2] Total Decisions' include approval, approvable, approvable pending GMP inspection, not approvable, withdrawal, and denial -

[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.

[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

[8] Total Decisions' include approval, approval with conditions, disapproved, acknowledge, incomplete, withdrawal, or other.

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

[10] Closures' include approval, approval with conditions, disapproved, acknowledge, incomplete, no response necessary,

[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 and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,667***	***2,864***	***2,864***
Bioresearch Monitoring Program Inspections	307	300	300
Pre-Market Inspections	61	67	67
Post-Market Audit Inspections	42	34	34
GMP Inspections	1,614	1,594	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	635	723	723
Inspections (MQSA) FDA Domestic (VHA)	48	43	43
Domestic Radiological Health Inspections	56	205	205
Domestic Field Exams/Tests	89	215	215
Domestic Laboratory Samples Analyzed	185	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***585***	***603***	***603***
Foreign Bioresearch Monitoring Inspections	17	25	25
Foreign Pre-Market Inspections	21	31	31
Foreign Post-Market Audit Inspections	39	19	19
Foreign GMP Inspections	518	521	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	35	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,252***	***3,467***	***3,467***
IMPORTS			
Import Field Exams/Tests	25,782	18,821	18,821
Import Laboratory Samples Analyzed	1,014	1,123	1,123
Import Physical Exam Subtotal	**26,796**	**19,944**	**19,944**
Import Line Decisions	16,665,422	15,758,863	16,531,081
Percent of Import Lines Physically Examined	0.16%	0.13%	0.12%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,929***	***7,929***	***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS [1]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,775	6,800	6,800
Inspections (MQSA) by State non-Contract	1,100	1,110	1,110
GMP Inspections by State Contract	20	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$83,643	$86,078	$90,708
State Contract Mammography Funding	$9,089,063	$9,160,668	$9,232,836
Total State Funding	**$9,172,706**	**$9,246,746**	**$9,323,544**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,181***	***11,396***	***11,396***

[1] The FY 2014 actual unique count of foreign inspections includes 17 OIP inspections (12 for China & 5 for India).

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

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
National Center for Toxicological Research (BA Only).....	62,494	62,488	63,331	58,998	-4,333
FTE.....	242	286	287	288	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 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 science-based regulatory decisions and strengthens public-health assurance. NCTR accomplishes this by:

- accelerating FDA's capability to manage, analyze, and interpret research data generated from new technologies using bioinformatics
- understanding the risks and benefits of nanoscale materials used in FDA-regulated products
- expanding imaging capabilities to reduce the need for costly and dangerous surgical procedures and to prevent recurring illness
- providing 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 supporting the FDA Strategic Goals of Oversight and Improve and Safeguard Access are in the areas of pediatric anesthetics, drugs and adverse events, and globalization.

The following selected accomplishments demonstrate NCTR's delivery of its regulatory and public-health responsibilities within the context of current FDA Strategic Priorities and Goals.[43]

Enhance Oversight

NCTR's research allows FDA to use regulatory science to inform standards development, analysis, and decision-making for the safety of FDA-regulated products. NCTR conducts a full range of studies in support of FDA's product portfolio as seen in the illustrations below. Within the Goal of Oversight, NCTR conducts research in Pediatric Anesthetics, Drugs and Adverse Events, and Antimicrobial Resistance addresses the FDA Strategic Priority on Regulatory Science.

Pediatric Anesthetics

The effect of pediatric anesthetics on children is an important area of NCTR research. 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 on the pediatric anesthetics ketamine, isoflurane, and nitrous oxide to now include propofol and sevoflurane. In FY 2014, scientists from NCTR, Center for Drug Evaluation and Research, and the University of Arkansas for Medical Sciences found that certain concentrations of propofol had adverse effects. However, during the studies, scientists found that acetyl-L-carnitine provides neuroprotective properties when given prior to and during administration of pediatric anesthesia, such as propofol. This protective effect occurs in a variety of species. These data provide the scientific framework critical to updating the best practices for anesthetics.

Also in FY 2014, scientists studied use of an imaging compound that allows visualization of brain inflammation in a non-invasive fashion using innovative imaging technology. Thus, making it possible to follow the time course—in both rodents and primates—of neuroinflammation associated with pediatric exposures to general anesthetics. Using scientific tools like mathematical models and bio-imaging, FDA enhances the safety of regulated products. These noninvasive tools allow visualization of biological processes in "real time," with as little interference as possible with life processes.

NCTR scientists are also collaborating with laboratories at the Mayo Clinic in Rochester, Minnesota and the University of Iowa in Iowa City, Iowa. These scientists are studying the effects of pediatric anesthesia on brain function using an NCTR-developed method. The Mayo clinic plans to use NCTR-generated data to compare with some of the neuropsychological tests they are administering to the children in their study.

Two more collaborations with laboratories in Mexico City and New York City are focusing on the effects of environmental contaminants on brain function in children and are in the early stages.

[43] More information on NCTR Research Accomplishments can be found at: http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/ResearchAccomplishmentsPlans/default.htm

Drugs and Adverse Events

In FY14, NCTR and scientists from Germany's Hannover Medical School developed a model based on FDA-approved drug labeling to improve the prediction of potential risk of drug-induced liver injury (DILI) in humans. The model, which used 197 FDA-approved drug labels, demonstrated an overall accuracy of 68.9 percent in tests of 483 unique drugs. This accuracy improves to 77 percent in groups that are known to benefit from the therapy. This model may be useful in the early stages of the drug-development process by prioritizing compounds based on predicted DILI risk; especially for compounds such as analgesics, antibacterial agents, and antihistamines.

The results from this effort were incorporated into the online Liver Toxicity Knowledge Base (LTKB) resource which has been used by the FDA reviewers in review of new drug candidates submitted via the FDA Investigational New Drug and New Drug Application process to assess their likelihood to cause liver injury in humans. The results were also published in the *Toxicological Sciences* journal. With this information, FDA can offer patients and their health providers valuable information to guide the decision of whether or not to use a particular drug.

In another research project, NCTR scientists showed that treatment of rats with doxorubicin—an anti-cancer drug effective against pediatric lymphomas—carries a risk of cardiotoxicity as a serious adverse effect which limits the life-time dose and its utility as a chemotherapeutic agent. The research article describing this study was selected as the Editor's Choice and is highlighted in the January 2014 issue of *Environmental and Molecular Mutagenesis*.

Food Safety

Patient costs for treatment of foodborne illnesses are a heavy burden on the U.S. economy. NCTR plays a vital role in the Food Safety Modernization Act (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 negative economic effects.

Antimicrobial Resistance

NCTR scientists have shown that ceftiofur—a cephalosporin antimicrobial drug that is approved for veterinary use to treat respiratory disease in cattle, swine, horses, and sheep—is rapidly degraded by bovine intestinal bacteria. This antibiotic is structurally similar to the human-use drug cephalosporin ceftriaxone, and concerns have been raised that its use may adversely impact the effectiveness of other related antibiotics through the development of antimicrobial resistance. The data could be useful in carrying out risk-assessment models of veterinary antimicrobials and regulating current and future drugs to be used in food animals. The results of this study are available online at *Veterinary Microbiology*.

Improve and Safeguard Access

NCTR conducts research to increase regulatory science capacity to evaluate FDA-regulated products in a more predictable, consistent, and efficient way. Within this Goal area, research in Bioinformatics Technologies, Imaging Capabilities, and Nanotechnology addresses the FDA Strategic Priority on Regulatory Science.

Due to NCTR's exemplary reputation, the Center is often sought as a collaborator and advisor. NCTR partners internally and externally to share research knowledge, technical advice, and research training through global collaborations. Within this Goal area, the Global Summit on

Regulatory Science, Bioinformatics Collaborations, and Nanotechnology Collaborations address the FDA Strategic Priority on Globalization.

Bioinformatics
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. Below are some examples of NCTR's uses of bioinformatics.

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 precision 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 data points collected for 8,212 chemicals tested in 11 different species.

Both EDKB and EADB have been incorporated into larger government-initiated toxicological projects like ToxCast and Tox21. ArrayTrack is continually being improved for better usability, and in FY 2014, NCTR made improvements to the presentation of information requested by the Environmental Protection Agency (EPA) and the Tox21 program.

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 66,000 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 to 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 FY 2014, NCTR scientists developed FDALabel 2.0 which is being regularly used by CDER reviewers. This database can be used by:

- researchers for adverse drug reaction studies
- FDA medical officers for drug review
- pharmaceutical companies for drug development and repositioning

- physicians and consumers for drug-safety information.

Rat BodyMap Database
The Sequencing Quality Control Consortium, a large international effort led by NCTR scientists, generated a comprehensive gene expression atlas in May 2014 using next-generation sequencing technology. This technology catalogues variations in gene expression in 11 tissues at four developmental stages of male and female rats. The web-based, publicly-available Rat BodyMap database is expected to provide a comprehensive platform for biomedical research. The database is also expected to increase understanding of disease, drug efficacy, and toxicity in the rat model and ultimately improve the translation of preclinical findings to humans. This study was partially supported by the FDA Office of Women's Health and is published in *Nature Communications*.

Predictive Genes for Cancer
In FY 2014, NCTR and National Taiwan University scientists used a bioinformatics approach to identify a signature set of 16 predictive genes for non-small-cell lung cancer by analyzing four biological databases. This analysis also confirmed the efficacy of the anti-cancer drug ZD-6474. This signature panel may have potential as a predictive biomarker for non-small-cell lung cancer with clinical applications, allowing for earlier medical intervention.

Nanotechnology
Nanotechnology is science, engineering, and technology conducted at the nanoscale. 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. NCTR is conducting nanotechnology research to generate data FDA reviewers can use to assess the safety and responsible development of products using nanomaterials. This research also helps develop guidelines for the safe and effective use of nano materials in drug products, devices, foods, cosmetics, and dietary components.

NCTR toxicological research aims to understand the absorption, disposition, and toxicity of FDA-relevant nanomaterials. NCTR is also providing training for FDA scientists and reviewers to ensure they understand the techniques used to characterize and detect nanotechnology-based materials.

Exposure to nanoparticles—especially nanosilver 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 throughout the body, providing data for regulatory decisions. In FY 2014, NCTR scientists studied the effect of silver nanoparticles on the gastrointestinal system to assess its toxicity. Scientists studied the effects of nano-coated materials used to increase food's shelf-life since nanomaterials may cluster in food and interact with other components of the food matrix. This conclusion raises a major concern about consumed nanomaterials in the intestine. Results from this and future studies will help to establish science-based minimum standards for conducting hazard analysis of products containing nanoparticles.

Another project completed in FY14, requested by CDER, involved the characterization of nanoparticles in spray sunscreens. Using transmission and scanning electron microscopy (high powered microscopes) NCTR developed a methodology to extract the nanoscale and larger

particles from the sunscreen liquid and perform a variety of analysis for regulatory decision making. The results of this survey of 15 commercial products led CDER to the selection of one product for further testing at the National Institute for Occupational Safety and Health for lung deposition following particle inhalation.

Disease Surveillance Database

Scientists from NCTR and the Marshfield Clinic Research Foundation demonstrated the potential use of the FDA Adverse Event Reporting System (FAERS) to identify disease characteristics, in addition to its traditional application of drug-safety monitoring. In this pilot study, data-mining approaches were used to identify 115 diseases with the potential to affect one sex more than the other from the FAERS public database that contains patient demographic information for more than 4 million adverse-event cases reported from 1997-2011.

This approach could be further applied to other publically available disease surveillance databases and used to study other disease risk factors, such as age or ethnicity. The knowledge gained from this data-mining will help provide better care to subpopulations that may be more vulnerable to certain diseases.

Identifying and Developing Biomarkers

Another tool for predicting FDA-regulated product toxicity is biomarker development. A biomarker is a biological marker that is used to indicate a biological state or condition. NCTR scientists continue research to identify new biomarkers to identify toxicity of FDA-regulated products sooner and to provide precision medicine solutions. 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
- reduce or reverse cardiac injury
- improve therapeutic patient treatment.

Chronic cardiotoxicity induced by an anticancer drug, doxorubicin (DOX), is dose-dependent, cumulative, and irreversible. It is a major concern of clinical oncologists. In FY14, using a mouse model of doxorubicin-induced chronic cardiotoxicity developed at NCTR, 1179 microRNAs (also) were measured in the heart to identify early predictive biomarkers of cardiac tissue damage.

Also known as miRNAs, microRNAs are cellular RNA fragments that prevent the production of a particular protein by binding to and destroying the messenger RNA that would have produced the protein. Two miRNAs were found to be significantly altered in hearts of doxorubicin-treated mice before cardiac injury, suggesting that changes in these two miRNAs could potentially lead to the development of predictive biomarkers of cardiotoxicity.

NCTR scientists have also defined mitochondrial RNA (mtRNAs) biomarker genes that are associated with carcinogen exposure. To investigate the potential mtRNA biomarkers for chemical carcinogen exposure, scientists developed a project to determine if these carcinogen markers were in the tissues of mice and rats treated with different carcinogens and explored the possible mechanisms of mtRNAs.

The results demonstrate that most of the altered mtRNAs are tumor-causing. Thus, these mtRNAs can become potential biomarkers for exposure to carcinogens. Current tests, together mtRNA biomarkers, may better predict carcinogenicity of FDA-regulated products.

Magnetic Resonance Imaging (MRI)
NCTR has made significant progress towards the development of non-invasive diagnostic methods for characterizing nervous system tissue anomalies. The technology, derived from MRI instruments, is called magnetic resonance spectroscopy (MRS).

The NCTR contribution involves post-processing MRS scans to improve their reproducibility and usefulness for diagnosis. The goal is to use these methods for clinical translations, to identify the location, time course, and severity of tissue abnormalities without the need for biopsies or other tissue sampling. These methods could also define the range of localized problems to guide surgical or radiological interventions. FDA is exploring the modified scans to characterize:

- MRI-observed tumors that may be benign or cancerous or scar tissue
- MRI invisible non-localized diffuse tissue phenomena such as minimal traumatic brain injury, early stage Parkinson's disease, early Alzheimer's disease, primary and motor neuron diseases, and others.

Various embodiments of the MRS technology may lead to the discovery of new biomarkers that offer the possibility of diagnosis with much less risk to the patient.

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 fifth year. The 2014 Global Summit was hosted by FDA and the Canadian Food Inspection Agency in Montreal, Canada and included international participants with a focus on "Regulatory Genomics and Beyond."

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 comprised of regulatory science leaders from around the world. The Coalition collaborates to build knowledge of and promote regulatory science, defines research needs, and seeks to strengthen product safety worldwide by training regulatory scientists.

NCTR's Center Director serves as a co-chair of the Coalition's executive committee and works with the Coalition to promote global interaction between FDA and other agencies.

Bioinformatics Collaborations
NCTR and the Arkansas State University system are working together to form a virtual Arkansas Bioinformatics Consortium to leverage statewide bioinformatics capabilities. This consortium will increase resources for FDA regulatory science and strengthen the FDA Memorandum of Understanding (MOU) with the state of Arkansas. In FY 2014, NCTR, representatives from Arkansas colleges, and the Arkansas Research Alliance held three planning meetings where the Consortium's mission, goals, and 5-year plan were finalized. The Arkansas Bioinformatics Consortium will be hosting its first conference in Arkansas in 2015.

Nanotechnology Collaborations
NCTR and ORA Nanotechnology Core Facility (NanoCore) is supporting collaborative efforts within FDA and with external institutions. The State of Arkansas and FDA entered into a Memorandum of Understanding (MOU), and a research effort by a consortium of the five

Arkansas research universities focused on the synthesis, detection, and toxicity of graphene. Graphene is a carbon-rich nanoscale material made of a single layer of carbon atoms that are bonded together in a repeating pattern of hexagons. Graphene is one million times thinner than paper; so thin that it is actually considered two dimensional.

In FY 2014 the consortium, with contributions from the NanoCore, completed its first year and has provided FDA with comprehensive data on the synthesis and detection of graphene. This information is important because of the human exposure to graphene-based nanomaterials rapidly being developed for use in a variety of biomedical and food packaging applications, and which is being touted in the scientific literature as a platform for drug delivery.

Also in FY 2014, using a pristine graphene material, the NanoCore conducted high-resolution electron microscopic and spectroscopic evaluation of the graphene. The most noteworthy discovery was that the graphene was highly contaminated with elements such as aluminum, manganese, and potassium. These results point out that any graphene-based material should be carefully examined for contamination by other elements.

The Nanocore is collaborating with other U.S. government agencies and university researchers providing analytical project support. This work will inform FDA and other U.S. government agencies on the toxicity and safety of nanotechnology-based materials.

NCTR and the NanoCore are currently providing analytical support for nanotechnology investigative projects with FDA Product Centers CDRH, CDER, CFSAN, CVM, and ORA. A future study to understand how these tiny nanoparticles travel through the blood and distribute in different parts of the human body is planned between the NanoCore and FDA Product Centers CDER, CVM, and ORA. FDA scientists will use an advanced modeling approach, called Physiologically-Based Pharmacokinetic (PBPK) modeling, to quantitatively describe and predict the biodistribution of both the nanoparticles and drug molecules.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2012 Actual	$60,039,000	$60,039,000	$0
FY 2013 Actual	$54,965,000	$54,965,000	$0
FY 2014 Actual	$62,488,000	$62,488,000	$0
FY 2015 Enacted	$63,331,000	$63,331,000	$0
FY 2016 Request	$58,998,000	$58,998,000	$0

BUDGET REQUEST

The FY 2016 Budget Request for the National Center for Toxicological Research Program is $58,998,000, which is all budget authority. This amount is $4,333,000 less than the FY 2015 Enacted level.

The FY 2016 Budget allows NCTR to continue its ground-breaking research to support the FDA Strategic Goals of Oversight and Improve and Safeguard Access. These areas of research include emerging technologies, such as nanotechnology, bio-imaging, bioinformatics, and biostatistics.

In FY 2016, NCTR will continue to:

- 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.

Investments in these areas in recent years have built 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.

BUDGET AUTHORITY

Food Safety: -$4.3 million

Reductions: -$4.3 million
Center: -$4.3 million

As part of the FY 2016 Budget, NCTR will have to reduce the number of scientific projects conducted due to a 33 percent reduction of operating research funds in order to support FDA's highest priorities for FY 2016. This reduction will:

- delay advances in science needed for regulatory decisions
- scale back investment in new emerging research areas critical to public health.

Without the funding increase requested for the Other Rent and Rent-Related account to support NCTR facility needs, the impact to the research program would have been a 60 percent reduction of operating research funds.

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	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates *(Output)*	FY 2014: 1) Completed simulation protocol to help reduce the uncertainty of risk-assessment of BPA. (Target Met) 2) Determined that female rodents are more sensitive to methylphenidate when compared to males (Target Met)	1) Complete research that will provide information on toxicity of nanoscale silver 2) Present findings on research aimed at identifying biomarkers (biological indicators) to predict the effects of cancer drugs on the heart	Experimental data generated to demonstrate the advantages and benefits of new in vitro method to rapidly and accurately detect cellular toxicity
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies *(Output)*	FY 2014: 1) Identified a potential microRNA biomarker that can more efficiently indicate exposure to cancer causing agents. (Target Met) 2) A potential plasma biomarker was identified when using an animal model to detect acetaminophen-induced livery injury. (Target Met)	Outline and initiate research to find practical imaging approaches for studying developmental neurotoxicity produced by exposure to general anesthetics	Provide data that can inform FDA's regulatory need concerning sevoflurane and propofol use in children
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize therapeutic care	FY 2014: Researchers found that 18 out of 30 previously identified drug transporter genes exhibited sex differences in normal kidney tissue. Ethnicity and age also influenced	1) Complete pilot project that will promote women's health by facilitating the development of personalized approaches to treat breast cancer	Identify potentially predictable drug/drug receptor combinations that can cause rare and unpredictable side effects

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target
(Output)	gene expression levels in normal kidney tissue. (Target Met)	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)*	FY 2014: Established a real-time PCR assay to measure norovirus replication. (Target Met)	Initial results issued on research to find a robust and convenient method to verify the potency of potential bioterrorism agents in food supply	Data analysis completed on study to enhance immunity to norovirus-like particle vaccine
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates *(Output)*	FY 2014: Published a review article that summarizes issues surrounding the potential utility of blood and urine extracellular vesicle based biomarkers for detection of drug hepatotoxicity. (Target Met)	Use a new approach—antibody microarray analysis—to identify proteomic changes that may precede neurotoxicity	Utilize new omics technologies to provide translational insight into prevention and prognosis of drug induced liver injury
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products *(Output)*	FY 2014: Identified possible drug repurposing candidates for Cystic Fibrosis. (Target Met)	Establish a modeling tool that can be used to predict drug-repurposing opportunities	Statistical and data mining techniques identified for use in application to cancer therapeutics

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

- research to advance the safety of FDA-regulated products
- strong FDA science-base for emerging technologies
- personalized medicine solutions

Advance the Safety of FDA-Regulated Products

NCTR scientists have extended their original findings on pediatric anesthetics ketamine, isoflurane, and nitrous oxide to include propofol and sevoflurane. Initial research indicated that certain concentrations of propofol had adverse effects. However, scientists also found that acetyl-L-carnitine provides some neuroprotective properties when given prior to and during

administration of anesthetics. In 2015, NCTR will expand the utilization of in vitro models to study prototypic neurotoxicants including general anesthetics.

Develop Science Base for New and Emerging Technologies
Results from studies exploring miRNA responses in humans under conditions of hepatoxicity, suggest that miRNAs might provide needed information to those developing drugs and to clinicians managing patients undergoing drug-induced injury. In 2015, scientists will expand the application of in silico modeling approaches to areas that may provide screening opportunities, such as drug-related suicidality and drug abuse potential.

Personalized Medicine
Investigators determined that drug transporter genes exhibited sex differences, and ethnicity and age influenced gene expression levels, in normal kidney tissue. Investigators also identified genetic variants that contribute to the risk of carbamazeipine-induced (drug used to treat epilepsy) adverse reactions. Preliminary results revealed that two genetic markers in particular are highly associated with adverse drug reactions. In FY 2015, scientists will evaluate serum metabolic biomarkers to determine whether they are correlated to acute kidney illness diagnosis and prognosis.

PROGRAM ACTIVITY DATA

National Center for Toxicological Research Program Activity Data (PAD)

Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Research Outputs			
Research Publications	138	145	148
Research Presentations	150	158	158
Patents (Industry)	5	5	6
Leveraged Research			
Federal Agencies (Interagency Agreements)	3	3	2
Nongovernmental Organizations	20	19	19
Active Research Projects	160	164	149

OFFICE OF REGULATORY AFFAIRS – FIELD ACTIVITIES

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
ORA	**1,038,317**	**962,111**	**1,049,021**	**1,241,441**	**192,420**
Budget Authority	***917,329***	***917,317***	***934,454***	***1,002,709***	***68,255***
User Fees	***120,988***	***44,794***	***114,567***	***238,732***	***124,165***
Prescription Drug (PDUFA)	*15,489*	*8,727*	*16,263*	*13,932*	*-2,331*
Medical Device (MDUFA)	*2,105*	*1,956*	*2,105*	*2,360*	*255*
Animal Drug (ADUFA)	*472*	*31*	*404*	*399*	*-5*
Animal Generic Drug (AGDUFA)	*220*	*15*	*186*	*198*	*12*
Family Smoking Prevention and Tobacco Control Act	*14,989*	*8,760*	*15,887*	*16,663*	*776*
Voluntary Qualified Importer Program	---	---	*4,320*	*4,320*	---
Food and Feed Recall	*10,491*	---	*1,000*	*1,000*	---
Food Reinspection	*9,800*	---	*5,382*	*5,382*	---
Generic Drug (GDUFA)	*53,023*	*15,518*	*54,083*	*55,456*	*1,373*
Biosimilars (BsUFA)	*1,322*	---	*1,348*	*1,382*	*34*
Mammography Quality Standards Act (MQSA)	*13,077*	*9,787*	*13,339*	*13,612*	*273*
Third Party Auditor Program	---	---	---	*1,141*	*1,141*
Outsourcing Facility	---	---	*250*	*250*	---
Food Facility Registration and Inspection	---	---	---	*28,414*	*28,414*
Food Import	---	---	---	*84,530*	*84,530*
International Courier	---	---	---	*5,105*	*5,105*
Cosmetics	---	---	---	*4,588*	*4,588*
FTE	**4,570**	**4,625**	**4,836**	**5,175**	**339**

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 (FDA), 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. ORA advances FDA's mission to protect consumers and enhance public health through:

- inspections of firms and plants producing FDA-regulated products
- investigations of consumer complaints and criminal activity
- enforcement of FDA regulations and response to emergencies
- collection and analysis of samples
- review of imported products.

ORA collaborates with federal, state, local, tribal, territorial, and international counterparts to ensure appropriate and efficient oversight and compliance.

ORA accomplishes its mission through the operations of consumer safety officers (CSOs or field investigators) and compliance officers in five regional offices, 20 district offices, 172 resident posts and border stations, and CSOs temporarily assigned in foreign offices. ORA has 13 laboratories that perform highly specialized analyses of domestic and imported products.

ORA works with each Center Program Office to develop a work plan that outlines assignments in more than 500 activity areas that span all of FDA's regulated commodities. ORA must maintain flexibility to respond to unplanned activities, such as new product recalls, emergencies, and outbreaks that may arise, to ensure quick containment and mitigation. For example, in the Ebola outbreak, ORA increased surveillance and enforcement activities that were not planned as part of the overall FDA response.

Three of ORA's most significant accomplishments from the past year appear below.

Focus on Pharmacy Compounding
Following the fungal meningitis outbreak in 2012 and the Drug Quality and Security Act (DQSA) enacted in 2013, FDA, along with State Boards of Pharmacy, increased inspections of compounding pharmacies and outsourcing facilities. As a result, numerous recalls occurred and warning letters were issued to facilities where deficient sterile compounding practices were observed. FDA has conducted more than 90 inspections of compounding facilities in the past year.

Extending FDA's Global Presence
The foreign inspection program is critical to FDA's mission to protect public health. The global supply of FDA regulated products continues to grow in volume and complexity. In response to the growing trend, ORA conducted 3,000 inspections in 2014, a 300 percent increase from ten years ago. In addition to using its domestic staff, FDA is increasing the number of personnel stationed in its foreign offices. Additional CSOs are stationed in China and India to conduct drug and food inspections.

National Integrated Food Safety System (NIFSS)
FDA is committed to a fully integrated national food safety system, a hallmark component of the Food Safety and Modernization Act (FSMA). FDA and the Association of American Feed Control Official partnered to develop the Animal Feed Regulatory Program Standards (AFRPS), which became available for implementation in January 2014. The AFRPS provides a framework that every State can use for self-assessment to help them determine the strengths and needs of

their program. Implementation of these standards will build uniformity and consistency among State and Federal feed regulatory programs and further efforts to develop the NIFSS.

The following selected accomplishments demonstrate ORA's delivery of its regulatory and public health responsibilities within the context of FDA's Strategic Goal of Enhancing Oversight and Improving and Safeguarding Access that align with the current priorities.

Enhance Oversight

ORA has strengthened its surveillance and detection programs that monitor FDA regulated products. FDA has adopted strategies that focus on high risk products and manufacturers. FDA has also formed partnerships with various stakeholders to improve efficiency in regulating products and has developed technologies that streamline redundant processes and enhance inspectional capacity. Within this area, several activities support the FDA Strategic Priorities.

Advancing Public Health Through Regulatory Science and Innovation
ORA is developing new instruments and initiatives to:

- aid field work
- implement major legislative mandates
- utilize innovative oversight strategies
- advance regulatory science.

The ORA Office of Regulatory Science (ORS) provides a focal point for all aspects of ORA Field Laboratories and serves as the ORA headquarters for scientific and technical staff. Through ORS, ORA fosters partnerships within and outside of FDA and provides scientific, research, and analytical basis for regulatory decisions to protect and promote public health.

ORA applies risk-based principles to the life cycle of ORA scientific operations, including sample collection and analysis, methods development and validation, and data analysis and reporting. ORA supports and furthers regulatory science through the development of new methodologies for sample analysis including the utilization of innovative technologies in the execution of field activities and the oversight of laboratory standards.

ORA implemented a hand-held analytical tools pilot. Investigators use hand-held devices to screen FDA regulated products to detect toxic elements in imported products such as foods and dietary supplements.

During FY 2014, ORA evaluated the success of a pilot conducted for a Mobile Field Examination Application in hopes to expand its use to other locations. FDA field investigators used the application to conduct field examinations and sample collection work on FDA regulated imported products. The investigators were able to see tremendous efficiency improvement in the work that was performed with the application. For example, fewer transcription errors occurred, bar code technology was used to transfer FDA regulated products from the field to FDA lab, and electronic capture of documents and faster capture of pictures and documents took place while the Investigator was at a firm's location.

ORA provides oversight of regulatory science standards in laboratories through the use of programs, systems, and cooperative agreements. For example, the National Check Sample Program (NCSP) is being implemented by all FDA laboratories, which will implement specific procedures to help insure the quality of lab results.

ORA is implementing a Laboratory Information Management System (LIMS), an enhanced information technology platform, to improve the performance and efficiency of ORA laboratory operations by:

- automating the collection of information from lab instruments including the results of laboratory analyses of samples
- providing quick electronic access to data from the FDA laboratories that is not easily accessible
- enabling laboratory staff to process more samples
- supporting the standardization of lab processes and functions
- providing a foundation for data analysis and review, planning, decision making and data mining.

ORA's Office of Partnerships (OP) acts as a liaison to state governments, large food safety associations, and private industry, and also devotes resources towards the goals of improving regulatory science standards, commodity quality, and safety. OP funds and manages a Food Emergency Response Network (FERN) cooperative agreement designed to assist state laboratories with building their capability and capacity and demonstrating competency in FDA regulatory testing methodologies and reporting requirements.

In FY 2014, the FERN Microbiological Cooperative Agreement Program (mCAP) labs were involved in testing avocados for *Salmonella* and *Listeria monocytogenes* as part of a CFSAN large scale assignment. The testing involves quick turnaround times and significant weekend work for both the labs and CFSAN personnel tracking the results. Recently, a firm recalled avocados due to *Salmonella* contamination, a direct result of the testing done by the FERN labs. WEAC and FERN NPO are also working together to start a FERN Radiological Proficiency Test program. The first laboratory comparison study was sent out in September 2014 that will allow FERN NPO and WEAC to gain information regarding the proficiencies of FERN Radiological CAP labs in running various methodologies and help identify any analytical gaps or needs to be addressed in order to establish a network of labs with a harmonized methodology base that can prepared to respond in a synchronized fashion to any radiological emergency that occurs.

OP also funds and manages a grant program designed to assist food regulatory laboratories in pursuing certification under the International Organization for Standardization (ISO) accreditation program regarding microbiological, radiological, and chemical food analyses. In 2014, CFSAN organized and co-hosted the ISO Accreditation program meeting which had representation from over 30 states food/feed testing laboratories, accreditation bodies and food safety associations. This meeting enhanced the state-federal relationship and boosted program performance by sharing the best practices.

Leveraging and Collaborating with Global Partners

FDA continues to increase its regulatory presence globally to ensure that the food, feed and medical products imported into the U.S. are safe. ORA contributes to this global product safety net by leveraging and collaborating with domestic and foreign partners. Through enhancing existing partnerships and encouraging new partnerships and cross-agency coalitions, ORA improves and increases information sharing, joint work planning and compliance collaborations with federal, international, and state regulatory and public health partners.

FDA's foreign inspection program is a critical component of protecting the health and safety of U.S. citizens from unsafe foreign products. This program ensures that products produced in foreign countries intended for the U.S. market meet the same standards of quality, purity, potency, safety, and efficacy as those manufactured domestically. FDA uses a risk-based approach to target firms to inspect, enabling ORA to focus its on-site inspections in the most critical facilities and program areas. ORA leverages the work of its dedicated foreign inspections cadre, FDA inspection staff located at FDA's foreign offices, and its domestic-based investigators and scientists to continue to enhance the coverage of the foreign establishment inventory.

FDA's goal under FSMA is to prevent contaminated food product from entering the U.S. food supply. In FY 2014, ORA expanded foreign surveillance inspections of food facilities around the globe. This was achieved by using a mix of domestically based investigators, a dedicated foreign food inspection cadre and in-country stationed investigators. Furthermore, FDA uses in-country staff to gather information and collaborate with foreign authorities and other agencies to best target resources. FDA is committed to having a global presence and will continue to staff international offices in strategic locations around the world.

In an environment of increasing import entries, FDA is implementing two FSMA-initiated programs that will help facilitate the expedited import entry of products from highly compliant importers. ORA is working on the implementation of the Foreign Supplier Verification Program (FSVP) and the Voluntary Qualified Importer Program (VQIP). FSVP requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not adulterated and was produced in compliance with FDA's preventive controls requirements and product safety standards, where applicable. VQIP is a formal voluntary program under which importers may submit evidence of regulatory compliance and safety controls in return for the expedited release of import entries into the U.S. FDA is working on the operational design of VQIP authorized under FSMA; and the design will be implemented in coordination with the third party accreditation rule, which is one of the requirements of the program. FDA is also developing the IT requirements needed to support VQIP and the user fees that are also required under FSMA. FDA has also issued a proposed rule on accreditation of third party auditors, a program that when established could be used to help certify foreign firms' compliance with relevant rules.

Implementation of the Generic Drug User Fee User Fee Act (GDUFA) program illustrates ORA's focus on expanding FDA's global reach. GDUFA commits FDA to conduct risk-adjusted biennial current Good Manufacturing Practices (cGMP) surveillance inspections of human generic active pharmaceutical ingredient (API) and finished dose form (FDF) manufacturers, with the goal of achieving parity in domestic and foreign inspections by 2017 − defined as equal frequency of inspections with comparable depth and rigor, plus or minus 20 percent. As reported in FDA's FY 2013 GDUFA Performance Report to the President and Congress, 82 percent of domestic and 65 percent of foreign FDF generic user fee-paying facilities were inspected in the last two years. Over the past three years ORA has inspected 80 percent of domestic and 67 percent of foreign API user fee-paying facilities. ORA continues to build inspectional capacity to meet the requirements of GDUFA and to achieve parity between domestic and foreign inspections by the 2017 mandate.

FDA is involved in an analysis of Substandard, Spurious, Falsely-Labeled, Falsified and Counterfeit (SSFFC) Medical Products to enhance international standards for the track and trace of medical products.

ORA's Office of Criminal Investigations (OCI) has increased its international presence and, as part of these efforts, is working with Europol and Interpol to more effectively target those responsible for manufacturing and distributing violative FDA-regulated products. In FY 2014, OCI placed an agent at Europol, located in the Netherlands, to assist with international FDA cases with a nexus to any of Europol's 28 member states.

OCI has also formed a Cybercrime Investigations Unit (CcIU) which combines a team of agents and an intelligence research specialist. CcIU targets the infrastructure that supports the illegal sale of FDA-regulated products on the internet. CcIU's main objective is to disrupt and dismantle organized criminal networks that illegally sell FDA-regulated products on the internet. CcIU also provides training and field agent support and is responsible for intelligence collection and smart dissemination of this information. As part of Interpol's annual Operation Pangea, OCI's CcIU was responsible for seizing and shutting down more than 1,600 websites involved in the sale of violative FDA regulated products.

Analyzing and Utilizing Global Data to Manage Risk

ORA protects public health through facility inspections and product testing to ensure compliance with applicable FDA safety and quality standards. This oversight is accomplished through surveillance, investigation, outreach, and enforcement activities. FDA performs routine surveillance inspections both within the U.S. and globally to assess regulated industry compliance with appropriate regulations and conducts for-cause inspections when violations are discovered or outbreaks occur. FDA provides education and training to consumers, industry, and industry associations to ensure an understanding of the requirements for manufacturing, marketing, distributing, or consuming regulated products.

ORA is shifting the food safety focus from reactionary to prevention and detection approach as outlined in FSMA. In partnership with the Office of Food and Veterinary Medicine, ORA is building functional preventive measures across the food system platform creating a comprehensive regulatory framework for prevention and strengthening FDA's inspection, compliance, and outbreak response tools. Furthermore, ORA is modernizing oversight of food imports and actively advocating for enhanced partnerships with federal, state, local, and tribal regulatory and public health partners as part of a more integrated food safety system.

Protecting the U.S. food supply requires an integrated approach for identifying, investigating, and responding to foodborne illnesses and food related incidents. ORA reduced the response time to notifications of serious illness associated with food products. ORA's prompt mobilization of Rapid Response Teams (RRTs) reduces exposure times through quick identification of contaminated products and their removal from the marketplace. Reducing the timeline for conducting recalls will lessen the detrimental economic impact on industry, and minimize loss of consumer confidence while increasing consumer protection.

FDA's state partnerships allow states to contribute to domestic oversight by performing surveillance inspections including verification and compliance with hazard-based preventative controls and other applicable standards. The PFP allows FDA to work with regulatory and public health partners to:

- create national standards for inspections
- ensure coverage of domestic food facilities
- develop training and certification programs
- coordinate emergency response.

By working with federal, state, territorial, and local regulatory and public health partners, FDA aims to establish the NIFSS , making preventing foodborne illness, in food for humans and animals, through the adoption and uniform application of model programs, such as MFRPS, AFRPS, and other appropriate program standards a priority. ORA continues to conduct state assessments to assist FDA in ascertaining the states' progress in working towards the implementation of the MFRPS and awards the MFRPS grants, raising state participation to 41 states.

FDA is heavily invested in implementing requirements under the Food and Drug Administration Safety and Innovation Act (FDASIA) that reauthorized the Prescription Drug User Fee Act and various related user fee agreements between the drug and device industries and FDA. In February of 2014 FDA published the first annual report on inspections of establishments covered by the Act.

In November 2013, President Obama signed the Drug Supply Chain Security Act (DQSA) into law and allowed for the identification of compounding facilities that serve as outsourcing facilities, which requires them to comply with GMP standards. By holding these firms to the GMP standards, FDA can better ensure the drugs these firms are providing to hospitals and patients are safe. ORA is involved in the development of several draft guidance documents and is developing regulations that support implementation of the Compounding Quality Act of DQSA.

During FY 2014, ORA has increased activity conducting inspections of compounding pharmacies and outsourcing facilities, which have resulted in numerous regulatory actions including seven recalls. These recalls are often due to insanitary conditions and lack of sterility assurance. As a result of one of these recalls of products from a newly registered outsourcing facility, in July 2014, FDA issued a press release alerting health care professionals and hospitals not to use drugs produced by the firm and marketed as sterile. Additionally, the firm instituted a nationwide recall and operations were ceased in order to implement corrective actions.

In addition to the increased inspections of compounding pharmacies for cause, ORA has taken the lead on several work groups such as Compounding Training Subgroup (CTS) and Compounding Implementation Task Force. ORA recognizes that additional training related to pharmacy compounding will increase FDA's competencies and expertise leading to more efficient inspections and surveillance operations as well as more decisive enforcement actions. Both subgroups were chartered in FY 2014 and are developing key training deliverables.

Improve and Safeguard Access

ORA has taken steps to improve the predictability, consistency, transparency, and efficiency of its processes to benefit the health and wellness of the American public consumer with a focus on Safety and Quality.

Premarket Safety and Quality

ORA's increased focus on proactively preventing problems through quality policies, practices, and standards is apparent through several initiatives. ORA developed a more preemptive

approach to industry predictability through the implementation of FDA's pre-approval inspection program. The public health focus of ORA under the New Drug Review subprogram is to assess whether methods and facilities used for manufacturing, processing, and testing of products submitted under New Drug Applications (NDAs) are adequate to ensure strength, quality, and purity. ORA has a similar approach in inspecting new medical devices submitted through Premarket Approval applications and ensures manufacturers meet safety and effectiveness requirements.

ORA inspects establishments to verify their ability to manufacture products to the specifications stated in the application. ORA also confirms the authenticity of the data contained in the application and reports any information which may impact the firm's ability to manufacture the product in compliance with GMP. Inspectional coverage is necessary to assure that NDAs are not approved if the applicant has not demonstrated the ability to operate with integrity and in compliance with all applicable requirements.

ORA conducts Bioresearch Monitoring (BIMO) inspections of scientific studies which are designed to develop evidence to support the safety and effectiveness of investigational drugs, biological products, medical devices, animal drugs and other regulated products requiring premarket approval or clearance. Physicians and other qualified experts, the "clinical investigators" who conduct these studies, are required to comply with applicable statutes and regulations intended to ensure the integrity of clinical data on which product approvals are based and, for investigations involving human subjects, to help protect the rights, safety, and welfare of these subjects. ORA also inspects sponsors of clinical and non-clinical studies, laboratories conducting non-clinical studies and institutional review boards with oversight responsibilities for clinical studies. This effort ensures the integrity of the clinical data upon which product approvals are based and helps protect patient rights, safety, and welfare.

ORA collaborates with CDER to develop a priority listing of Abbreviated New Drug Applications (ANDA) inspections, targeting inspectional resources and creating efficiency by identifying generic drug manufacturing facilities for inspection to coincide with Center reviews of applications.

Strengthen Organizational Excellence

Engagement and collaboration with external stakeholders remains of great importance to FDA. Increasing both regulatory and industry expertise helps ensure a safe supply chain for global consumers. Through a transparency initiative, FDA will usher in a new era of open and accountable government to bridge the gap between the public and government. In April 2014, as part of the final phase of this initiative, FDA released a report recommending ways to enhance the transparency and public accessibility of FDA compliance and enforcement data.

FDA developed and implemented the Import Trade Auxiliary Communications System (ITACS) to improve communication between the import trade community and FDA. This internet portal, that allows importers to provide more specific entry and line data than what can be transmitted and allows users to electronically submit documents and the location of goods that have been targeted for examination. Future enhancements include account management capabilities which, once in place, will allow FDA to expand the information that can be communicated via this portal.

FDA is also collaborating with U.S. Customs Border Patrol (CBP) and the International Trade Data System (ITDS) Board of Directors to establish a fully electronic "single-window portal" through which industry can submit the data required by all government agencies for international trade. FDA is one of 47 participating government agencies (PGAs) engaged in the modernized ITDS technology which includes Automated Commercial Environment (ACE). ACE will ultimately become the single-window for all trade and government agencies involved in cargo processing of imports and exports. ACE will allow FDA and other agencies to obtain more data quickly and process cargo more expeditiously. This additional data will allow FDA to more easily identify unsafe, dangerous, or prohibited shipments.

ORA enhances program integrity through its commitment to operational, workforce, and organizational excellence. This investment includes training, certification programs, and the creation of leadership roadmaps to support professional development.

FDA employees must be highly qualified and meet professional standards to carry out their responsibilities. FDA is establishing investigator and analyst certification programs to institute professional standards for regulatory employees who execute the authority of FDA as defined in the Food Drug and Cosmetic (FD&C) Act and related acts. These certification programs provide a foundation to ensure highly skilled individuals are available to carry out FDA's mission. ORA will continue to develop, design, and deliver training to FDA's workforce, as well as to state and local partners, to ensure that regulators at every-level possess the scientific and technical competence and skills to oversee the diverse commodities over which FDA has jurisdiction. FDA also continues its work with the Seafood Alliance in developing and delivering training on Seafood HACCP inspections to FDA and State partners.

ORA examines the existing training curriculum against ORA's diverse job requirements to identify potential gaps in employee competencies and develops innovative training modules and new materials to address these new training needs. This training includes increased incorporation of web modules, webinars, and on-the-job training at the student's locality.

The Management and Leadership Development Program (MLDP) offers training and development opportunities for all ORA staff, with an emphasis on those seeking a future management position or wanting to develop into a candidate better qualified for career advancement. The development of the ORA leadership pipeline continues to be a high priority. The purpose of the pipeline is to propose a framework for moving forward with succession management in the effort to strengthen the leadership skills of employees at all levels. ORA senior management emphasizes the need to strengthen leadership skills throughout the organization to be prepared for future needs. ORA's Division of Human Resource Development (DHRD) recently received a second place award for their Potential Leadership Development Program in an award competition sponsored by the Human Capital Management Government Conference, to recognize best practices among several human capital categories across Government. This is a very prestigious award in which many Federal and State Agencies participate.

ORA is committed to quality and continual improvement in meeting the customers' needs. ORA's Quality Management System (QMS) responsibilities include providing centralized QMS guidance, leadership, communications, training, and collaboration with internal and external stakeholders. These efforts help to ensure that QMS is an effective, efficient, practical, and long-

term system that provides feedback to ORA on the quality of its work and results in continual improvement for all of ORA's processes, products, and services.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$962,111,000	$917,317,000	$44,794,000
FY 2015 Enacted	$1,049,021,000	$934,454,000	$114,567,000
FY 2016 Request	$1,241,441,000	$1,002,709,000	$238,732,000

BUDGET REQUEST

The FY 2016 Budget Request is $1,241,441,000 of which $1,002,709,000 is budget authority and $238,732,000 is user fees. This amount is $192,420,000 more than the FY 2015 Enacted level. The FY 2016 Budget provides a net budget authority increase of $68,225,000. This amount includes $5,315,000 in reductions to targeted, lower priority enforcement, compliance, inspection, and training activities. In addition, user fees increase by $124,165,000.

The FY 2016 Budget will enable FDA to ensure that food, feed and medical products available to the American public are safe and effective. The FY 2016 Budget will allow FDA to accomplish its mission through ORA managing a network of investigators and lab analysts that will conduct all of FDA’s field inspections, investigations (including criminal), exams, sample collection, lab analysis, import operations, 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 supply chain of FDA regulated products as well as new statutory requirements.

With the funding for the Medical Product Safety initiative, ORA can execute provisions within the Food and Drug Administration Safety and Innovation Act (FDASIA) legislation requiring the implementation of a Unique Facility Identifier (UFI). UFI will enable ORA to ensure accuracy and coordination of relevant FDA databases, enabling a better official establishment inventory which is a critical need for identification of risk-based inspections of all FDA regulated commodities.

ORA is also working to strengthen FDA’s domestic food safety program by expanding partnerships with, federal, state, local, territorial and tribal regulatory and public health agencies to develop and maintain a national integrated food safety system (NIFSS). This new system will require training that strengthens the competency of authorities conducting food safety regulatory programs. Additional funding will specifically be used to modernize the inspection training that will allow for more focus on a risk-based proactive approach to preventing foodborne illness.

BUDGET AUTHORITY

Food Safety: + $70.5 million

Inspection Modernization and Training: +$22.0 million
Foods: +$18.7 million / Animal Drugs and Feeds: +$3.3 million

With this funding increase, FDA will also invest in the modernization of inspections and training of FDA investigators. Currently, investigators are trained to inspect food manufacturers using a compliance model focused on finding evidence of adulteration or misbranding. The new method of a more targeted, risk-based, and efficient inspection model will focus on prevention and other improvements. These funds will allow ORA to continue to recruit knowledgeable technical experts who can ensure that the new prevention standards and guidelines are based on the best science and intimate knowledge of current industry best practices.

National Integrated Food Safety System: +$28.0 million
Foods: +$23.8 million / Animal Drugs and Feeds: +$4.2 million

The requested funding will enhance ORA's ability to ensure that the national integrated food safety system (NIFSS) cooperative agreements and grants are continued and expanded, as well as provide additional investments in the modernization of inspections and training of FDA investigators.

NIFSS focuses on building state capacity to coordinate among all relevant federal, state, local, tribal and territorial regulatory and public health agencies. Throughout the fiscal year, the states are projected to conduct over half of the food and feed facility inspections required by FSMA and the new FSMA prevention standards that are anticipated to begin in 2016. To be successful in aligning state programs with FDA's new inspection and compliance approach, the states will need:

- inspector training
- inspector certification programs
- state laboratory coordination
- enhanced information sharing capacity.

Additional investments to the modernization of inspections and training for FDA partners will allow FDA to enhance the new method of a more targeted, risk-based and efficient inspection model that will focus on preventing food contamination through requiring better data about hazards at food and feed facilities, new IT systems to identify and track risks, and methods for measuring inspection efficiency while investing in continuous improvement in our internal system.

Import Safety – Foreign Supplier Verification Program (FSVP) Implementation: +$20.5 million
Foods: +$17.4 million / Animal Drugs and Feeds: +$3.1 million

The requested funding will support 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 U.S. is safe and meets the same regulatory requirements as domestically produced food.

With this funding increase, ORA will support the implementation of the Foreign Supplier Verification Program (FSVP). FDA will implement foreign establishment registration verification of foreign firms by verifying the existence of a manufacturing facility and the type of manufacturing they are conducting. The implementation of the FSVP will transform import safety screening by requiring importers to develop supplier verification plans to help ensure greater food safety before food or feed is sent to the U.S. and examined at the border.

FSVP will require extensive training and technical assistance for importers, substantial regulatory development, staffing, and training within FDA to enforce the regulation. The food and feed industry has expressed concern that FDA's current approach and ability to screen food and feed imports is an impediment to business' "just in time" practices, which is a strategy that strives to improve return on investment by reducing in-process inventory and associated carry costs. FDA is challenged by the thousands of inquiries that come in each year from importers about operations at ports of entry, and without enhancements through FSVP implementation, these complaints will likely expand several fold.

One of FDA's best opportunities for return on investment is helping foreign governments ensure the safety of food and feed before it is even shipped to the U.S. FDA continues to invest in this effort in three ways by:

- placing staff in foreign offices
- increasing the number of foreign inspections
- developing partnerships with its counterparts overseas.

Some of those efforts are focused more on technical assistance, such as helping other nations strengthen their regulatory systems and upgrading their public health laboratory methods and training. Other efforts include working with more developed countries on "systems recognition," a process by which FDA will assess if another country's food and feed safety system provides protections comparable to those in the U.S., and thus food from that country will be of a lesser concern when it is exported to the U.S. This approach will allow FDA to focus import screening efforts on areas of higher risk. The first such recognition was completed with New Zealand in 2012. Recognition of Canada's system is now under development, and others will be reviewed in the future.

To streamline processes and realize program efficiencies, FDA will use Remote Access Devices. These devices allow field import staff to perform their day to day work on site – at the docks, borders, or airports – examining shipments and completing required electronic submissions, printing labels for samples collected, and completing collection reports and necessary documentation. These efficiencies, in addition to expediting review, examination, and sampling of products, will decrease the time required to release product into commerce because field staff can now perform the majority of these activities in real time and on-site.

FDA also plans to expand the use of handheld analytical tools by field import staff. Handheld analytical tools allow for on-site screening of products for specific contaminants, aiding in the identification of products that pose a public health risk. This advanced technology will enhance 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 also allow for improved risk analytics by permitting the targeting of products with the highest probability of being volatile and the expedited release of compliant shipments into U.S. commerce.

Medical Product Safety: +$3.1 million

FDASIA Implementation – Unique Facility Identifier / Unique Device Identifier: +$3.1 million
Biologics: +$1.1 million / Devices and Radiological Health: +$2.0 million

Domestic and foreign drug manufacturers are required to register annually with FDA. Each registration, as mandated by FDASIA, must include a UFI. With this funding increase, FDA will be able to support electronic registration and integration of the UFI into FDA's IT systems that support ORA's medical product related regulatory work, including ORA's Official Establishment Inventory (OEI). The ultimate result will be a more reliable inventory of manufacturers that will enable the Centers and ORA to accurately identify firms and allocate inspectional resources accordingly.

The increased funding will also be used to continue the implementation of a Unique Device Identifier (UDI) system, which will provide a consistent, standardized, unambiguous way to identify medical devices. UDI will provide the ability to quickly and efficiently identify marketed devices when recalled and improve the accuracy and specificity of adverse event reports.

USER FEES

Current Law User Fees: +$1.5 million

The Office of Regulatory Affairs request includes an increase of $1.5 million for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry.

Third Party Auditor Program User Fee: +$1.1 million
Foods: +$1.1 million

The Food Safety Modernization Act directed FDA to establish a program to accredit entities to conduct food safety audits and to issue certifications for foreign food facilities to ensure compliance with United States safety standards. This program will optimize federal resources by allowing FDA to leverage third-party auditors to enhance the assurance of the safety of food and animal feed products imported and facilitates the movement of regulated products in international trade in a more efficient way. In FY 2016, FDA will begin collecting user fees in support of this program. The final regulation is scheduled to be finalized in 2015.

Proposed User Fees: +$122.6 million

Proposed Food Import Fee: +84.5 million
Foods: +84.5 million

The Field Foods Program request for the proposed Food Import Fee is $84,530,000. With this funding request, ORA will provide outreach and education on FSMA import provisions to all stakeholders, including the import community and other federal agencies involved in the import process. FDA will establish and implement a national call center, aimed at improving responsiveness to inquiries concerning the import process or the status of imported foods. The call center will help meet FSMA requirements for industry assistance, improve overall compliance with FSMA rules, and reduce time to solve problems. FDA will implement a quality management system and quality control measures for the import review process at all locations

while providing dedicated quality management measures to assess and assure the consistency of the import review process.

FDA will expand import staffing by strategically applying increased hours of operations at specified border stations and ports of entry. Expanding hours and increasing staff will provide increased capacity for screening of shipments for food safety. This will enable FDA to:

- increase operational efficiency
- improve industry and FDA communication
- reduce time to resolve problems, and
- improve movement of trade through greater availability of knowledgeable FDA staff.

Improving information technology to enhance risk-based decision-making for import personnel will result in a higher percentage of unauthorized imports from crossing the U.S. borders. These enhanced IT tools, systems, and infrastructure will allow FDA to improve and expedite the identification of threats to public health and reduce the incidence of foodborne illness outbreaks. With this user fee, 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. This investment will also allow for the development of FDA's fee collection system.

Proposed Food Facility Registration and Inspection User Fee: +$28.4 million
Foods: +$27.4 million / Animal Drugs and Feeds: +$1.0 million

With this user fee, 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. 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.

ORA will continue to assist the states in the implementation of the Manufactured Food Regulatory Program Standards (MFRPS) and the Animal Feed Regulatory Program Standards (AFRPS), as well as provide support and coordinate with the states as FDA moves towards establishing national standards for laboratories.

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 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 NIFSS are coordinated and provide support for the governance structure. ORA will develop and validate certification testing instruments, serve as OEI Coordinators for FDA, and support the states as FDA moves to national standards for laboratories. FDA will implement and enforce preventative controls in food processing facilities, and begin training more than 3,400 (1,100 FDA and 2,300 state) inspectional personnel in preventive controls inspections and enforcement methods. This training will ensure that inspectional 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 preventative controls and other FSMA policies.

Proposed Cosmetics Safety User Fee: +$4.6 million
Foods: +$4.6 million

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 postmarket 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: +$5.1 million
Foods: +$0.8 million, Human Drugs: +$0.5, Devices +$3.8 million

Millions of shipments of food and medical product 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

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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
214201: Number of prior notice import security reviews. *(Output)*	FY 2014: 82,821 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2014: 183,224 Target: 160,158 (Target Exceeded)	160,000	160,000	maintain
214203: Number of Filer Evaluations. (Output)	FY 2014: 1,247 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2014: 9,817 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2014: 12 labs Target: 13 labs (Target Not 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 2014: 44% Target: 33% of approximate inventory every three years based on 19,500 firms (Target Exceeded)	67%	100%	+33%
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2014: 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

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2014: 918 Target: 750 (Target Exceeded)	750	750	maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2014: 1,026 Target: 1,000 (Target Exceeded)	900	900	maintain
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2014: 650 Target: 570 (Target Exceeded)	570	570	maintain
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2014: 286 Target: 250 (Target Exceeded)	250	250	maintain
244203: Number of targeted prohibited material BSE inspections. *(Output)*	FY 2014: 537 Target: 500 (Target Exceeded)	500	500	maintain
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2014: 322 Target: 300 (Target Exceeded)	300	300	maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2014: 1,976 Target: 1,600 (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. 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. As FY 2014 represents the completion of the first year in the new three-year cycle, ORA has made significant progress towards this requirement having accomplished inspections of 44% of the high-risk domestic inventory. FY 2016 will mark the completion of the next three year cycle for 100 percent coverage of the high-risk inventory.

Laboratory Accreditation Corrective Actions
Appropriate corrective actions have been initiated to address not meeting the measure. We anticipate meeting this measure in FY 2015.

Increased Laboratory Surge Capacity
A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially adulterated 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.

Decrease in Domestic Blood Bank Inventory for Inspection
The number of blood banks in the United States has decreased over the last several years due to significant changes in the industry, driven by less transfusions and the associated decrease in the amounts of stored blood, as well as consolidations and firms going out of business. FDA historically inspects 50 percent of the blood bank inventory each year to meet the statutory requirement to inspect each firm once every two years. With fewer firms to inspect, FDA is reducing the FY 2015 and 2016 target levels to 900 respectively to reflect the new inventory level.

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 inherent risk, outbreaks, 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 2014 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 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,133***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,032	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk**
Imported and Domestic Cheese Program Inspections	285		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	334		
Domestic Fish & Fishery Products (HACCP) Inspections	970		
Import (Seafood Program Including HACCP) Inspections	214		
Juice HACCP Inspection Program (HACCP)	159		
Interstate Travel Sanitation (ITS) Inspections	872		
Domestic Field Exams/Tests	2,280	3,945	3,945
Domestic Laboratory Samples Analyzed	11,350	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,339***	***1,200***	***1,200***
All Foreign Inspections	1,339	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***8,472***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	183,224	160,200	160,200
Import Laboratory Samples Analyzed	24,540	35,300	35,300
Import Physical Exam Subtotal	**207,764**	**195,500**	**195,500**
Import Line Decisions	12,180,223	13,033,779	13,874,509
Percent of Import Lines Physically Examined	1.71%	1.50%	1.41%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	82,821	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,667***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***91***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,615	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	948	1,104	1,104
State Contract Juice HACCP	94	103	103
State Contract LACF	110	68	68
State Partnership Inspections	94	273	273
State Contract Foods Funding	$13,564,985	$14,514,534	$15,530,551
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$21,876,992	$23,408,381	$25,046,968
Total State & Annual FERN Funding	**$35,441,977**	**$37,922,915**	**$40,577,519**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS [2]	***18,230***	***20,496***	***20,496***

[1] The FY 2014 actual unique count of foreign inspections includes 139 OIP inspections (65 for China, 67 for India, & 7 for Latin America).

[2] The Actual count of establishment inspections conducted in FY 2014 was less than projected due to the loss of approximately one month of activity during the government shutdown in October of 2013. Efforts were made to minimize the impact as much as possible. In addition, FDA completed 8,607 high risk inspections, which are a subset of total establishment inspections.

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***103***	***100***	***100***
Domestic Inspections	103	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***4***	***0***	***0***
Foreign Inspections	4	0	0
IMPORTS			
Import Field Exams/Tests	6,809	1,600	1,600
Import Laboratory Samples Analyzed	448	500	500
Import Physical Exam Subtotal	**7,257**	**2,100**	**2,100**
Import Line Decisions	2,596,057	2,611,156	2,704,653
Percent of Import Lines Physically Examined	0.28%	0.08%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***107***	***100***	***100***

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,869***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	161	171	171
Pre-Approval Inspections (ANDA)	140	216	216
Bioresearch Monitoring Program Inspections	635	563	563
Drug Processing (GMP) Program Inspections	780	591	591
Compressed Medical Gas Manufacturers Inspections	218	295	295
Adverse Drug Events Project Inspections	90	120	120
OTC Monograph Project and Health Fraud Project Inspections	60	79	79
Compounding Inspections[1]	92	130	130
Domestic Laboratory Samples Analyzed	1,320	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***993***	***999***	***999***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	168	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	116	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	200	255	255
Foreign Drug Processing (GMP) Program Inspections	757	843	843
Foreign Adverse Drug Events Project Inspections	8	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,862***	***2,855***	***2,855***
IMPORTS			
Import Field Exams/Tests	7,314	7,200	7,200
Import Laboratory Samples Analyzed	353	490	490
Import Physical Exam Subtotal	**7,667**	**7,690**	**7,690**
Import Line Decisions	641,908	643,990	672,765
Percent of Import Lines Physically Examined	1.19%	1.19%	1.14%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS [3]	***0***	***0***	***0***
State Partnership Inspections: Compressed Medical Gas Manufacturers Inspections	0	0	0
State Partnership Inspections: GMP Inspections	0	0	0
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,862***	***2,855***	***2,855***

[1] The number of compounding inspections includes inspections of compounding pharmacies and outsourcing facilities under sections 503A and 503B respectively.

[2] The FY 2014 actual unique count of foreign inspections includes 102 OIP inspections (36 for China, 62 for India and 4 for Latin America).

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

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,929***	***2,047***	***2,047***
Bioresearch Monitoring Program Inspections	95	100	100
Blood Bank Inspections	994	1,060	1,060
Source Plasma Inspections	167	194	194
Pre-License, Pre-Market Inspections	18	7	7
GMP Inspections	32	28	28
GMP (Device) Inspections	4	7	7
Human Tissue Inspections	650	661	661
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***68***	***47***	***47***
Bioresearch Monitoring Program Inspections	25	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	7	8	8
Pre-License, Pre-market Inspections	11	2	2
GMP Inspections (Biologics & Device)	23	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,997***	***2,094***	***2,094***
IMPORTS			
Import Field Exams/Tests	49	45	45
Import Line Decisions	82,710	96,091	109,202
Percent of Import Lines Physically Examined	0.06%	0.05%	0.04%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,997***	***2,094***	***2,094***

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2014 Actual			FY 2015 Estimate			FY 2016 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	***1,677***	***230***	***1,465***	***1,792***	***299***	***1,524***	***1,792***	***299***	***1,524***
Pre-Approval /BIMO Inspections	38	38	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	192	192	0	222	222	0	222	222	0
BSE Inspections	1,248	0	1,248	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	15	0	15	25	0	25	25	0	25
Illegal Residue Program Inspections	490	0	490	473	0	473	473	0	473
Feed Manufacturing Program Inspections	161	0	161	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,507	13	1,494	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***78***	***71***	***7***	***76***	***69***	***6***	***76***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	26	26	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	64	64	0	33	33	0	33	33	0
Foreign Feed Inspections	7	0	7	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	***1,755***	***301***	***1,472***	***1,868***	***368***	***1,530***	***1,868***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	3,910	237	3,673	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	694	1	693	750	2	748	750	2	748
Import Physical Exam Subtotal	**4,604**	**238**	**4,366**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	391,388			455,140			505,859		
Percent of Import Lines Physically Examined	1.18%			0.96%			0.86%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***5,031***	***0***	***5,031***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [1]	***4***	***0***	***4***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***415***	***0***	***415***	***600***	***0***	***600***	***600***	***0***	***600***
State Contract Inspections: BSE	4,603	0	4,603	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	646	0	646	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	246	0	246	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	5	0	5	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	415	0	415	600	0	600	600	0	600
State Contract Animal Drugs/Feeds Funding	2,765,193	0	2,765,193	2,958,757	0	$2,958,757	3,165,870	0	$3,165,870
BSE Cooperative Agreement Funding	2,315,621	0	2,315,621	2,246,156	0	$2,246,156	2,178,772	0	$2,178,772
State Contract Tissue Residue Funding	553,409	0	553,409	590,025	0	$590,025	631,326	0	$631,326
Total State Funding	**$5,634,223**	**$0**	**$5,634,223**	**$5,794,938**	**$0**	**$5,794,938**	**$5,975,968**	**$0**	**$5,975,968**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***6,790***	***301***	***6,507***	***6,913***	***368***	***6,575***	***6,913***	***368***	***6,575***

[1] 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 and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,667***	***2,864***	***2,864***
Bioresearch Monitoring Program Inspections	307	300	300
Pre-Market Inspections	61	67	67
Post-Market Audit Inspections	42	34	34
GMP Inspections	1,614	1,594	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	635	723	723
Inspections (MQSA) FDA Domestic (VHA)	48	43	43
Domestic Radiological Health Inspections	56	205	205
Domestic Field Exams/Tests	89	215	215
Domestic Laboratory Samples Analyzed	185	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***585***	***603***	***603***
Foreign Bioresearch Monitoring Inspections	17	25	25
Foreign Pre-Market Inspections	21	31	31
Foreign Post-Market Audit Inspections	39	19	19
Foreign GMP Inspections	518	521	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	35	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,252***	***3,467***	***3,467***
IMPORTS			
Import Field Exams/Tests	25,782	18,821	18,821
Import Laboratory Samples Analyzed	1,014	1,123	1,123
Import Physical Exam Subtotal	**26,796**	**19,944**	**19,944**
Import Line Decisions	16,665,422	15,758,863	16,531,081
Percent of Import Lines Physically Examined	0.16%	0.13%	0.12%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,929***	***7,929***	***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS [1]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,775	6,800	6,800
Inspections (MQSA) by State non-Contract	1,100	1,110	1,110
GMP Inspections by State Contract	20	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$83,643	$86,078	$90,708
State Contract Mammography Funding	$9,089,063	$9,160,668	$9,232,836
Total State Funding	**$9,172,706**	**$9,246,746**	**$9,323,544**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,181***	***11,396***	***11,396***

[1] The FY 2014 actual unique count of foreign inspections includes 17 OIP inspections (12 for China & 5 for India).

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

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TOBACCO CONTROL ACT

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Family Smoking Prevention and Tobacco Control Act	**501,476**	**570,536**	**531,527**	**564,117**	**32,590**
Center (UF Only)	486,487	561,776	515,640	547,454	*31,814*
Field (UF Only)	14,989	8,760	15,887	16,663	*776*
FTE	**640**	**592**	**773**	**962**	**189**

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 (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA works to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public about tobacco products and the dangers their use poses.

FDA executes its regulatory and public health responsibilities in 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. FDA requires tobacco product manufacturers, importers, and distributors to register and provide a list of tobacco products and ingredients they sell. Industry must report harmful and potentially harmful constituents and FDA prohibits inaccurate or misleading tobacco product labeling and marketing.

Some of CTP's authorized activities include:

- inspecting tobacco product manufacturing establishments and tobacco retailers to assure compliance with FDA laws and tobacco product regulations
- 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
- taking enforcement action, when appropriate, for violations of the Tobacco Control Act and implementing regulations.

Recent Accomplishments

As of September 30, 2014, FDA awarded contracts for compliance check inspections at tobacco retail establishments to be conducted in 58 states, territories, and Tribal jurisdictions to ensure compliance. Compliance check inspections oversee tobacco marketing, sales, and distribution of

tobacco products at retail locations. In total, FDA has completed over 346,000 compliance check inspections at tobacco retail establishments as of September 30, 2014.

FDA issued a proposed rule − the "deeming rule" − on April 25 2014, to deem additional products that meet the statutory definition of a "tobacco product" to be subject to FDA's regulatory authority.

FDA research leads to a better understanding of regulated tobacco products and patterns of tobacco use. As of September 30, 2014, CTP funded 98 active research projects grants, cooperative agreements, and intramural projects via the National Institutes of Health (NIH), including the 14 Tobacco Centers of Regulatory Science (TCORS). TCORS is a first-of-its-kind program designed to generate research to inform the regulation of tobacco products to protect public health and train the next generation of tobacco regulatory scientists.

FDA has also made progress in the important area of Substantial Equivalence, where we have built a rigorous, science-based process to review new tobacco products applications to determine substantial equivalence (SE) to current market products. In October 2014, FDA implemented performance measures that include timeframes for SE and Exemption from SE requests.

On March 24, 2014, FDA announced it no longer had a backlog of Substantial Equivalence reports awaiting scientific review, and as of September 30, 2014, 45 percent of regular SE submissions were resolved by a final decision.[44]

FDA issued the first decisions on provisional SE reports in February 2014. FDA is committed to completing the review of provisional tobacco products and will continue to advance our efforts to review and act on provisional SE reports while also working to meet the performance measures for regular SE reports and Modified Risk Tobacco Product (MRTP) Applications.

FDA is establishing public education campaigns to educate the public about the dangers of regulated tobacco products. In February 2014, FDA launched "The Real Cost," a national public education campaign designed to reduce initiation rates among youth ages 12-17 and reduce the number of youth already experimenting with cigarettes who progress to regular use.

FDA established a framework for industry registration, product listing, and submission of ingredients and harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

Enhance Oversight

FDA is committed to regulating the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use, especially among youth. FDA's strong oversight of the Tobacco Program is carried out with the use of scientific supported regulations and guidance that interpret the statute, clarify aspects of regulatory authority, and explain the Agency's expectations to the regulated industry. Furthermore, FDA ensures industry compliance within the regulatory requirements by enforcing warning label and advertising requirements, and by restricting access and the marketing of cigarettes and smokeless tobacco products to youth through the use of compliance inspections and civil monetary penalties.

[44] Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE)

Maintaining a Strong Science Base for Oversight Actions
FDA reduces tobacco harms through numerous research and scientific endeavors. Research results expand the scientific evidence to inform implementation of the regulatory authorities specified in the Tobacco Control Act and help assess the impact of regulatory actions. Through research, FDA better understands patterns of tobacco use, the harms caused by use of tobacco and where regulatory intervention consistent with FDA's statutory authority is most needed.

CTP builds the tobacco regulatory base by partnering with other agencies, such as the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and FDA's National Center for Toxicological Research.

In FY 2014, FDA and NIH's Tobacco Regulatory Science Program (TRSP) continued their collaboration, stimulating investigator-initiated research and releasing targeted Funding Opportunity Announcements (FOAs) to study:

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

In FY 2016, FDA will continue to fund, the Population Assessment of Tobacco and Health (PATH) Study. This national longitudinal cohort study of users of tobacco products, and those at risk for tobacco use, including youth ages 12 to 17 will provide:

- research on reducing harm, evaluating patterns of tobacco use such as switching products and using multiple products
- an understanding of perceptions, knowledge, attitudes, and use of products that are perceived as lower risk.

FDA will continue support for TCORS with the overall objective to conduct multidisciplinary research that will inform FDA's regulatory actions related to the manufacture, distribution, and marketing of tobacco products.

The National Center for Toxicological Research (NCTR) assists with research on toxicology of compounds and cigarette smoke, biomarker discovery, the toxic and addictive potential of tobacco products, and developmental bioinformatics projects.

Enforcement of the Tobacco Control Act
FDA has a comprehensive compliance and enforcement program to ensure industry compliance with regulatory requirements and restrict access and marketing of cigarettes and smokeless tobacco products to youth. As of September 30, 2014, FDA awarded contracts for compliance check inspections at tobacco retail establishments to be conducted in 58 states, territories, and Tribal jurisdictions to ensure their compliance with the law.

FDA does compliance check inspections in states and territories under contract with FDA at tobacco retail establishments to ensure compliance with the law, including age and ID verification requirements. In FY 2013, FDA conducted about 109,908 tobacco retailer inspections, resulting in about 5,992 Warning Letters and 534 Civil Monetary Penalties. As of September 30, 2014, FDA completed over 346,000 inspections, levied 1,950 civil monetary

penalties, and issued 19,200 warning letters. FDA provides a training program for FDA-commissioned inspectors including commissioning more than 1,100 state and territorial officials.

FDA also regularly inspects registered establishments involved in the manufacture or processing of a tobacco product to determine compliance with existing laws and regulations. FDA conducts surveillance of websites, social media, and magazines and other publications that promote and sell regulated tobacco products in the U.S. Market. FDA has also created an Office of Small Business Assistance within CTP to assist small tobacco product manufacturers and retailers in complying with the Tobacco Control Act.

FDA recently developed the "Sales to Minors: Age and ID Requirements for Sales of Regulated Tobacco" video as a new tool to assist industry and retailers in protecting America's youth.

FDA regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On April 25 2014, FDA issued a proposed rule (the "deeming rule") to deem additional products that meet the statutory definition of a "tobacco product." Under the proposed rule, products that would be "deemed" to be subject to FDA regulation include currently unregulated marketed products, such as electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (hookah) tobacco, and dissolvables not already under the FDA's authority.

Manufacturers of newly deemed tobacco products would be required, among other things to:

- register their establishments with the FDA, report product and ingredient listings, and report harmful and potentially harmful constituents
- market new tobacco products only after FDA review
- make direct and implied claims of reduced risk only if the FDA confirms that scientific evidence supports the claim and that marketing the product will promote public health
- not distribute free samples.

Improve and Safeguard Access to FDA-Regulated Products to Benefit Health

FDA's authority to regulate tobacco products includes premarket review of new tobacco products to determine if their marketing is appropriate for the protection of the public health, or if they are substantially equivalent to existing products. Tobacco products are inherently dangerous. FDA's responsibility is not to improve access to tobacco products, but to safeguard that access by responsibly controlling it in accordance with FDA's authorities.

New products and product changes are reviewed following three submission pathways including:

- premarket tobacco product application (PMTA)
- reports demonstrating substantial equivalence (SE) to certain commercially marketed products
- exemption from demonstrating substantial equivalence.

Furthermore, before making marketing claims that imply modified risk, manufacturers must submit a Modified Risk Tobacco Product Application (MRTPA), and receive an FDA Order authorizing a claim to reduce harm or the risk of tobacco-related disease.

FDA informs small businesses about existing guidance and regulations about the submission pathways through publications and online webinars that aim to provide easily accessible educational opportunities.

FDA has prioritized the review of regular SE submissions and has made progress in each of the three phases in the SE review process:

- administrative review
- notification
- scientific review.

As of September 30, 2014, FDA completed administrative reviews of 4,438 of the 4,614 SE submissions. On March 24, 2014, FDA announced it no longer had a backlog of regular[45] SE reports. All regular SE reports received have immediately been entered into review.

- As of September 30, 2014, 45 percent of regular SE submissions have been resolved by a final decision.[46]
- FDA has issued a Scientific Advice and Information Request Letter or a Preliminary Finding Letter for 81 percent of the regular SE reports that are pending.
- Sixty-nine percent of the regular SE Report withdrawals were withdrawn by the manufacturers after FDA issued an action letter identifying deficiencies in the submission.

FDA expects the time required for review of SE submissions to get substantially shorter as CTP continues to improve the efficiency of its review process.

Promote Informed Decisions

"The Real Cost" and Public Education Campaigns

Public education is a key component of FDA's continued .efforts to prevent youth from using the tobacco products it regulates, which currently includes cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco, while encouraging young people who use tobacco products to quit. As authorized by the Tobacco Control Act, these activities involve planning, developing, producing, and delivering national multimedia public education campaigns Multimedia campaigns enable FDA to educate the public about the harms and risks of regulated tobacco products. Specifically, the campaigns will equip the public with important facts about:

- the health risks of regulated tobacco products
- the addictiveness of regulated tobacco products
- the harmful and potentially harmful constituents in regulated tobacco products.

In February 2014, FDA launched its first ever national youth tobacco prevention campaign, "The Real Cost," which is designed to reduce smoking among youth ages 12-17.

A critical factor in reducing youth tobacco use is to produce and maintain effective levels of campaign awareness within the target population. The Centers for Disease Control and Prevention (CDC) indicates that new tobacco prevention campaigns that reach 75 to 85 percent

[45] SE reports received before March 23, 2011, for new products introduced to market between February 15, 2007 and March 22, 2011 are considered "provisional," and the products covered by those reports can remain on the market unless FDA finds that they are "not substantially equivalent." The other category is "regular" SE reports (reports that do not meet the definition of "provisional"). Products covered by "regular" reports cannot be marketed unless FDA first issues a finding of substantial equivalence.

[46] Final decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE)

of the target audience within one year can expect to produce attitude and behavior change within two years if the time in market is adequately sustained.

FDA is positioned to sustain "The Real Cost" campaign at the reach, frequency and time in-market recommend by CDC to achieve behavior change and improve public health.

FDA is implementing a large, two-year outcome evaluation study for "The Real Cost" campaign. The study design is longitudinal, meaning the study will attempt to follow the same youth over time. Evaluation results will be used to assess changes in key tobacco-related knowledge, attitudes, beliefs, and behaviors among the target audience to measure the impact and effectiveness of the campaign. Ultimately, results will be used to determine if exposure to the campaign is associated with a decrease in smoking among youth aged 12 to 17.

FDA will launch several additional public education campaigns in 2015 and 2016. Subsequent campaigns will target other discrete audiences, including multicultural youth such as African American, Hispanic, Asian and Pacific Islander, and American Indian and Alaska Native; rural youth; and lesbian, gay, bisexual, and transgender young adults.

Strengthen Organizational Excellence

FDA provides the infrastructure necessary to support the agency's responsibilities and authorities under the Tobacco Control Act. Examples include: strategic IT systems which support industry applications, compliance inspections, and collection of tobacco user fees. In addition, FDA is hiring additional staff to expand its research capabilities, conduct SE reviews, support inspection efforts, and draft regulations and guidance.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2012 Actual	$277,136,000	$0	$277,136,000
FY 2013 Actual	$848,807,000	$0	$848,807,000
FY 2014 Actual	$570,536,000	$0	$570,536,000
FY 2015 Enacted	$531,527,000	$0	$531,527,000
FY 2016 Request	$564,117,000	$0	$564,117,000

BUDGET REQUEST

The FY 2016 Budget Request for the Tobacco Control Act Program is $564,117,000, all from user fees. This amount is the FY 2016 level authorized in the Tobacco Control Act less the amounts for GSA Rent and FDA Headquarters, which are shown in their own sections of the budget request. This amount is an increase of $32,590,000 above the FY 2015 Enacted level.

The Center for Tobacco Products amount in this request is $547,454,000. The Office of Regulatory Affairs amount is $16,663,000. The Tobacco Control Act requires this funding be used only for FDA tobacco regulatory activities. Conversely, the law prohibits the use of non-tobacco funds for FDA tobacco regulatory activities.

In FY 2016, FDA will expand efforts on oversight and enforcement of tobacco products and outreach to protect Americans from tobacco-related death and disease by regulating the

manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

CTP is focusing its efforts on five strategic priorities: Product Standards; FDA-wide Comprehensive Nicotine Regulatory Policy; Premarket and Postmarket Control, Regulations, and Product Reviews; Compliance and Enforcement; and Public Education. Specifics on CTP's FY 2016 efforts and support for the five strategic priorities are provided below.

Strategic Priorities

Product Standards
Section 907 of the Federal Food, Drug, and Cosmetic Act gives FDA the authority to issue, via notice-and-comment rulemaking, tobacco product standards that are appropriate for the protection of the public health. This authority is one of the most powerful tools that FDA has to regulate tobacco. CTP is advancing a product standard strategy to yield strong standards to improve public health that can withstand legal challenge, by exploring potential standards for addictiveness, toxicity, and appeal.

FDA-wide Comprehensive Nicotine Regulatory Policy
With passage of the Tobacco Control Act, FDA now regulates a broad range of nicotine-delivering products, from cigarettes to medicinal nicotine gum and patch. FDA is establishing an integrated, agency-wide policy on nicotine-containing products that is public health based and recognizes the reality that people use tobacco for the nicotine but die from the toxins in the tobacco. Beyond finalizing the "deeming rule," related activities include:

- developing jurisdiction policy on nicotine-containing products across FDA
- working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
- exploring options at CTP for an expedited premarket review policy based on the principle of relative toxicity and risk.

Premarket and Postmarket Control, Regulations, and Product Reviews
FDA's reviews act as a gatekeeper between tobacco products and consumers. Requiring manufacturers to seek FDA authorization before marketing new tobacco products or modifying existing ones allows FDA to ensure that new products cannot be commercially sold without review and that potential population-level health impacts are considered when evaluating the marketing of new products. CTP is exploring developing rules and guidances for product review pathways (SE, PMTA, MRTP), Tobacco Product Manufacturing Practices (TPMP), registration and product listing, and continuing to establish and then meet performance standards for product reviews.

Compliance and Enforcement
FDA focuses on the utilization of a national program of inspections, investigations, monitoring, and review of covered tobacco products, sales, manufacturing, and advertising. FDA's compliance programs focus on appropriate enforcement actions that are supported by evidence of violations of the law.

Public Education
FDA maximizes its impact on public health by focusing our public education efforts on at-risk audiences such as general market youth who are already experimenting with cigarettes or open to

it, multicultural (e.g., African American, Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native) youth, rural youth, and lesbian, gay, bisexual, and transgender (LGBT) young adults.

Additional FY 2016 Support Activities

In FY 2016, FDA will continue to fund via NIH, the PATH Study, an on-going national longitudinal, cohort study of users of tobacco products and those at risk for tobacco use, including youth ages 12 to 17. This study will provide research on reducing harm and evaluating patterns of tobacco use, such as switching products and using multiple products, and increase understanding of perceptions, knowledge, attitudes and use of products that are perceived as lower risk.

FDA will build regulatory science capabilities through partnerships with the National Institutes of Health (NIH) including grants for the Tobacco Centers of Regulatory Science (TCORS). This first-of-its-kind program is designed to generate research to inform the regulation of tobacco products to protect public health and train the next generation of tobacco regulatory scientists.

The objective is to conduct programs of multidisciplinary research that will inform FDA's regulatory actions related to the manufacture, distribution, and marketing of tobacco products. Research will be conducted in a number of areas including chemistry, engineering, toxicology, and behavioral and social sciences.

Enforcement of the Tobacco Control Act and implementation of regulations are a priority in FY 2016 including:

- implementing the Tobacco Retail Inspection Program[47] that conducts compliance check inspections of retail establishments that sell regulated tobacco products
- expanding the program to additional States and territories
- increasing outreach and education efforts for small tobacco manufacturers and retailers about the Tobacco Control Act and regulations through a webpage, compliance training webinars, and Retailer Education program, and responding to inquiries
- enforcing warning label requirements, including review of warning plans for smokeless tobacco products
- addressing potentially false and misleading claims made in the labeling and advertising of regulated tobacco products to eliminate deceptive information and provide accurate information to encourage cessation
- including coverage of some tribally affiliated tobacco product manufacturers to build on FDA's existing contracts with Native American-owned companies.

ORA assists in conducting surveillance, investigations, inspections, sample collections, and other regulatory actions to ensure the compliance of manufacturers, distributors, and importers of tobacco products with the requirements of the FD&C Act. ORA also identifies criminal violations in tobacco-related cases.

[47] The results of the Tobacco Retail Inspection Program can be found on FDA's website at on the inspections page, where the public can find inspections, Warning Letters or Civil Monetary Penalties, listed by retailer name, location, or date.

On April 25 2014, FDA issued a proposed "deeming rule" providing the public the opportunity to comment on FDA's proposal to regulate currently unregulated products, such as electronic cigarettes (e-cigarettes), cigars, pipe tobacco, nicotine gels, waterpipe (hookah) tobacco, and dissolvables not already under the FDA's authority. FDA will review and monitor the manufacture, advertising, and sale of tobacco products and publish new regulations and guidance as needed.

In addition to research and enforcement, FDA is committed to communicating to the public the risks associated with the use of tobacco products, which result in about 480,000 deaths each year. In FY 2016, FDA will continue to develop public health education campaigns and key messages, and support effective design, development, implementation, and evaluation of its public health education efforts. Specifically, FDA will:

- complete its longitudinal evaluation of the first two years of "The Real Cost" campaign to measure the effectiveness of the campaign
- roll out additional unique tobacco education campaigns targeting other discrete audiences
- develop highly responsive and interactive digital communication technologies and products to support its public health education and regulatory activities.

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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
280005: Total number of compliance check inspections of retail establishments in States under contract. *(Outcome)*	FY 2014: 124,296 Target: 100,000 (Target Exceeded)	105,000	110,000	+5,000
280006: Review and act on original Regular SE Reports within 90 days of FDA receipt.	New Goal	50%	60%	+10%

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
280007: Educate at-risk general market 12-17 year olds about the harmful effects of tobacco use. *(Output)*	FY 2014 Historical Actual: Launched public education campaign, "The Real Cost," designed to reach at-risk general market 12-17 year olds and educate them about the harmful effects of tobacco use.	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	maintain

Compliance Check Inspections

Highlighted from the above table, a key element in enforcing the Tobacco Control Act is contracts with U.S. states, territories, tribes, and private contractors to conduct retailer compliance checks. As of September, 2014, under these state contracts, FDA conducted 124,296 compliance check inspections of retail establishments. Although this number was much higher than the expected FY 2014 full year target of 100,000, 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 in order for these efforts to continue. Although most states are expected to renew their contracts, there are always outside factors that may prohibit them from doing so. The FY 2015 and 2016 targets consider these challenges, but have still been increased.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Tobacco Retailer Inspections			
Number of Inspections [1,2]	124,296	105,000	110,000
Tobacco Manufacture Inspections			
Number of Inspections [3,4]	49	50	60
Substantial Equivalence Reviews			
Workload [5]	63	100	100
Total Decisions [6]	459	300	200

[1] Actual numbers as of September 30, 2014

[2] Outyear estimates are based on FY 2014 estimate

[3] Actual numbers as of September 30, 2014

[4] Outyear estimates are based on FY 2014 actuals

[5] Limited to Regular SE Reports for currently regulated products

[6] Total Decisions include refuse-to-accept, withdrawn, substantially equivalent (SE), not substantially equivalent (NSE)

FDA HEADQUARTERS

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
FDA Headquarters	**275,439**	**244,990**	**277,453**	**299,453**	**22,000**
Budget Authority	***172,107***	***172,021***	***173,362***	***181,314***	***7,952***
User Fees	***103,332***	***72,969***	***104,091***	***118,139***	***14,048***
Prescription Drug (PDUFA)	*46,323*	*43,520*	*48,639*	*50,583*	*1,944*
Medical Device (MDUFA)	*6,485*	*6,588*	*6,733*	*6,113*	*-620*
Generic Drug (GDUFA)	*23,988*	*10,337*	*24,205*	*24,819*	*614*
Biosimilars (BsUFA)	*1,321*	*5*	*1,321*	*1,354*	*33*
Animal Drug (ADUFA)	*944*	*795*	*898*	*886*	*-12*
Animal Generic Drug (AGDUFA)	*293*	*200*	*277*	*297*	*20*
Family Smoking Prevention and Tobacco Control Act	*19,500*	*11,249*	*20,668*	*20,789*	*121*
Mammography Quality Standards Act (MQSA)	*238*	*275*	*243*	*248*	*5*
Food and Feed Recall	*691*	---	*75*	*75*	---
Food Reinspection	*3,549*	---	*480*	*480*	---
Voluntary Qualified Importer Program	---	---	*277*	*277*	---
Third Party Auditor Program			---	*73*	*73*
Outsourcing Facility			*275*	*285*	*10*
Food Facility Registration and Inspection			---	*4,576*	*4,576*
Food Import	---	---	---	*5,659*	*5,659*
International Courier	---	---	---	*307*	*307*
Cosmetics	---	---	---	*1,041*	*1,041*
Food Contact Substance Notification			---	*277*	*277*
FTE	**1,326**	**1,090**	**1,179**	**1,234**	**55**

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); Pandemic and All-Hazards Preparedness Act, 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); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, and the Drug Quality and Security Act (2013)

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA Headquarters (HQ) provides strategic direction and a wide array of services across FDA's programs. The following narrative describes FDA HQ activities within the FDA Strategic Goal framework.

Enhance Oversight

FDA HQ provides strategic leadership, coordination, and expertise to enhance FDA's oversight of production, manufacturing, the global supply chain, and postmarket product use. FDA HQ provides policy direction and expertise to establish standards and guidance to protect the safety of patients and consumers. FDA HQ provides advice and assistance to develop and standardize policies and best practices across FDA, consistent with statutes and regulations. FDA HQ also advances regulatory science to inform standards development, analysis, and decision-making to improve FDA oversight before and after FDA-regulated products enter the marketplace.

FDA HQ helps reduce risks in FDA-regulated products through surveillance and enforcement activities, such as inspections of manufacturing and production facilities and active surveillance of adverse events. FDA HQ supports eight foreign offices and conducts activities to promote oversight of the global supply chain. In addition to foreign inspections, these activities include advancing diplomacy, strengthening global regulatory systems, collecting and sharing intelligence and information, and utilizing global data networks and analytics.

FDA HQ leads emergency response and crisis management policies and programs, including global public health issues such as the recent Ebola outbreak. FDA HQ enhances transparency and working relationships with internal and external stakeholders to address foodborne outbreaks and safety issues with regulated products. FDA HQ also plays a key role in providing the legal, regulatory, and policy framework that ensures laws, regulations and policies help support preparedness for and response to Chemical, Biological, Radiological, Nuclear (CBRN) and emerging infectious disease threats.

Within the area of Oversight, FDA provides Smart Regulation, Safety and Quality, Regulatory Science and Globalization. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[48]

Food Safety Modernization Act (FSMA) Rules Published
In 2013 and early 2014, FDA proposed seven new foundational 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 new food safety rules on preventive controls for human food and standards for produce safety.

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

In September of 2014, FDA issued supplemental notices of proposed rulemaking for both of these rules in response to stakeholder in response to stakeholder input in an effort to make the focused proposals more flexible.

The first proposed rule on preventive controls for human food would require manufacturers of food to be sold in the United States to take steps such as creating written plans that identify likely hazards, identifying monitoring procedures, recording monitoring results, and implementing corrective actions if problems occur. The second proposed rule on standards for produce safety would establish enforceable science and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms. The 2014 supplemental proposals would make the criteria for determining the safety of agricultural water for certain uses more flexible and introduced a tiered approach to water testing. FDA is deferring its decision on an appropriate time interval between the application of raw manure and the harvesting of a crop until additional research is conducted, and FDA removed the nine-month interval originally proposed. FDA proposed eliminating the 45-day minimum application interval for composted manure that meets proposed microbial standards and application requirements.

The third and fourth FSMA rules were proposed in July 2013 and will 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 will need to verify that their suppliers are meeting the same level of public health protection as 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 controlling the hazard. FDA issued a supplemental proposal for this rule in September 2014 as well, which included a more comprehensive analysis of potential risks associated with foods and foreign suppliers, and more flexibility for importers in determining appropriate supplier verification measures based on their evaluation of those risks.

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 may 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 published in October 2013 and focused on animal food safety.

The sixth FSMA rule was proposed in December 2013. This rule would require the largest domestic and foreign food businesses take steps to prevent facilities from being the target of intentional attempts to contaminate the food supply.

The seventh FSMA rule published in January 2014 and would require those who transport food to use sanitary transportation practices.

Regulatory Policy and Guidance

FDA HQ published several draft and final guidance documents including: (1) "*Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board.*" This guidance describes the regulatory responsibilities of clinical investigators, sponsors, and IRBs when oversight of a previously approved clinical investigation is transferred from one IRB to another IRB. The guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred, and (2) " *A Guide to Informed Consent – Draft Guidance*." This

guidance describes in detail basic and additional elements of informed consent and includes topics such as review of patient records, children as subjects, and subject participation in more than one study.

FDA headquarters led FDA review of and drafting of detailed comments on various Health and Human Services' regulatory proposals (e.g., Common Rule Notice of Proposed Rulemaking) and guidance documents aimed at facilitating low risk research and reducing burdens on sponsors, researchers, and Institutional Review Boards while still ensuring the protection of participating subjects. FDA staff honed their attention to evaluating the impact of such revisions and new guidance on FDA-regulated research and the extent to which the agency's regulations could be harmonized without adversely affecting human subject protections or the ethical oversight of clinical trials.

FDA HQ and other FDA offices collaborated with the Clinical Trials Transformation Initiative (CTTI) effort to improve clinical investigator training and qualifications by identifying key elements that are essential to ensuring Good Clinical Practice (GCP) and quality in the conduct of clinical trials. This project is also gathering information about current clinical trial practices and discussing strategies to reduce the burden of redundant GCP training.[49] FDA HQ sponsored a Pediatric Clinical Investigators Training meeting to ensure academic investigators understand their responsibilities when conducting product development trials involving children.

Updated Nutrition Facts Label

On March 3, 2014, FDA published two proposed rules, one on updating the Nutrition and Supplement Facts labels, and one on updating FDA's serving size regulations for conventional foods. The proposal to update the Nutrition and Supplement Facts label reflects new public health and scientific information, including the link between diet and chronic diseases such as obesity and heart disease. The proposal for updating FDA's serving size regulations incorporates new developments including the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and recent consumer research on the use and understanding of the Nutrition Facts label. These proposals also feature a fresh design to highlight key parts of the label such as calories and serving sizes.

Medical Countermeasures Initiative Regulatory Science Program

FDA HQ provides funding for targeted research on projects related to the Public Health Emergency Countermeasures Enterprise. This research addresses regulatory science challenges for medical countermeasures designed to mitigate the effects of CBRN and emerging infectious disease threats such as pandemic influenza. Notable accomplishments include the development of organs-on-a-chip technology to use in the development of drugs for acute radiation syndrome. FDA scientists have also discovered vaccination strategies that could lead to better responses against influenza. In addition, FDA scientists have identified quantitative electroencephalographic markers of traumatic brain injury, which will help inform scientists creating animal models for testing therapies and help in the development of devices to diagnose brain injury. FDA Scientists are members of the new HHS National Advisory Committee on Children and Disasters that is assessing national preparedness for pediatric national disasters.

[49] http://www.ctti-clinicaltrials.org/what-we-do/study-start/gcp-training

International Inspections
FDA has investigators based overseas with foreign offices residing in India, China, Mexico, and Chile. Investigators deployed overseas provide FDA with the capability to respond quickly to emerging problems without delays caused by the need for international travel, for example, obtaining a visa. In FY 2014, 45 percent (or 134) of FDA inspections conducted in India were performed by investigators based within FDA's India Office and on short term assignments. Similarly, 25 percent (or 113) of FDA inspections conducted in China were performed by investigators based in FDA's China Office and on short term assignments. In addition, FDA's Mexico and Chile offices have begun performing inspections in FY 2014 with in-country staff, including FDA's Chile Office's first collaborative food inspections in Uruguay.

China Safety Initiative
In FY 2014, FDA expanded upon its efforts to regulate the quality and safety of products entering the U.S. from China through the China Safety Initiative. The China Safety Initiative includes a project to better assess inspection prioritization needs by verifying 1150 manufacturing and production sites of FDA-regulated commodities in China, in addition to other projects that utilize innovative methodologies and monitoring of non-traditional data sources to better inform FDA decision-making.

International Partnerships
In FY 2014, FDA implemented six new Confidentiality Commitments to promote information sharing with foreign counterpart agencies and international organizations; these include agencies in Denmark, Italy, Estonia, Spain, the United Kingdom, and one Confidentiality Commitment with the World Health Organization in support of information sharing related to Ebola. In February 2014, FDA and Indian regulatory authorities signed the first-ever Statement of Intent to facilitate collaboration and further enhance lines of communication to ensure products exported from India to the U.S. are safe and of high quality. FDA also signed a Statement of Intent announcing the FDA-Mexico Produce Safety Partnership, which focuses on preventive practices and verification measures supporting compliance with produce safety standards, guidelines, and best practices. With this new partnership in place, FDA expects to help improve the safety of fruits and vegetables for consumers on both sides of the border. Additionally, in FY 2014, FDA participated in a number of Trans-Pacific Partnership (TPP) and Transatlantic Trade and Investment Partnership (TTIP) negotiating rounds to ensure public health, consumer safety and FDA's mandates were reflected in U.S. Government policy positions and incorporated into the negotiating texts for the agreements. Because of this effort, FDA was able to successfully close negotiations on the TPP chapter on sanitary and phytosanitary (SPS) measures.

During FY 2014, FDA HQ coordinated agency-wide responses to international health events of concern, in collaboration with the International Food Safety Authorities Network (INFOSAN) and other World Health Organization (WHO) organizations, in regards to an outbreak of multiple *Salmonella* serovars linked to chia seed products, an adverse event to a dietary supplement, and product recalls involving spices and stone fruits. FDA HQ facilitated upstream regulatory cooperation with the European Union (EU) and its member states by exchanging critical recall information (distribution records, shipping records, laboratory reports, and inspectional information) of adulterated product shipped from an EU member country manufacturer to the United States, and vice versa. This collaboration enhanced and strengthened EU-US communication, and further enhanced effective product recall activities and public health protection.

During FY 2014, FDA HQ resolved almost 70 percent of issues between the U.S. and European Union related to pediatric development for 30 products. In addition, collaborative documents were published for pediatric inflammatory bowel disease, Gaucher's disease, and diabetes.

Regulatory Cooperation Council

In 2011, President Obama and Canadian Prime Minister Stephen Harper announced a two-year mandate to promote economic growth and job creation through increased regulatory transparency and coordination between Canada and the U.S. called the Regulatory Cooperation Council (RCC). FDA, Health Canada, and the Canadian Food Inspection Agency (CFIA) supported the mandate by developing six work plans. In FY 2014, phase 1 of RCC was completed and five new commitments were announced in the areas of: food safety, medical devices, over-the-counter products, pharmaceutical and biological products, and veterinary drugs.

Ebola Response

FDA HQ led extensive intra- and inter-agency coordination and facilitated international coordination of response activities to the Ebola epidemic in West Africa. FDA HQ facilitated the expedited development and availability of medical countermeasures, including vaccines, drugs, protective equipment and diagnostic tests, for Ebola, supported regulatory science programs, and developed policies for the development, use, and export of investigational products. FDA HQ provided ongoing review and consultation on the care of Ebola patients receiving treatment in the United States. FDA HQ participated in the development of innovative, efficient, and robust clinical trial design protocols to determine the safety and efficacy of investigational products for Ebola. FDA HQ issued warnings against products being marketed with unsubstantiated or fraudulent claims of treatment or prevention of Ebola. FDA HQ also led domestic and supported international policy development activities and provided technical support and scientific advice to the World Health Organization (WHO) and international regulatory counterparts.

Emergency Preparedness and Response

FDA HQ coordinated the emergency response to 58 incidents (including 30 serious adverse or injury event incidents, 7 serious adverse or injury event incidents related to drug compounding, 18 natural disasters, and 3 man-made disasters) and 21 reports of suspected product tampering. FDA HQ evaluated 3,691 consumer complaints in FY 2014, to ensure FDA's timely identification of and response to emerging safety concerns related to FDA-regulated products, and

FDA HQ worked diligently to develop, maintain, and coordinate an effective emergency preparedness and response capability for public health emergencies by developing guidance detailing FDA's operational approach for responding to emergencies, including revising FDA's Emergency Operations Plan and Annexes, the FDA Joint Information Center Handbook, and the FDA Incident Management Handbook. These documents improve understanding and communication across the agency and with the public during emergency responses, furthering public perception of the FDA's ability to respond in crisis situations.

Improve and Safeguard Access

FDA HQ serves as the agency focal point for special programs and initiatives that are cross-cutting and clinical, scientific, and regulatory in nature. FDA HQ provides for the coordination of internal and external review of pediatric science, safety, ethical and international issues as

mandated by law and agency activities. FDA HQ schedules the scientific agenda and administers the Pediatric Advisory Committee, the Pediatric Ethics Subcommittee, and the Neonatology Subcommittee. In addition, FDA HQ promotes high standards of scientific integrity to ensure ethical and responsible research practices, such as human subjects protection, and offers support for accelerated research and development for medical products to improve greater access to safe and effective medical products for children, and rare disease populations.

FDA HQ advances regulatory science needed to evaluate new products, collaborating with our colleagues in the private, public, and academic settings to facilitate product development and ensuring that our product review process is effective and efficient. FDA HQ is dedicated to improve review efficiency through data standardization and data integrity requirements. FDA HQ will continue to increase consideration of health disparities and health outcomes in regulatory decision-making.

Within the area of Improve and Safeguard Access, FDA provides Safety and Quality as well as Regulatory Science. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[50]

Grants and Designations

FDA HQ reviewed a record 434 original requests for orphan drug designation, including requests for therapies for rare pediatric cancers, sickle cell disease, and Ebola. FDA HQ provided financial incentives for development to a total of 285 drugs by designating them as orphans. These incentives include tax credits for qualified clinical studies costs, waiver of the marketing application user fee and the potential for 7 years of marketing exclusivity upon approval. FDA HQ also funded 14 new grants and provided continued support for approximately 60 ongoing clinical studies of promising products for rare diseases under the Orphan Products Grants Program. In addition, the FDA HQ reviewed 17 new Humanitarian Use Device Designation applications and designated 12 devices to promote their development for the treatment or diagnosis of rare diseases and funded 8 pediatric device consortia to provide multidisciplinary advice and funding to assist pediatric device innovators.

Rare Pediatric Disease Priority Review Voucher Program

FDA HQ, the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER) collaborated to develop the Rare Pediatric Disease Priority Review Voucher Program, which provides incentives for the development of products for rare pediatric diseases. The incentive is a voucher that is given to a sponsor by FDA that will grant a future priority review to the voucher-holder. When the appropriate program criteria are met, a priority review voucher is provided to the sponsor that has obtained marketing approval of a product for a rare pediatric disease. That voucher, which may be sold to another sponsor, may be used to claim a priority review status for a future product review that would not otherwise meet the criteria for the priority review benefits. FDA HQ established the Rare Pediatric Disease Designation Program and reviewed 16 requests for rare pediatric disease determinations. FDA HQ published draft guidance on *Rare Pediatric Disease Priority Review Vouchers*, which explains how FDA plans to implement section 908 of the Food and Drug Administration Safety and Innovation Act (FDASIA) including the process by which sponsors who are interested in receiving Rare Pediatric Disease Priority Review Vouchers may first request designation of their

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

drug or biological product as a drug for a "rare pediatric disease." [51] FDA HQ led the development of FDA's strategic plan to encourage the development of products for rare pediatric diseases.

Premarket and Postmarket Support

FDA HQ responded to 390 requests for premarket review assistance from the FDA staff and regulated industry (including products that are on the shortage list). FDA HQ issued 17 combination product requests for designation decisions with 100 percent of these decisions meeting the 60-day statutory decision time requirement. FDA HQ provided timely informal jurisdictional assistance for approximately 233 separate informal inquiries. FDA HQ provided clarification and support for 57 separate postmarket activities.

FDA HQ promoted high standards of scientific integrity to ensure ethical and responsible research practices by providing expert ethical opinions to agency Centers and Offices for more than 100 pediatric ethics issues, more than 600 pediatric development programs, and nearly 50 adult issues. The pediatric ethics consultation service is Congressionally-mandated. These ethical consultations have included issues related to the development of FDA policies for emergencies and crises as seen in the current Ebola crisis affecting West Africa.

FDA HQ hosted the first Pediatric Clinical Investigators Workshop on Pediatric Product Development Trials which helps clinical investigators develop the skills and knowledge required to conduct pediatric product development trials.

FDA HQ enhanced the efficiency of its' Congressional-mandated pediatric safety review process which examines and presents the postmarket pediatric adverse events and safety reporting issues to Pediatric Advisory Committee. FDA HQ works closely with numerous FDA Centers and conducts literature reviews and provides consults that relate to safety concerns for the pediatric population. In 2014, 31 pediatric-focused product safety reviews (drugs, biologics, vaccine and device reviews) were prepared for review by FDA's Pediatric Advisory Committee

Guidance for Stakeholders

FDA HQ issued draft guidance on informed consent. The guidance addresses topics such as basic and additional elements of informed consent, review of patient records, children as subjects, and subject participation in more than one study. The guidance is intended to assist research sites with appropriate methods for informing potential subjects about the risks and potential benefits of participation in clinical trials so that each individual can make an informed choice about whether to enroll.[52]

FDA HQ met to resolve scientific differences between European Medicines Agency (EMA) and FDA on 153 products in 2014. Out of the total number of products addressed, 30 involved product-specific discussion and 29 covered general topics (i.e. on average, two to three issues monthly). Of the 153 issues related to pediatric product development that were discussed with the EMA, important advances were made in arriving at common approaches for 68 percent. Examples of issues discussed included study design, endpoints, and safety concerns.

[51] http://www.fda.gov/RegulatoryInformation/Guidances/ucm423313.htm

[52] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

In collaboration with CDER, FDA HQ issued a draft guidance addressing general clinical pharmacology considerations for pediatric studies for drugs and biologics. This draft guidance includes sections on (1) legislative background, (2) an expanded clinical pharmacology considerations section that includes pharmacogenomics, (3) an ethical considerations section, and (4) a pediatric study design section which covers approaches to pediatric studies, pediatric dose selection, formulations, sample size, and covariates including the estimation of pediatric renal function.[53]

Collection and Availability of Demographic Subgroup Data
Section 907 of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) directed FDA to take a closer look at the inclusion and analysis of demographic subgroups including sex, race and ethnicity, and age— in applications for drugs, biologics and devices, report on our findings and develop an Action Plan to address the findings. In August 2014, FDA issued its Action Plan with three overarching priorities: data quality, participation, and transparency. Implementation of the Action Plan will result in greater assurance in the safety and effectiveness of approved medical products in demographic subgroups. The plan calls for a broad range of collaborative activities with the National Institutes of Health (NIH), the Institute of Medicine, as well as the continued engagement with stakeholders. FDA will provide regular updates as well as careful ongoing review of the effectiveness of this initiative.

Establishment of New Centers of Excellence in Regulatory Science and Innovation
In addition to supporting two existing Centers of Excellence in Regulatory Science and Innovation (with the University of Maryland and with Georgetown University), in 2014, two new Centers of Excellence in Regulatory Science and Innovation (CERSI) were initiated through a University of California-Stanford University consortium and at Johns Hopkins University to work collaboratively on projects that promote the emerging field of regulatory science—including innovative research, education, outreach, and scientific exchange. The two new CERSI work closely with FDA staff and provide modern technological tools that will help FDA evaluate medical products for safety, efficacy, quality, and performance. The CERSI share their expertise nationally and internationally through academic courses, Masters Programs, and training opportunities in regulatory science, which are readily available to FDA, academics, and industry scientists.

Broad Agency Announcement
FDA HQ manages a Broad Agency Announcement (BAA) to support extramural innovative research and development projects of varying scope and size. In FY 2014, FDA reviewed over 100 proposals submitted under the BAA and funded 28 of the proposals to promote regulatory science activities in one of the nine priority areas identified in FDA's Advancing Regulatory Science Strategic Plan. The total amount of funding awarded in FY 2014 was $20 million. This type of research can make significant strides toward achieving our long-term goal of performing priority regulatory science projects to inform, improve, and accelerate the development and evaluation of FDA regulated medical products and foods.

[53] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425885.pdf

Promote Informed Decisions

FDA HQ leads the effort to enhance FDA's communications to better serve the public. FDA HQ manages the communications to key stakeholders including the media, Congress, health professionals, patient advocates, and the general public. FDA HQ ensures important information about the benefits and risks of products is readily available in plain language using different communication methods, such as social media and the FDA website. FDA HQ also educates the public and encourages healthy choices by providing more general information about nutrition and tobacco prevention.

Within the area of Promote Informed Decisions, FDA provides Smart Regulation, Safety and Quality, and Regulatory Science. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[54]

FDA Strategic Priorities: 2014 - 2018

In order to tackle the many new responsibilities Congress has given FDA, FDA senior leaders and program experts worked together to publish *FDA Strategic Priorities 2014-2018,*[55] a document that articulates FDA's goals and priorities that will guide the FDA over the next four years. The framework describes how FDA will integrate and achieve five cross-cutting strategic priorities – regulatory science, globalization, safety and quality, smart regulation, and stewardship. The cross-cutting nature of this plan will help FDA achieve the greatest benefits for public health as FDA pursues its core mission goals and objectives, such as improving and safeguarding access to and making better informed decisions about the products FDA regulates. The document also describes key strategies for achieving its objectives to protect and promote the public health.

21st Century Cures Initiative

As part of the 21st Century Cures Initiative, Congress is considering potential legislation that could impact medical product approval and regulatory pathways to expedite getting innovative products onto the market. FDA has consolidated input from Centers and Offices across FDA. In FY 2014, FDA participated in seven hearings and roundtable discussions, as well as several briefings with Committee staff. The 21st Century Cures Initiative is a priority for FDA's authorizing committees. FDA is working closely with the congressional offices to provide timely feedback.

Regulatory Action to Discourage the Use of Power Morcellation to Remove Uterine Fibroids

Power morcellation is a procedure in which uterine fibroids (a common and benign uterine mass) are cut up to permit removal from the abdominal cavity through a small laparoscopy incision. In a small number of cases, the fibroid turns out to contain a hidden cancer, and the action of the device may disseminate cancerous tissue throughout the abdominal cavity. In response to a report of such a case in December 2013, FDA HQ undertook an investigation and data analysis that showed that the risk of a hidden cancer is considerably higher than had previously been assumed. FDA HQ worked closely with the Center for Devices and Radiological Health

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

[55] http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm

(CDRH) to generate a Safety Communication discouraging the use of morcellation in April 2014, a presentation before an FDA advisory panel in July 2014, and an Immediately-In-Effect Guidance in November 2014 that laid out expected warning language and contraindications. In less than a year, FDA HQ identified a significant public health risk, and triggered data-driven regulatory action that will save the lives of countless women.

Communication with Stakeholders
In FY 2014, FDA HQ developed FDA's first set of mobile-friendly webpages, over 14, 000 pages, to better serve site visitors that accessed the site through mobile devices. FDA HQ also created and established FDA's first-ever Social Media Policy. The policy governs the use of social media throughout FDA.

FDA HQ produced and promoted more than 100 Consumer Updates (CUs), leading to an increase in online traffic to CUs by 45 percent. FDA HQ published 125 FDA Voice Blogs and increased website visits by 148 percent.

FDA HQ conducted over 200 stakeholder meetings, increased external stakeholder communications by over 13 percent, with over 576,130 subscribers to our multiple communications vehicles such as MedWatch Alerts, various newsletters, and disease-specific subscriptions. FDA HQ has trained and recruited over 200 patient representatives to advise FDA, and is responsible for managing the multi-Center MedWatch Council, which generates new laws and policies on the reporting impact of safety information to the public.

FDA HQ published a series of questions and answers on its website to assist the public in understanding how FDA advisory committee meetings are conducted. In addition, FDA HQ published a set of slides on its website to educate the public on conflicts of interest for members of advisory committees.[56]

Strengthen Organizational Excellence

FDA HQ ensures the timely and effective implementation of operations and the high quality delivery of services across the agency and centers. FDA HQ plans and manages all resources including the budgets, human resources, information technology, facilities, security and safety, ethics, equal employment opportunity, and acquisitions. FDA HQ is committed to developing its workforce, recruiting, retaining, and strategically managing diversity. FDA HQ invests in infrastructure, evolving our management systems and practices to ensure accountability for accomplishing meaningful results which enhance productivity and workforce capabilities.

Within the area of Organizational Excellence, FDA provides Stewardship. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[57]

Effective Emergency Preparedness and Response Capabilities
In FY 2014, FDA HQ continued to provide and enhance a robust Geographic Information System (GIS) for the agency with improved mechanisms for mapping of FDA regulated firms in

[56] http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm; http://www.fda.gov/downloads/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ApplyingforMembership/UCM381051.pdf

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

foreign countries and performed complex spatial analysis when events impacting FDA regulated products occurred. FDA HQ expanded access to the agency's GIS through a web-based portal and completed 946 maps for 92 project requests, which is a 27 percent increase from last fiscal year. FDA HQ upgraded the platform for its Emergency Operations Network Incident Management System (EON IMS), which is used to capture near real-time information on emergency incidents involving FDA regulated products, resulting in improved data collection and analysis, including real-time capture of 100 percent of emergency calls received by the agency outside of normal business hours.

Information Technology Enhancements
FDA HQ developed IT enhancements to improve the efficiency of the combination products review process. In collaboration with CDER, CBER, and CDRH, FDA HQ strengthened the safety review and preparation process for pediatric products scheduled for evaluation by the Pediatric Advisory Committee (PAC). This new process optimizes the presentation format in a manner which allows the Committee to focus on products with important safety concerns.

FDA HQ launched the advisory committee membership nomination portal that enables nominees to submit their application for membership on an advisory committee from the FDA's website, creating a paperless, streamlined process that will enable the agency to accept, evaluate, and ultimately nominate qualified individuals for membership in a timely fashion.[58,59]

OpenFDA
OpenFDA is an FDA initiative to provide software developers and researchers Application Programming Interfaces (APIs) to a number of high-value structured datasets, including adverse events, product labeling, and recall enforcement reports. Since the launch, on June 2, 2014, OpenFDA has received over 7.5 million data calls. Half of these API calls are from global sources and has more than 20,000 connected internet devices worldwide.

OpenFDA provides access to: Adverse events such as FDA's publically available drug adverse event and medication error reports (up to 4.3 million records 2004 to 2014), and medical device adverse event reports (up to 3.9 million records since 1991); recalls and enforcement report data, containing information gathered from public notices about certain recalls of FDA-regulated products (up 41,000 recalls records since 2012); and Structured Product Labeling for FDA-regulated human drugs (prescription or over the counter) and biologics (over 67,000 records).

[58] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm382437.htm

[59] https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$244,990,000	$172,021,000	$72,969,000
FY 2015 Enacted	$277,453,000	$173,362,000	$104,091,000
FY 2016 Request	$299,453,000	$181,314,000	$118,139,000

BUDGET REQUEST

The FY 2016 Budget Request is $299,453,000, of which $181,314,000 is budget authority and $118,139,000 is user fees. This amount is $22,000,000 more than the FY 2015 Enacted level. This increase in funding will improve FDA's overall performance in the Strategic Goal Areas of Enhanced Oversight, Improve and Safeguard Access, Promote Informed Decisions, and Strengthen Organizational Excellence. The FY 2016 Budget Request also includes restoration of a $1,500,000 transfer from FDA HQ to the Health and Human and Services Office of the Inspector General in FY 2015.

FDA HQ will continue to provide policy direction and oversight, advance scientific development, and provide oversight of the global supply train. FDA HQ will continue working to increase transparency and accountability in the supply chain, developing better enforcement and regulatory tools, encouraging greater responsibility by industry, and enhancing collaboration with international regulatory counterparts and other third parties. FDA HQ along with the Centers and Offices, will evaluate and improve the effectiveness of preventive control standards, and advance the development of predictive safety models. FDA HQ will coordinate across FDA to develop improved methods for rapidly detecting, investigating, and stopping foodborne contaminants, as well as develop comprehensive regulatory approaches for integrating pre- and post-approval and compliance functions.

FDA HQ will continue to promote the development and availability of medical countermeasures to protect and promote public health, both domestically and abroad, in response to chemical, biological, radiological, nuclear and emerging infectious disease threats (such as pandemic influenza and Ebola). FDA's activities will include: working with product sponsors and US government agencies that support medical countermeasure development to clarify regulatory pathways and help expedite development; collaborating with the national and international partners (including international regulatory counterparts) to support regulatory harmonization and preparedness and response efforts; facilitating timely access to available medical countermeasures when necessary under an appropriate regulatory mechanism; and monitoring for fraudulent products and taking actions, as warranted, to protect public health.

FDA HQ will explore and test interdisciplinary approaches of integrating qualitative and quantitative social science data with traditional and social media analysis and pharmaco-epidemiological data to assess communication effectiveness in the use of regulated products. FDA HQ will analyze the intersection of economic and behavioral effects of health and safety information about regulated products.

FDA HQ will continue to support the China Initiative in the areas of medical products and food safety. FDA HQ will continue to conducting inspections at facilities that manufacture FDA-regulated goods and broadening the range of inspections FDA performs in China including clinical trial sites. In addition, FDA HQ will continue to conduct outreach to regulated Chinese firms that wish to export their products to the U.S. to enhance understanding of – and compliance with – FDA requirements.

In addition, FDA HQ will continue to provide program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA HQ is committed to delivering cutting-edge technology, innovation, and support to all stakeholders.

BUDGET AUTHORITY

Food Safety: +$4.5 million

Risk Analytics and Evaluation: +$4.5 million
The FY 2016 Budget Request provides a budget authority increase for Food Safety. One key element of Food Safety Modernization Act (FSMA) is the vision of future regulatory action focused on the degree of risk posed by a given food or feed. FDA is developing new tools to provide the information needed to focus decisions and resources on areas of greatest health risk. These new tools include tools for ranking risks, prioritizing program activities based on opportunities to reduce risk, and linking risk-based priorities more clearly with budget formulation and execution. For example, this funding might better inform FDA about which foods and feeds are most vulnerable to which bacterial contaminants or where FDA should invest research efforts to identify how to reduce contamination of food and feed. These activities will improve FDA's productivity in all areas, including research and standard setting, inspections, and technical assistance to industry.

Medical Product Safety: +$2.0 million

Precision Medicine: +$2.0 million
Precision Medicine is defined as the use of genomic, epigenomic, exposure, and other data to define individual patterns of disease, potentially leading to better individual treatment. Funding this initiative will permit FDA to keep pace with scientific advancements and help speed the development of promising new therapeutics that are needed for integrating genetic information into device development. FDA HQ will utilize Precision Medicine funding for information technology and informatics support. FDA will need to create the IT infrastructure to support the integration of genetic information into device development. This will include upgrading the FDA's capabilities in the following ways: storage and computing infrastructure with development of a cloud based environment; increased capability to handle data securely, such as healthcare records, genomes, consumer-provided information, and results of experimental tests and treatments; public availability of information for customers who contribute data to FDA will be rewarded with information tailored to them. Healthcare providers will evaluate the information for recommendations for their patients.

USER FEES

Current Law User Fees: +$2.2 million

FDA HQ will utilize these current law user fees to provide support to FDA Centers and Offices. FDA HQ will provide strategic coordination, direction, and oversight across FDA UF programs.

Proposed User Fees: +$11.9 million

Proposed Food Import Fee: +$5.7 million
FDA will use $5.7 million in new resources provided by the proposed import user fee to facilitate the entry of safe food through enhanced border staffing, improved information systems and other importer support and port of entry streamlining.

Proposed Food Facility Registration and Inspection User Fee: +$4.6 million
The $4.6 million proposed fee will provide resources to further modernize the FDA inspection program through the further development and implementation of new inspection models and tools, including training in the new models and information technology to improve targeting and risk-based efficiency of inspection.

Proposed Cosmetics Safety User Fee: +$1.0 million
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 Food Contact Substances Notification User Fee: +$0.3 million
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 International Courier User Fee: +$0.3 million
Millions of shipments of food and medical product 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.

PERFORMANCE

The FDA Headquarters' 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 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)*	Conducted a pilot with FDA field offices to enter and maintain incidents in the FDA Emergency Operations Network Incident Management System. FDA's Agency-wide web-based GIS portal was enhanced with spatial analytical tools; agency-wide training provided resulting in a 27% increase in mapping usage over FY 2013. FDA participated in 14 emergency preparedness exercises in 2014, including the National Capstone Exercise (NEPCE 2014) from March 31-April 2 which simulated the response to a historic earthquake in Alaska with international implications. (Targets Met)	Review and update 95% of the FDA After Hours Call Center prepared responses to ensure accurate and effective response to crises and emergencies that involve FDA regulated products. Successfully coordinate 20 incidents involving FDA regulated products during the year. Participate in six exercises during the year.	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 seven exercises during the year.	N/A Maintain +1
291305: Number of electronic and print communications disseminated to women's health stakeholders. *(Output)*	FY 2014: 33 Target: 25 (Target Exceeded)	39	39	maintain
291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)*	FY 2014: 78% Target: 50% (Target Exceeded)	40%	40%	Maintain
293205: Percentage of requests for combination product designations processed within the 60 day statutory requirement. *(Output)*	FY 2014: 100% Target: 95% (Target Exceeded)	95%	95%	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
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)*	FY 2014: FDA completed 6 more intramural research projects under the Nanotechnology CORES program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. (Target Met)	24 CORES projects Completed	30 CORES projects Completed	+6
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, and Canada, with Australia as observers. *(Output)*	FY 2014: 153 Target: 40 (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 2014: 31 Target: 30 (Target Exceeded)	30	30	maintain
292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)*	FY 2014: 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 2014: 25 Target: 25 (Target Met)	25	25	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2015 Target	FY 2016 Target	FY 2016 +/- FY 2015
291406: Increase the timeliness of managing accounts receivables (A/R). Percentage of invoices issued on time within predefined dates in the month. *(Output)*	FY 2014: 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 2014: 89% (Historical Actual)	75%	75%	maintain
293208: Percentage of Humanitarian Use Device designation reviews completed in 45 days or less. *(Output)*	FY 2014: 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 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. From 2011 to 2014, FDA has completed 18 CORES projects, and plans to complete 24 by the end of FY 2015, and 30 by the end of FY 2016.

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
FDA White Oak Consolidation	**61,922**	**61,603**	**47,116**	**52,218**	**5,102**
Budget Authority	***58,044***	***58,044***	***43,044***	***48,044***	***5,000***
Prescription Drug (PDUFA)	***3,878***	***3,559***	***4,072***	***4,174***	***102***
Other Rent and Rent Related	**116,439**	**109,416**	**116,406**	**136,531**	**20,125**
Budget Authority	***74,674***	***74,674***	***72,943***	***89,137***	***16,194***
User Fees	***41,765***	***34,742***	***43,463***	***47,394***	***3,931***
Prescription Drug (PDUFA)	*26,794*	*21,076*	*28,134*	*28,837*	*703*
Medical Device (MDUFA)	*3,546*	*3,671*	*4,027*	*4,452*	*425*
Generic Drug (GDUFA)	*6,598*	*6,719*	*6,730*	*6,898*	*168*
Biosimilars (BsUFA)	*590*	*197*	*602*	*617*	*15*
Animal Drug (ADUFA)	*236*	*721*	*225*	*221*	*-4*
Animal Generic Drug (AGDUFA)	*73*	*238*	*69*	*74*	*5*
Family Smoking Prevention and Tobacco Control Act	*3,050*	*2,120*	*3,233*	*3,502*	*269*
Food and Feed Recall	*259*	*---*	*43*	*43*	*---*
Food Reinspection	*619*	*---*	*204*	*204*	*---*
Voluntary Qualified Importer Program	*---*	*---*	*170*	*170*	*---*
Third Party Auditor Program			*---*	*45*	*45*
Outsourcing Facility			*26*	*26*	*---*
Food Facility Registration and Inspection			*---*	*827*	*827*
Food Import	*---*	*---*	*---*	*689*	*689*
International Courier	*---*	*---*	*---*	*188*	*188*
Cosmetics	*---*	*---*	*---*	*535*	*535*
Food Contact Substance Notification			*---*	*66*	*66*
GSA Rental Payments	**219,907**	**209,372**	**228,428**	**242,085**	**13,657**
Budget Authority	***162,076***	***162,076***	***168,882***	***176,683***	***7,801***
User Fees	***57,831***	***47,296***	***59,546***	***65,402***	***5,856***
Prescription Drug (PDUFA)	*22,997*	*24,548*	*24,147*	*24,751*	*604*
Medical Device (MDUFA)	*6,216*	*4,265*	*7,058*	*7,792*	*734*
Generic Drug (GDUFA)	*14,138*	*7,818*	*14,421*	*14,782*	*361*
Biosimilars (BsUFA)	*1,033*	*220*	*1,054*	*1,080*	*26*
Animal Drug (ADUFA)	*1,180*	*872*	*1,123*	*1,107*	*-16*
Animal Generic Drug (AGDUFA)	*440*	*286*	*417*	*446*	*29*
Family Smoking Prevention and Tobacco Control Act	*9,974*	*9,287*	*10,572*	*10,592*	*20*
Food and Feed Recall	*454*	*---*	*73*	*73*	*---*
Food Reinspection	*1,399*	*---*	*348*	*348*	*---*
Voluntary Qualified Importer Program	*---*	*---*	*290*	*290*	*---*
Third Party Auditor Program			*---*	*77*	*77*
Outsourcing Facility			*43*	*43*	*---*
Food Facility Registration and Inspection			*---*	*1,467*	*1,467*
Food Import	*---*	*---*	*---*	*1,175*	*1,175*
International Courier	*---*	*---*	*---*	*326*	*326*
Cosmetics	*---*	*---*	*---*	*937*	*937*
Food Contact Substance Notification			*---*	*116*	*116*

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

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
- White Oak.

The Infrastructure Program supports the FDA Strategic Goal to Strengthen Organizational Excellence and the FDA Strategic Priority of Stewardship. FDA invests in infrastructure to enhance productivity and provide the capabilities needed for the agency to achieve its public health mission.

FDA ensures the appropriate square footage offset in accordance with the OMB Freeze the Footprint guidance and promotes maximum utilization of Federal workspace. FDA's energy saving projects decrease long-term energy usage and operating and maintenance costs while increasing facility life span and efficiency to support Executive Order 13514 − Federal Leadership in Environmental, Energy, and Economic Performance.

In addition, FDA is replacing and centralizing existing geographically disparate facilities with new, state-of-the art laboratories, office buildings, and support facilities as part of the White Oak Campus consolidation. This consolidation creates a high quality work environment, optimizes the use of taxpayer dollars, and enhances productivity.

GSA Rental Payments

The GSA Rental Payments 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 in approximately 290 buildings, including district offices, regional offices, laboratories, and resident posts across the nation and in Puerto Rico.

The GSA Rental Payments account ensures that the FDA workforce has the space necessary to carry out FDA's public health mission.

During FY 2014, FDA:

- occupied two new office buildings and two new lab buildings on the White Oak Campus and one new leased office building in Rockville, Maryland
- relocated from and released eight leased headquarters office buildings
- completed decommissioning and vacated a CDER lab in Saint Louis
- collocated two OCI field offices into one new leased location
- opened one new Sample Processing Center
- acquired expansion space for one resident post
- relocated five resident posts
- vacated two resident posts.

During FY 2015, FDA plans to:

- relocate from and release two headquarters office buildings to collocate in one leased location in Rockville, Maryland
- complete decommissioning and release a CBER lab at headquarters
- relocate one OCI field office
- relocate five ORA resident posts
- open one new resident post.

FDA strives to be cost effective and energy efficient when it acquires the necessary space to meet the mission in accordance with 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
- above standard security and guard services contracts
- standard utilities in FDA owned facilities
- essential overtime utilities in laboratories and data centers
- other above-standard level services not provided by GSA in GSA-managed facilities.

This account supports the FDA workforce in meeting its public health mission by providing safe, efficient, and secure facilities.

FDA is implementing energy efficiencies that will result in significant savings in the Other Rent and Rent-Related Activities account. These projects support Executive Order 13514, Federal Leadership in Environmental, Energy, and Economic Performance and 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 (ESPCs) 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 a memorandum 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.

Under this agreement, 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. 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 strategically manages its resources to achieve cost savings. For example, 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 two million dollars with utility cost savings of approximately $250,000 annually in water, sewer, electricity, and fuel costs. This change will generate a simple payback 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 in the early stages of developing additional energy conversation measures that will be included in a fourth UESC with Washington Gas.

FDA 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 and cost savings of about $254,741 per year with a simple payback of 10.1 years.

GSA is performing audits in FDA occupied leased facilities, such as the Queens, New York lab. UESCs in 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 greenhouse gas emissions.

White Oak

The White Oak Campus replaces and centralizes 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 various user fees fund building infrastructure, fit-out, specialized equipment, move costs, and operations and logistics at the Campus.

White Oak funding supports campus operations and requirements for the Life Sciences-Biodefense Laboratory Complex including:

- relocation activities
- internal communications and information technology − infrastructure, equipment, cabling and audiovisual
- security − infrastructure and equipment
- surplus of furniture and equipment
- decommissioning of FDA vacated laboratories final commissioning and certification of the specialized laboratories
- critical support and maintenance of vital specialized laboratory equipment
- start up and operation of a critical Safety Program to support the new labs Complex
- security features to expand the CUP.

FDA initiated relocation activities to White Oak in FY 2002. The total number of employees currently assigned to the White Oak Campus is approximately 9,000 as a result of completing the occupancy of the Biodefense Laboratory Complex (two office and two lab buildings) in FY 2014.

FUNDING HISTORY – GSA RENTAL PAYMENTS

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$209,372,000	$162,076,000	$47,296,000
FY 2015 Enacted	$228,428,000	$168,882,000	$59,546,000
FY 2016 Request	$242,085,000	$176,683,000	$65,402,000

FUNDING HISTORY - OTHER RENT AND RENT-RELATED ACTIVITIES

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$109,416,000	$74,674,000	$34,742,000
FY 2015 Enacted	$116,406,000	$72,943,000	$43,463,000
FY 2016 Request	$136,531,000	$89,137,000	$47,394,000

FUNDING HISTORY - WHITE OAK

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$61,603,000	$58,044,000	$3,559,000
FY 2015 Enacted	$47,116,000	$43,044,000	$4,072,000
FY 2016 Request	$52,218,000	$48,044,000	$4,174,000

BUDGET REQUEST

The FY 2016 Budget Request is $430,834,000, of which $313,864,000 is budget authority and $116,970,000 is user fees. This amount is $38,884,000 more than the FY 2015 Enacted level. This increase is associated with costs related to programmatic growth for food and medical product safety activities, and also directly supports new hires.

GSA Rental Payments

The FY 2016 Budget for GSA Rental Payments is $242,085,000, which is a $13,657,000 increase above the FY 2015 Enacted level. The increase includes $7,801,000 in budget authority and $5,856,000 in user fees. The increase of $1.8 million in budget authority directly supports new hires requested for food safety activities supporting FSMA implementation and medical product safety activities supporting Precision Medicine.

The rental properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2016 Budget Request 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.

In FY 2014 FDA moved approximately 2,900 employees to the White Oak Campus from the Human Drugs, Biologics, and Tobacco Control Act Programs, increasing the Campus population to approximately 9,000 employees. GSA Rent Costs increased disproportionately because FDA will be occupying four new buildings on White Oak for the full 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 2016 Budget Request for Other Rent and Rent-Related is $136,531,000, which is a $20,125,000 increase from the FY 2015 Enacted level. The increase includes $16,194,000 in budget authority and $3,931,000 in user fees. $541 thousand in budget authority directly supports new hires requested for food safety activities supporting FSMA implementation and medical product safety activities supporting Precision Medicine.

It is important that FDA keep its infrastructure up-to-date and working efficiently and reliably to support FDA. The FY 2016 Budget will allow FDA to operate, maintain, and secure its facilities in an appropriate and sustainable manner. The FY 2016 Budget will cover the escalating costs in commercial rent, security, service contracts, and utilities without reducing essential FDA programs, and will directly support the increased population on the White Oak Campus. The increase will also support facility operations costs at NCTR.

FDA has 16,000 staff members for which operational rent costs continually increase beyond FDA's control. FDA cannot absorb these costs and at the same time meet increasing programmatic responsibilities. Without new funding to cover rent costs, FDA will have to reduce program activities to pay rent, significantly hampering food safety and medical product safety priorities.

The FY 2016 Budget also 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 now provides the utilities needed to operate the newly occupied Biodefense Complex on the Campus.

White Oak

The FY 2016 Budget Request for White Oak consolidation and operations activities is $52,218,000, which is a $5,102,000 increase from the FY 2015 Enacted level at the total program level. This increase includes $5,000,000 in budget authority and $102,000 in user fees.

The FY 2016 Budget supports mission support services for the White Oak Campus. There are now almost 9,000 employees occupying the Campus. The FY 2016 Budget will fund expanded support services, transportation services, labor, and loading dock services, and a centralized safety program.

White Oak Master Plan Update: +$5 million
FDA requires additional staff not anticipated in the 2009 Master Plan due to new and expanded authorities and public health responsibilities. FDA will initiate a study to update the Master Plan in FY 2016 to identify the most cost effective way to house current and projected personnel. With FDA's growing staff and responsibilities the Master Plan update is an essential part of the budget request.

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BUILDING AND FACILITIES

(dollars in thousands)	FY 2014 Final	FY 2014 Actuals	FY 2015 Enacted	FY 2016 President's Budget	FY 2016 +/- FY 2015
Buildings and Facilities (Budget Authority).....	8,788	7,808	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.

Strengthen Organizational Excellence

FDA recruits, develops, retains and strategically manages a world-class workforce, improves the overall operation and effectiveness of FDA, and invests in infrastructure to enhance productivity and capabilities.

Under the goal of Organizational Excellence FDA has demonstrated stewardship by providing high quality, reliable buildings that support FDA's mission critical work. B&F funding is used to:

- construct new mission-critical laboratory, office, and support space
- renovate and repair site infrastructure at 85 existing FDA-owned facilities at six sites in the United States and Puerto Rico.

HHS developed a Real Property Asset Management Plan (AMP) to outline 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 include a substantial amount of laboratory facilities and site infrastructure, is critical. 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 to 5-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 which 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 identifies and prioritizes short- and long-term projects using B&F funding. At of the end of FY 2014, the BMAR for the six FDA-owned sites, including renewals, is approximately $118 million. Approximately 66 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, and to ensure the suitability and reliability of FDA-owned assets.

The Muirkirk Road Complex (MRC) -- Laurel, Maryland
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 FY 2014, FDA:

- modified a steam vent to conserve energy
- replaced epoxy flooring in animal research support areas
- replaced components and controls on two additional elevators
- increased emergency power capacity
- renovated walk-in freezer boxes and offices that support laboratory operations
- patched and painted an atrium
- addressed accessibility issues.

In FY 2015, FDA will:

- create additional workstations for laboratory support personnel
- conduct an investment grade audit to identify additional energy conservation measures for the Campus

- renovate restrooms to address leaks and reduce water consumption and associated costs
- replace flooring in a critical animal research area
- renovate additional walk-in freezer boxes
- study the utilization of emergency power to determine available capacity and develop recommendations to provide additional coverage for mission critical laboratories.

Jefferson Laboratories Complex (JLC) -- Jefferson, Arkansas
The Jefferson Laboratories Complex (JLC) in Jefferson, Arkansas, houses the 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 at ARL can be found in the NCTR Narrative.

ARL provides analytical laboratory support to FDA's regulatory mission in the Southwest Region. In FY 2014, FDA awarded a project to improve an aged electrical infrastructure at the JLC site with replacement of the site's main electrical switchgear. The project included the installation of a new campus monitoring and control system for the main switchgear and an electrical underground medium voltage system.

This ongoing project began with a significant, unexpected, campus-wide power outage in the winter of FY 2010 that led to a need to take immediate action to replace the 60-year-old electrical infrastructure, including the installation of needed emergency power.

In addition, FDA awarded a project to replace the third of three inefficient and maintenance-intensive boilers that serve the one million square foot campus with a dependable, more efficient, "right-sized" boiler. FDA also upgraded lighting in several buildings, repaired campus roads, and designed renovations for various laboratory and animal research areas.

In FY 2015, FDA will initiate additional site infrastructure projects including:

- designing a project to replace a chiller connected to the Campus chilled water loops
- repairing the domestic water system
- installing a new water well
- designing a project to renovate a processing facility that supports animal research on the entire Campus.

Building improvement projects will also be initiated that include:

- renovating animal research areas
- replacing large air handlers that serve a critical laboratory, office and vivarium
- completing the third phase of replacing the HVAC controls in a critical laboratory building
- repairing a passenger elevator and a fire alarm and reporting system
- renovating a tiered classroom, to include upgrading audio-visual equipment, to increase seat capacity
- designing a project to replace air compressors.

Pacific Regional Laboratory Southwest -- Irvine, California
The Pacific Regional Laboratory Southwest in Irvine, California, provides analytical laboratory support to FDA's regulatory mission in the Pacific Region. In FY 2014, FDA completed the repair of excessive soil erosion beneath the parking area, including site restoration, and designed an office renovation project. In FY 2015, FDA will replace drinking fountains with bottle filler

stations, convert a computer room to a multiuse space for holding meetings and for employees in need of a touch-down or hoteling space, and replace the security gate house.

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 2014, FDA:

- replaced an aged fire alarm panel
- performed emergency repairs to the main laboratory sanitary waste line
- renovated four laboratory rooms
- repaired portions of the roof
- corrected a humidity problem in several laboratories.

In FY 2015, FDA will:

- replace an exhaust fan, front entrance, and walkway
- replace HVAC units in multiple laboratories
- improve parking areas to provide additional spaces, including handicap spaces, and better lighting.

The Gulf Coast Seafood Laboratory -- Dauphin Island, Alabama
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 2014, FDA replaced the handrails and concrete stairs at two entrances to meet accessibility codes.

In FY 2015, FDA will:

- make additional accessibility improvements at various entrances
- replace the entrance doors and frame.

San Juan District Office and the National Drug Servicing Laboratory -- San Juan, PR
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 2014, FDA replaced the interior doors and frames of the main laboratory building and corrected various life safety deficiencies that improved the ability for staff to more safely evacuate buildings in the event of an emergency.

In FY 2015, FDA will modify the access ramp to the main laboratory building.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2012 Actual	$9,080,000	$9,080,000	$0
FY 2013 Actual	$5,635,000	$5,635,000	$0
FY 2014 Actual	$7,808,000	$7,808,000	$0
FY 2015 Enacted	$8,788,000	$8,788,000	$0
FY 2016 Request	$8,788,000	$8,788,000	$0

BUDGET REQUEST

The FY 2016 Budget Request is $8,788,000, consisting solely of budget authority. This amount is the same as the FY 2015 Enacted Amount. FDA will use the requested resources to fund various projects at the six mission-critical FDA owned sites.

At the Jefferson Labs Complex, FDA will complete an additional phase of replacing HVAC controls in a critical laboratory building and renovate a processing facility that supports animal research on the entire Campus.

At the Muirkirk Road Complex, FDA will:

- renovate animal research processing area
- repaint animal research areas with epoxy paint and replace flooring
- install programmable light cycle times in several large animal research buildings
- upgrade switchgear to digital controls to increase reliability
- improve ventilation and humidity control in two large animal procedure rooms
- replace windows
- install Phoenix valves to better control environmental conditions in a cagewash area
- modify flooring in large animal research room to eliminate fall hazard
- grade and improve drainage along Campus roadways.

At the Winchester Engineering & Analytical Center, FDA will:

- recommission radiant heat serving offices
- replace exhaust fans serving two rooms
- renovate several rooms to replace aged finishes and improve the work environment.

In the Pacific Regional Laboratory Southwest, FDA will:

- replace variable frequency drive on an exhaust fan
- modify various doors for accessibility.

At the Gulf Coast Seafood Laboratory facility, FDA will:

- install a boat lift to replace the existing boat ramp
- repair the sea water piping system
- convert office and support space to an Algal Culture System laboratory
- implement various energy and water conservation measures.

In the San Juan District Office and Laboratory, FDA will:

- replace floor finishes in the main laboratory building
- replace carpet and tile in the main administration building
- modify multiple building entrances and restrooms for accessibility
- improve hot water supply for three buildings
- make various laboratory improvements, including adding casework, painting, replacing the vacuum system, creating space for additional refrigerators, and installing a recirculation system for distilled water.

The following table provides an allocation plan by site for use of the FY 2016 funds.

FY 2016 BUILDINGS AND FACILITIES ALLOCATION PLAN

Site	Total
CFSAN Gulf Coast Seafood Laboratory	$473,000
Jefferson Laboratories Complex (NCTR & ARL) – Jefferson, AR	$4,394,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$2,259,000
ORA Pacific Regional Laboratory SW – Irvine, CA	$130,000
San Juan District Office and Laboratory – San Juan, PR	$1,317,000
Winchester Engineering and Analytical Center – Winchester, MA	$215,000
B&F Project Total	**$8,788,000**

In FY 2016, 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. Without ongoing repair and improvement projects, the increase in BMAR each year will result in 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 2016 will help reduce Scope 1, 2, and 3 greenhouse gas emissions by:

- replacing aged, inefficient HVAC controls and equipment
- upgrading lighting in multiple buildings
- replacing existing inefficient windows
- replacing entrance doors and frames
- replacing leaking restroom fixtures with low flow fixtures
- tinting windows
- implementing energy conservation measures identified in a recent energy audit in Dauphin Island.

PROGRAM ACTIVITY DATA[1]

Facility	Average FCI Score		
	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
CFSAN Gulf Coast Seafood Laboratory[2]	94	94	94
Jefferson Laboratories Complex[3]	73	74	75
Muirkirk Road Complex[4]	81	82	82
ORA Pacific Regional Laboratory Southwest[5]	97	97	97
San Juan District Office and Laboratory[6]	78	78	80
Winchester Engineering And Analytic Center[7]	67	67	67

[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 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 2015 and FY 2016, the BMAR for this site will decrease by approximately $3.5K. Remaining BMAR for this site is approximately $287.6K.
[3] Based on funding levels in FY 2015 and FY 2016 the BMAR for this site will decrease by approximately $5.5M. Remaining BMAR total will be approximately $88.1M.
[4] Based on funding levels in FY 2015 and FY 2016 the BMAR for this site will decrease by approximately $631.4K. Remaining BMAR total will be approximately $16.3M.
[5] Based on funding levels in FY 2015 and FY 2016, the BMAR for this site will not decrease. Remaining BMAR for this site is approximately $1.01M
[6] Based on funding levels in FY 2015 and FY 2016 the BMAR for this site will decrease by approximately $349K. Remaining BMAR total will be approximately $2.66M.
[7] Based on funding levels in FY 2015 and FY 2016, the BMAR for this site will decrease by approximately $6.2K. Remaining BMAR total will be approximately $4.5.

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OBJECT CLASSIFICATION TABLES

BUDGET AUTHORITY

(dollars in thousands)	FY 2015 Enacted	FY 2016 Budget	FY 2016 +/- FY 2015
Personnel Compensation and Benefits:			
Personnel Compensation:			
Full-time permanent (11.1)	841,843	883,681	41,838
Other than full-time permanent (11.3)	97,948	102,817	4,869
Other personnel compensation (11.5)	56,363	59,165	2,802
Military personnel (11.7)	66,413	67,227	814
Special personnel services payments (11.8)	518	544	26
Subtotal, Personnel Compensation	**1,063,085**	**1,113,434**	**50,349**
Benefits:			
Civilian benefits (12.1)	297,864	312,668	14,804
Military benefits (12.2)	34,786	35,213	427
Benefits to former personnel (13.0)	275	275	---
Subtotal, Benefits	**332,925**	**348,156**	**15,231**
Total Personnel Compensation and Benefits	**1,396,010**	**1,461,590**	**65,580**
Contractual Services and Supplies			
Contractual Services:			
Travel and transportation of persons (21.0)	42,653	45,664	3,011
Transportation of things (22.0)	2,906	3,111	205
Rental payments to GSA (23.1)	168,882	176,581	7,699
Rent payments to others (23.2)	1,611	1,725	114
Communication, utilities, and misc. charges (23.3)	47,327	50,668	3,341
Printing and reproduction (24.0)	1,438	1,539	101
Subtotal, Contractual Services and Supplies	**264,817**	**279,288**	**14,471**
Other Contractual Services:			
Consulting services (25.1)	49,352	52,836	3,484
Other services (25.2)	386,527	415,430	28,903
Purchase of goods and svcs from Govt Acts. (25.3)	135,276	144,827	9,551
Operation and maintenance of facilities (25.4)	106,996	114,551	7,555
Research and Development Contracts (25.5)	19,983	21,394	1,411
Operation and maintenance of equipment (25.7)	30,698	32,865	2,167
Subtotal, Other Contractual Services	**728,832**	**781,903**	**53,071**
Supplies and Materials:			
Supplies and materials (26.0)	40,106	42,938	2,832
Equipment (31.0)	63,121	67,578	4,457
Land and Structures (32.0)	433	464	31
Grants, subsidies, and contributions (41.0)	101,470	108,635	7,165
Insurance claims and indemnities (42.0)	1,025	1,097	72
Interest and dividends (43.0)	10	10	---
Subtotal, Supplies and Materials	**206,165**	**220,722**	**14,557**
Total Contractual Services and Supplies	**1,199,814**	**1,281,913**	**82,099**
Total Budget Authority by Object Class	**2,595,824**	**2,743,503**	**147,679**

USER FEE

(dollars in thousands)	FY 2015 Enacted	FY 2016 Budget	FY 2016 +/- FY 2015
Personnel Compensation and Benefits:			
Personnel Compensation:			
Full-time permanent (11.1)	545,886	601,494	55,608
Other than full-time permanent (11.3)	56,076	61,788	5,712
Other personnel compensation (11.5)	31,677	34,903	3,226
Military personnel (11.7)	30,563	30,937	374
Special personnel services payments (11.8)	255	281	26
Subtotal, Personnel Compensation	**664,457**	**729,403**	**64,946**
Benefits:			
Civilian benefits (12.1)	188,550	207,757	19,207
Military benefits (12.2)	15,928	16,123	195
Benefits to former personnel (13.0)	151	151	---
Subtotal, Benefits	**204,629**	**224,031**	**19,402**
Total Personnel Compensation and Benefits	**869,086**	**953,434**	**84,348**
Contractual Services and Supplies			
Contractual Services:			
Travel and transportation of persons (21.0)	11,797	14,046	2,249
Transportation of things (22.0)	645	768	123
Rental payments to GSA (23.1)	59,546	65,402	5,856
Rent payments to others (23.2)	4,088	4,868	780
Communication, utilities, and misc. charges (23.3)	15,615	18,592	2,977
Printing and reproduction (24.0)	882	1,051	169
Subtotal, Contractual Services and Supplies	**92,573**	**104,727**	**12,154**
Other Contractual Services:			
Consulting services (25.1)	183,289	218,228	34,939
Other services (25.2)	279,994	333,367	53,373
Purchase of goods and svcs from Govt Acts. (25.3).	235,538	280,436	44,898
Operation and maintenance of facilities (25.4)	24,605	29,295	4,690
Research and Development Contracts (25.5)	24,240	28,860	4,620
Operation and maintenance of equipment (25.7)	17,069	20,322	3,253
Subtotal, Other Contractual Services	**764,735**	**910,508**	**145,773**
Supplies and Materials:			
Supplies and materials (26.0)	17,477	20,809	3,332
Equipment (31.0)	23,985	28,557	4,572
Land and Structures (32.0)	---	---	---
Grants, subsidies, and contributions (41.0)	141,031	167,914	26,883
Insurance claims and indemnities (42.0)	440	523	83
Interest and dividends (43.0)	24	29	5
Subtotal, Supplies and Materials	**182,957**	**217,832**	**34,875**
Total Contractual Services and Supplies	**1,040,265**	**1,233,067**	**192,802**
Total Reimbursable by Object Class	**1,909,351**	**2,186,501**	**277,150**

TOTAL PROGRAM

(dollars in thousands)	FY 2015 Enacted	FY 2016 Budget	FY 2016 +/- FY 2015
Personnel Compensation and Benefits:			
Personnel Compensation:			
Full-time permanent (11.1)	1,387,729	1,485,175	97,446
Other than full-time permanent (11.3)	154,024	164,605	10,581
Other personnel compensation (11.5)	88,040	94,068	6,028
Military personnel (11.7)	96,976	98,164	1,188
Special personnel services payments (11.8)	773	825	52
Subtotal, Personnel Compensation	**1,727,542**	**1,842,837**	**115,295**
Benefits:			
Civilian benefits (12.1)	486,414	520,425	34,011
Military benefits (12.2)	50,714	51,336	622
Benefits to former personnel (13.0)	426	426	---
Subtotal, Benefits	**537,554**	**572,187**	**34,633**
Total Personnel Compensation and Benefits	**2,265,096**	**2,415,024**	**149,928**
Contractual Services and Supplies			
Contractual Services:			
Travel and transportation of persons (21.0)	54,450	59,710	5,260
Transportation of things (22.0)	3,551	3,879	328
Rental payments to GSA (23.1)	228,428	241,983	13,555
Rent payments to others (23.2)	5,699	6,593	894
Communication, utilities, and misc. charges (23.3)	62,942	69,260	6,318
Printing and reproduction (24.0)	2,320	2,590	270
Subtotal, Contractual Services and Supplies	**357,390**	**384,015**	**26,625**
Other Contractual Services:			
Consulting services (25.1)	232,641	271,064	38,423
Other services (25.2)	666,521	748,797	82,276
Purchase of goods and svcs from Govt Acts. (25.3)	370,814	425,263	54,449
Operation and maintenance of facilities (25.4)	131,601	143,846	12,245
Research and Development Contracts (25.5)	44,223	50,254	6,031
Operation and maintenance of equipment (25.7)	47,767	53,187	5,420
Subtotal, Other Contractual Services	**1,493,567**	**1,692,411**	**198,844**
Supplies and Materials:			
Supplies and materials (26.0)	57,583	63,747	6,164
Equipment (31.0)	87,106	96,135	9,029
Land and Structures (32.0)	433	464	31
Grants, subsidies, and contributions (41.0)	242,501	276,549	34,048
Insurance claims and indemnities (42.0)	1,465	1,620	155
Interest and dividends (43.0)	34	39	5
Subtotal, Supplies and Materials	**389,122**	**438,554**	**49,432**
Total Contractual Services and Supplies	**2,240,079**	**2,514,980**	**274,901**
Total Program Level by Object Class	**4,505,175**	**4,930,004**	**424,829**

SALARY AND EXPENSES

(dollars in thousands)	FY 2015 Enacted	FY 2016 Budget	FY 2016 +/- FY 2015
Personnel Compensation and Benefits:			
Personnel Compensation:			
Full-time permanent (11.1)	841,843	883,681	41,838
Other than full-time permanent (11.3)	97,948	102,817	4,869
Other personnel compensation (11.5)	56,363	59,165	2,802
Military personnel (11.7)	66,413	67,227	814
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Subtotal, Personnel Compensation	**1,063,085**	**1,113,434**	**50,349**
Benefits:			
Civilian benefits (12.1)	297,864	312,668	14,804
Military benefits (12.2)	34,786	35,213	427
Benefits to former personnel (13.0)	275	275	---
Subtotal, Benefits	**332,925**	**348,156**	**15,231**
Total Personnel Compensation and Benefits	**1,396,010**	**1,461,590**	**65,580**
Contractual Services and Supplies			
Contractual Services:			
Travel and transportation of persons (21.0)	42,653	45,664	3,011
Transportation of things (22.0)	2,906	3,111	205
Rent payments to others (23.2)	1,611	1,725	114
Communication, utilities, and misc. charges (23.3)	47,327	50,668	3,341
Printing and reproduction (24.0)	1,438	1,539	101
Subtotal, Contractual Services and Supplies	**95,935**	**102,707**	**6,772**
Other Contractual Services:			
Consulting services (25.1)	49,352	52,836	3,484
Other services (25.2)	386,527	415,430	28,903
Purchase of goods and svcs from Govt Acts. (25.3)	135,276	144,827	9,551
Operation and maintenance of facilities (25.4)	106,996	114,551	7,555
Research and Development Contracts (25.5)	19,983	21,394	1,411
Operation and maintenance of equipment (25.7)	30,698	32,865	2,167
Subtotal, Other Contractual Services	**728,832**	**781,903**	**53,071**
Supplies and materials (26.0)	40,106	42,938	2,832
Total Non-Pay Costs	**864,873**	**927,548**	**62,675**
Total Salary and Expenses	**2,260,883**	**2,389,138**	**128,255**
Rental payments to GSA (23.1)	168,882	176,581	7,699
Grant Total, Salaries & Expenses and Rent	**2,429,765**	**2,565,719**	**135,954**
Direct FTE	**10,118**	**10,466**	**348**

DETAIL OF FULL-TIME EQUIVALENTS

	FY 2014 Actual			FY 2015 Estimate			FY 2016 Estimate		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Food Safety and Applied Nutrition	908	35	943	978	36	1,014	1,207	36	1,243
Center for Drug Evaluation and Research	3,362	430	3,792	4,083	440	4,523	4,091	440	4,531
Center for Biologics Evaluation and Research	1,027	66	1,093	1,031	68	1,099	1,040	68	1,108
Center for Veterinary Medicine	519	8	527	529	8	537	560	8	568
Center for Devices and Radiological Health	1,485	100	1,585	1,482	102	1,584	1,513	102	1,615
National Center for Toxicological Research	286	---	286	287	---	287	288	---	288
Office of Regulatory Affairs	4,318	307	4,625	4,522	314	4,836	4,861	314	5,175
Headquarters and Office of the Commissioner	1,037	53	1,090	1,125	54	1,179	1,180	54	1,234
Export Certification	19	---	19	19	---	19	19	---	19
Color Certification	36	---	36	37	---	37	37	---	37
Family Smoking Prevention and Tobacco Control Act	534	25	559	667	26	693	786	26	812
Total	**13,531**	**1,024**	**14,555**	**14,760**	**1,048**	**15,808**	**15,582**	**1,048**	**16,630**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2012	13
FY 2013	13
FY 2014	13
FY 2015	13
FY 2016	13

* Totals do not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR FTE.

** FY 2015 FTE totals do not include an estimated 37.5 FTE related to the $25 million received in one-time emergency funding for the ongoing Ebola epidemic.

DETAIL OF POSITIONS

	FY 2014 Actual	FY 2015 Base	FY 2016 President's Budget
Executive Level			
Executive Level I	---	---	---
Executive Level II	---	---	---
Executive Level III	---	---	---
Executive Level IV	---	---	---
Executive Level V	1	1	1
Total Executive Level	**1**	**1**	**1**
Executive Service (ES)			
Executive Service	63	69	73
Total Executive Service	**63**	**69**	**73**
General Schedule (GS)			
GS-15	1,378	1,503	1,587
GS-14	2,982	3,253	3,433
GS-13	3,955	4,314	4,554
GS-12	2,092	2,282	2,409
GS-11	737	804	849
GS-10	20	22	23
GS-9	553	603	637
GS-8	103	112	118
GS-7	331	362	382
GS-6	66	72	76
GS-5	87	95	100
GS-4	89	97	102
GS-3	25	27	29
GS-2	17	19	20
GS-1	4	4	4
Total General Schedule	**12,439**	**13,569**	**14,323**
Administrative Law Judges (AL)	---	---	---
Scientific/Senior Level (ST/SL)	4	4	5
Senior Biomedical Research Service (RS)	40	44	46
Scientific Staff Fellows (RG) (Title 42)[3]	793	864	913
Distinguished Consultants/Senior Science Managers (RF) (Title 42)[3]	131	143	151
Commissioned Corps (CC):			
Commissioned Corps - 08/07/06	236	241	241
Commissioned Corps - Other	788	807	807
Total Commissioned Corps	**1,024**	**1,048**	**1,048**
Administratively Determined (AD) (includes Title 42)[2]	17	19	20
Wage Grade	25	27	29
Consultants[2]	18	20	21
Total FTE (End of Year)[1]	**14,555**	**15,808**	**16,630**
Average ES Level	3	3	3
Average ES Salary	$171,137	$172,848	$174,577
Average GS grade	13	13	13
Average GS Salary	$105,086	$106,137	$107,198

[1] Does not include an estimated 83 reimbursable, 2 CRADA, 3 FOIA, and 39 PEPFAR 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. However, no longer includes scientists hired under Title 42 as explained in footnote 3.

[3] New pay plans established in FY 2014 for employees (scientists) previously hired and compensated under Title 42 U.S.C. 209 (f) and (g). This conversion effort is part of the Hire to Retire (H2R) Modernization Program that will be implemented when HHS converts its existing payroll system over to USDA's National Finance Center (NFC). This effort will allow FDA to readily distinguish those scientists who are hired under the two authorities for reporting requirements.

PHYSICIANS' COMPARABILITY ALLOWANCE (PCA) WORKSHEET

		FY 2014* (Actuals)	FY 2015** (Estimates)	FY 2016*** (Estimates)
1) Number of Physicians Receiving PCAs		1	1	1
2) Number of Physicians with One-Year PCA Agreements		0	0	0
3) Number of Physicians with Multi-Year PCA Agreements		1	1	1
4) Average Annual PCA Physician Pay (without PCA payment)		$149,993	$151,496	$153,465
5) Average Annual PCA Payment		$27,000	$27,000	$27,000
6) Number of Physicians Receiving PCAs by Category (non-add)	Category I Clinical Position	0	0	0
	Category II Research Position	1	1	1
	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 2014 Actual data through September 30, 2014.
**FY 2015 estimated average salary includes a 1% pay increase thru September 30, 2015.
***FY 2016 data will be approved during the FY 2017 Budget cycle; and estimated average salary includes an estimated 1.3% increase.

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 II to hire physicians that are not eligible for Title 38 PDP. The maximum annual PCA for this category for FY 2014 was $27,000 for the employee receiving PCA. The amounts were determined based upon the qualifications of the physician. The PCA service agreement for employee receiving PCA was extended in October 2014 to expire October 2016.

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).

FDA made a decision in 2008 to convert all eligible physicians to Title 38 which is useful in allowing the agency to effectively recruit and retain medical officers across the FDA. The minimal continued use of PCA 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.

FDA did not experience recruitment or retention problems as we use PCA sparingly across the agency. 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.

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APPROPRIATIONS COMMITTEE SIGNIFICANT ITEMS

CONSOLIDATED AND FURTHER CONTINUING APPROPRIATIONS ACT, 2015 (HR 83)

1. Organizational Chart

The agreement also directs the Food and Drug Administration, Commodity Futures Trading Commission and the Farm Credit Administration to provide an organizational chart of each agency respectively to the division and subdivision level, as appropriate, by January 30, 2015.

FDA Response
FDA will provide the report the Committee requested.

2. Nutrition Labeling

On December I, 2014, FDA published a final regulation entitled "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants." Prior to implementation or enforcement of the regulation, FDA shall work with industry and other stakeholders to identify questions and concerns, and provide any clarification necessary, including publication of any necessary guidance, not later than March 1, 2015.

FDA Response
FDA is aware of the Committee's concerns about FDA's definition of "restaurant" and similar retail food establishments; 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 of 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 also 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.

The FDA fully evaluated and considered all comments received before issuing a final regulation on December 1, 2014. The menu labeling final rule applies to restaurants and similar retail food establishments if they are part of a chain of 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items. The vending machine final rule requires operators who own or operate 20 or more vending machines to disclose calorie information for food sold from vending machines, subject to certain exceptions.

Restaurants and similar retail food establishments that are covered will have one year from the date of publication of the menu labeling final rule to comply with the requirements. Vending machine operators that are covered will have two years from the date of publication of the vending machine labeling final rule to comply with the requirements. The FDA will continue to work with industry and other stakeholders to respond to questions and concerns prior to the enforcement of this regulation.

3. Mitochondrial DNA Diseases

Congress is closely following the advancement of the field of mitochondrial manipulation technologies and is aware of a study commissioned from the Institute of Medicine on "Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases." FDA is directed to notify the Committees when the final report becomes available. As science progresses in this field, the agency is also directed to notify the Committees within three business days of issuing reports or press releases related to decisions on this matter, including the approval of clinical trials and future reviews.

FDA Response
FDA will notify the committees when the final report becomes available and provide notification as the science progresses in this field.

4. Plasma

The FDA Circular of information for the Use of Human Blood and Blood Components states that plasma from different sources has identical clinical indications. Plasma from manual donation may be transfused, and if not needed for that indication may be sent for further manufacture into biologics such as immunoglobulin, clotting factor concentrates, and albumin. However, plasma from automated donation may be transfused but cannot be shipped for further manufacture until approximately one year after the donation. At that point, the plasma is too old to be manufactured into other biologics and is destroyed and wasted. FDA is directed to report to the Committees on the scientific or medical justification for the different post –donation manufacturing policies and under what circumstances those policies might be adjusted to allow for the more timely use of plasma from automated donations into other biologics.

FDA Response
The Committee report notes that there is a shortage of products manufactured from plasma in the United States. FDA has seen no evidence of such a shortage, and in fact, collections of Source Plasma have increased substantially over the past decade. The United States even contributes a significant amount of Source Plasma for further manufacture to meet global needs. The Committee report also states that plasma stored beyond its one-year expiration as a product for direct transfusion cannot be further manufactured into biologics and must be "destroyed or wasted." However, if the plasma is frozen and stored according to certain standards, it is suitable for use in the manufacture of plasma derivatives after its one year expiration and is referred to as recovered plasma at that time. FDA is not aware of any commercial plasma fractionators who are unwilling to use one year old plasma for further manufacture, provided that donor testing meets all requirements.

As noted in the Committee report, plasma made by separation from a collection of whole blood and intended for direct transfusion may not always be needed for direct transfusion. It can be relabeled and sold at any time for further manufacture, mainly fractionation into plasma derivatives such as clotting factors and immune globulins. This plasma is called recovered plasma. Based upon the policies in place at blood collection establishments in the United States, it is collected from volunteer donors who receive no payment. In contrast, Source Plasma is apheresis plasma that, at the time of collection, is intended to be used solely for further manufacturing, which is mainly for fractionation into plasma derivatives such as clotting factors and immune globulins. Source Plasma is collected predominantly from paid donors in the United States, and the regulations limit it use to further manufacture. A distinction between Source

Plasma and recovered plasma is maintained for several reasons, including the paid versus unpaid volunteer donor characteristics, and the requirement that Source Plasma be frozen immediately after collection to maximize the recovery of labile proteins.

Blood collectors have the option to collect Source Plasma by implementing Source Plasma standards and procedures and by applying for a Source Plasma license, but they have generally opted not to do so. Instead, blood establishments have been permitted to sell apheresis plasma as recovered plasma for further manufacturing after outdate, when it is no longer suitable for transfusion. This policy assured that plasma collected from unpaid volunteer donors was not collected with an actual intent of sale for further manufacturing, potentially creating a source of revenue for blood collection establishments at the expense of the good will of unpaid voluntary blood donors. Blood collection establishments that collect plasma for transfusion are presently seeking to convert and sell apheresis plasma at an earlier date, prior to expiration, to help maintain the pool of voluntary donors, to ease the logistics of inventory management, and to avoid the costly storage of apheresis plasma for one year. FDA understands the concerns of the blood collection establishments and is currently exploring the development of a pathway that could address these concerns by allowing a portion of apheresis plasma to be used for further manufacturing within a certain timeframe after collection (e.g., a few weeks after collection), provided certain criteria distinguishing it from Source Plasma are met.

5. Labeling Changes for Approved Drugs and Biological Products

FDA issued the proposed rule "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products" in November 2013 to propose changes to the current regulations and practices that govern labeling changes of an approved drug or biological product to reflect certain types of newly acquired safety information. In addition to FDA's continued review of comments submitted in response to the proposed rule, the agreement supports a listening meeting between the regulated industries and FDA within 30 days of enactment to consider alternative solutions to the proposed rule on safety labeling that will meet all public health goals relating to multisource drugs.

FDA Response

FDA is carefully reviewing comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), health care associations, drug and pharmacy associations, brand and generic drug companies, law firms, state governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment. FDA also met with the Generic Pharmaceutical Association (GPhA) on September 8, 2014, to listen to their comments and views regarding the proposed rule, and a summary of this meeting has been posted to the public docket. As requested by the House Committee on Appropriations' recent report language, which supported a listening meeting between FDA and representatives of the regulated industries to consider alternatives to the proposed rule, FDA is planning to hold such a listening meeting as soon as it can be conveniently scheduled. To promote transparency and consistent with the Agency's obligation to treat all stakeholders fairly, the listening meeting will be a public meeting at which all who are concerned with this proposed rule may present any proposed alternatives and may comment on any proposals presented about how to best accomplish our shared public health goals. FDA intends to reopen the docket for the proposed rule to allow the submissions of written comments concerning proposals advanced during the public meeting. FDA will also arrange for a transcript of the meeting to be

made part of the public docket. FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting.

6. Veterinary Feed Directive rule

The agreement directs the Commissioner to finalize the Veterinary Feed Directive rule prior to April 1, 2015.

FDA Response

The comment period for the proposed changes to the existing Veterinary Feed Directive (VFD) rule ended March 12, 2014, and FDA received over 2000 comments. FDA has completed analysis of these comments and is now focused on drafting the final regulation, which is currently targeted for publication in May 2015.

HOUSE APPROPRIATIONS COMMITTEES SIGNIFICANT ITEMS

HOUSE COMMITTEE REPORT (113-468)

1. FSMA Food Safety Preventative Controls for Human Food Rule

FDA is directed not to implement an interim final or final rule regarding food safety plans under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) until regulatory requirements for supplier verification and testing programs are proposed for public review and comment as well as an economic analysis of the costs and benefits associated with the regulatory requirements pursuant to the Administrative Procedure Act. Given the diversity in the food industry, FSMA was designed to be risk-based, flexible, and science-based. A one-size-fits-all approach will not work. Yet, the Committee is very concerned with the overly prescriptive regulatory approach that the agency is taking with many of the regulations including the monitoring of preventive controls and verification testing activities. Accordingly, FDA shall ensure all FSMA regulations are risk-based, flexible, and science-based, and embrace the well-established and recognized standards for food safety already employed through much of the industry.

FDA Response
FDA issued a supplemental notice of proposed rulemaking on September 29, 2014 on the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, which included regulatory language for potential requirements for supplier verification, product testing, and environmental monitoring for public review and comment. This supplemental notice was accompanied by a revised preliminary regulatory impact analysis, which included the costs and benefits of these potential requirements. FDA is committed to ensuring that the agency's implementation of FSMA is risk-based, flexible as appropriate, and science-based, and gives due consideration to established and recognized industry standards for food safety.

2. Need to Manage Priorities

The Committee is concerned that FDA is not taking necessary and required steps to provide agency stakeholders adequate input or economic consideration on an expanding list of highly technical regulatory proposals. In addition, the agency has provided questionable cost estimates on proposed rules, guidance documents, and notices of tentative determination. The food supply chain has been forced to provide comment on OMB Redline text on important FSMA proposed rules, not formally published in the *Federal Register*. Moreover, the agency's dramatic shift in how it determines ingredient safety has tremendous potential to expose the Nation's largest manufacturing sector and the agency to costly litigation that may unnecessarily lead to higher costs and taxpayer dollars with unknown benefits. At a time when the agency is requesting additional appropriations and revenue from user fees, the Committee recommends that the agency not overextend itself at the cost to consumer confidence and the Nation's economic health.

FDA Response
FDA believes it is taking the necessary and required steps to provide stakeholders with adequate input and economic consideration on our proposals. In September 2014, FDA even issued supplemental notice of proposed rulemaking on four of the foundational FSMA rulemakings in response to stakeholder input. These supplemental documents were accompanied by revised economic analyses and they were open to public comment until December 15, 2014. FDA has not published its preliminary regulatory impact analyses in the Federal Register for these rulemakings, though our notices of proposed rulemaking and supplemental notices of proposed rulemaking in

the Federal Register do include summaries of economic analyses we performed. Importantly, the full economic analyses are references to the Federal Register notices and are made available in the corresponding dockets for public comment.

We note that FDA does not, as a matter of course, conduct economic analyses for guidance documents or notices of tentative determination that are based on safety assessments. The agency has consistently considered a substance is generally recognized as safe (GRAS) for a specific use if it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures. GRAS status of a specific use of a particular substance in food is time-dependent. Put another way, as new scientific data and information develop about a substance or the understanding of the consequences of consumption of a substance evolves, expert opinion regarding the safety of a substance for a particular use may change such that there is no longer a consensus that the specific use is safe. If FDA determines that a particular use of a substance is not GRAS, then that substance would be considered a food additive and subject to premarket review and approval by FDA. Under this authority, FDA could determine that the use of a substance is GRAS at certain levels but not others, or that certain uses of a substance are GRAS but other uses are not GRAS. Such a determination, however, would have to be based on generally available scientific information and supported by the views of qualified experts regarding certain uses in order to not be arbitrary or capricious. Guidance documents represents the Agency's current thinking on a given topic and do not establish legally enforceable responsibilities.

3. FDA Partnerships Under FSMA

The purpose of FSMA is to reform the nation's food safety laws to ensure a safe public food supply. As FDA continues implementation of FSMA, the Committee encourages FDA to work in partnership with existing government food safety programs through Memorandum of Understandings to verify compliance with FSMA to rules once they are finalized as a way to eliminate duplication of activities under the law.

FDA Response
FDA agrees that a strong partnership with existing state and local food programs is critical to achieving high rates of compliance with FSMA and other existing food safety laws and regulations. FDA is committed to continuing our strong partnership with existing government food safety programs to implement FSMA and achieve an Integrated Food Safety System. FDA will continue to use Memoranda of Understanding, in addition to contracts, grants, and cooperative agreements and other vehicles for this partnership.

4. Pharmacy Compounding

The Committee provides an increase of $12,000,000 for pharmacy compounding activities specified in the Drug Quality and Security Act (DQSA). The Committee urges FDA to complete inspections of compounding facilities that clearly fall within the agency's jurisdiction and take all necessary enforcement actions needed to promote the safety of the drug supply chain. For those pharmacies unaffected by DQSA, state boards of pharmacy are the proper regulator of state licensed pharmacies and should remain so. The Committee will continue to monitor FDA spending and oversight over compounding pharmacies to ensure the intent of both funding and legislation approved by Congress is observed.

FDA Response

Title I of the DQSA, the Compounding Quality Act, relates to human drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 503A of the FD&C Act describes conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act regarding new drug approval requirements, compliance with current good manufacturing practice (CGMP), and requirements for labeling with adequate directions for use. The validity of section 503A had been in question as a result of legal challenges until enactment of the DQSA, which removed from section 503A of the FD&C Act the provisions that were held unconstitutional by the U.S. Supreme Court in 2002. As a result of the DQSA, it is now clear that section 503A is valid and enforceable nationwide.

When FDA finds that a pharmacy compounds drugs in accordance with section 503A and does not violate other applicable Federal laws, FDA generally defers regulatory oversight of the pharmacy to the state, but when a pharmacy fails to produce drugs in accordance with section 503A or violates other Federal laws, FDA may pursue regulatory action. For example, in May and June 2013, the FDA inspected Main Street Family Pharmacy, LLC, a compounding pharmacy in Newbern, Tennessee, and found insanitary conditions and numerous deviations from the current good manufacturing practice (CGMP) requirements for drug products. FDA analyses of product samples also found microbial contamination in certain injectable drug products. In May 2013, Main Street announced a recall of all of its products compounded for sterile use. This followed 26 reports of adverse events, including skin abscesses, from patients in four states who received methylprednisolone acetate (MPA) injections compounded by Main Street. FDA investigators noted, among other observations, that the company did not adequately clean and disinfect rooms and equipment, and failed to conduct laboratory testing to ensure that products have the identity, strength, quality, and purity they purport to possess.

On December 4, 2014, Main Street Family Pharmacy, LLC and the company's co-owner each pleaded guilty in the United States District Court for the Western District of Tennessee to one misdemeanor criminal violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The pleas are in connection with Main Street's interstate shipment of MPA that was adulterated under the FD&C Act because the MPA contained microbial contamination. At sentencing, the District Court Judge sentenced the co-owner to 12 months of probation and ordered the co-owner and the pharmacy to each pay a fine of $25,000.

The court also entered a civil consent decree of permanent injunction against Main Street and its co-owners. The consent decree prohibits Main Street and the co-owners from manufacturing, holding, and distributing drug products until the company comes into compliance with the FD&C Act and its regulations, among other requirements. These actions stemmed directly from FDA's inspections of the pharmacy, which was purporting to operate under the conditions of section 503A.

With regard to the Committee's recommendation that FDA complete inspections of compounding facilities that clearly fall within the agency's jurisdiction, we note that we are generally only able to determine whether a pharmacy operates in accordance with section 503A after we inspect the pharmacy. During the inspection, FDA looks at the products that are compounded, the ingredients used to compound, whether the pharmacy is receiving prescriptions for the products it compounds, and other relevant matters necessary to determine whether the pharmacy is operating in accordance with section 503A. FDA also looks to see whether the facility is compounding drugs

under insanitary conditions, which is prohibited under section 501(a)(2)(A) of the FD&C Act from which pharmacies operating under section 503A are not exempt.

In fiscal year 2014, FDA conducted 62 inspections of compounding pharmacies, including risk-based surveillance inspections of pharmacies that have a known history of adverse events or deviations from adequate sterile processes, for-cause inspections based on reports of serious adverse events or product quality deficiencies such as drug contamination, and follow-up inspections to evaluate corrective actions after a prior inspection, warning letter or other action. In fiscal year 2014, FDA issued 22 warning letters to pharmacies whose drugs failed to comply with section 503A or other applicable Federal law, and nine letters referring inspectional findings at a pharmacy that compounded drugs in accordance with section 503A to the state board of pharmacy.

The DQSA also added section 503B to the FD&C Act. Under section 503B, a compounder may elect to register with FDA as an "outsourcing facility." Drugs compounded by outsourcing facilities may qualify for exemptions from the new drug approval, adequate directions for use, and drug supply chain security provisions of the FD&C Act, but are subject to CGMP requirements and risk-based inspection by FDA, among other requirements. In fiscal year 2014, FDA conducted 30 inspections of outsourcing facilities and issued seven warning letters, including one warning letter that addressed violations at four outsourcing facilities.

In fiscal year 2015, FDA intends to continue to conduct risk-based surveillance and for-cause inspections of compounding pharmacies and registered outsourcing facilities, as well as follow-up inspections of these pharmacies and facilities whose drugs FDA determined fail to meet the conditions necessary to qualify for exemptions under section 503A or 503B of the FD&C Act or violate other Federal laws. In addition, FDA will continue to take action or refer inspectional findings to state regulatory authorities, as appropriate, to promote the safety of compounded drugs.

5. Menu Labeling

The Committee remains concerned with FDA's proposed rule to regulate Nutrition Labeling of Standard Menu Items at Chain Restaurants. The Committee is further concerned that FDA has not properly considered alternatives or appropriately measured their impact on affected entities. The Committee continues to urge FDA to adopt the proposed alternative Option 2 definition of similar retail food establishments, which only applies the rule to restaurants or retail establishments where the primary and majority of business is the selling of food for immediate consumption or the selling of food that is processed or prepared on the premises. The Committee directs FDA to complete and submit to the Committee a detailed cost-benefit analysis, to be used in the final rule's review by the Office of Management and Budget, including an analysis of the agency's proposed options for the defining of ''similar retail food establishments'' that fully incorporates the information provided by affected non-restaurant entities and determines which option is most compliant with Executive Order 2866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review). The Committee believes that the agency should take into account the increased costs and logistical challenges chain restaurants will face in meeting the requirements of the proposed rule. 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. Consistent with the intent of Congress to enhance the provision of accurate and accessible nutritional information to consumers, the Committee urges FDA to modify the respective provisions in the proposed rule to permit restaurants and similar retail food establishments to: (1)

label the number of calories in a multi-serving menu item that is typically divided before presentation to the consumer, by labeling the number of calories in the common unit division of that multi-serving menu item, or by labeling the number of servings and number of calories per serving; (2) determine and disclose nutrient content for variable standard menu items that come in different flavors, varieties, or combinations using methods that will enhance accuracy and accessibility to consumers, including ranges, averages, individual labeling of flavors or components, or labeling of one preset standard build; and (3) disclose nutrient content using a remote-access menu, such as one available on the Internet instead of an in-store menu, in cases where the majority of orders are placed by customers who are off-premises. Furthermore, regarding the ''reasonable basis'' standard applied to restaurants and similar retail food establishments under Section 403(q)(5)(H)(iv) of the Federal Food, Drug, and Cosmetic Act, the Committee urges FDA to accept allowances for variation in nutrient content, such as brought about by variations in serving size, inadvertent human error in formulation of menu items, and variation in ingredients. FDA should not hold restaurants and similar retail food establishments liable for such variation in nutrient disclosure. If FDA's proposed rule has been finalized prior to the issuance of this report, the Committee directs FDA to issue guidance within six months of the date of this report to inform regulated industry of the interpretations of the nutrition labeling requirements set forth above.

FDA Response
We appreciate the committee's feedback. The final rule for menu labeling displayed in the federal register on November 25, 2014 and officially published on December 1, 2014. A completed Regulatory Impact Analysis for the final regulation can be found at: http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/LabelingNutrition/UCM423985.pdf FDA is working on a guidance document to help inform the regulated industry of the requirements for menu labeling and plans to release it in the near future.

6. Bioethics Committee

The Committee directs the agency to utilize a bioethics committee within the Department of Health and Human Services to review novel cellular and gene therapy matters before the Office of Cellular, Tissue, and Gene Therapies. The bioethics committee should be tasked with reviewing scientific and bioethical considerations prior to the approval of clinical trials, especially those involving oocyte modifications. FDA is directed to report to the Committee at a minimum of 30 days prior to a final agency decision on such matters.

FDA Response
In February 2014, FDA held an Advisory Committee to discuss oocyte modification in assisted reproduction for the prevention of transmission of mitochondrial disease or treatment of fertility. The Advisory Committee meeting was a public meeting that covered scientific issues and ethical issues as they related to the subjects in the trial. FDA commissioned a consensus study from the Institute of Medicine (IOM) on "Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases." FDA has requested that the IOM produce a consensus report regarding the ethical and social policy issues related to genetic modification of eggs and zygotes to prevent transmission of mitochondrial disease. IOM has informed FDA that the report should be issued by April 2016.

7. Imported Pet Food Product Transparency

As of December 2013, FDA has received more than 4,600 complaints of illness related to consumption of chicken, duck, or sweet potato jerky treats, nearly all of which are imported from China. The reports involve more than 5,400 dogs, 23 cats, and include more than 900 canine deaths. These incidents date back to 2007. The Committee requests that FDA provide it with a summary of all activities, including discussion of noteworthy timeframes, associated with the investigation into the pet illnesses related to these products within 60 days of the enactment of this Act. In addition, the Committee requests that the agency provide it with an annual summary report on the status of the investigation into these illnesses beginning in April 2014 until the issue has been resolved.

FDA Response
FDA will provide the summary and annual reports as requested by the Committee.

8. Over-the-Counter (OTC) Cold Medicines for Children

The Committee is concerned that FDA has not issued a proposed rule revising the monograph regulating the labeling of OTC cough and cold products for children. The Committee directs the agency to publish a proposed rule by June 30, 2014, based on scientific evidence for safety and efficacy in pediatric populations and consistent with the October 19, 2007, joint recommendations of its Pediatric Advisory Committee and Nonprescription Drugs Advisory Committee. While the Committee appreciates the agency's effort to explore possible improvements to the OTC drug monograph process, these efforts should not impede the prompt publication of this proposed rule.

FDA Response
FDA remains committed to the publication of the Over-the-Counter (OTC) Cold Medicines for Children proposed rule and is heartened that Agency, industry, and stakeholders' attention on this issue has contributed to a significant decline in pediatric-related adverse events. FDA has published a number of consumer updates, available on its website, to inform consumers about the safe and effective use of OTC products. These include a checklist to help parents and caregivers choose OTC medicines for children, guidance on how to choose medicine for children, and consumer updates on using OTC cough and cold products for children and caring for infants and young children with a cold. In addition, FDA's actions led to voluntary industry labeling and packaging improvements, including advising against use of cough and cold medications in children under four years of age. As a result, emergency department visits for adverse drug events attributed to cough and cold medications have been reduced by more than a third in this most vulnerable age group. [60]

New scientific methods and considerations for assessing medication use in children, particularly related to cough and cold products, are evolving rapidly and have undergone significant changes since the 2007 joint Pediatric and Nonprescription Drugs Advisory Committee meeting. FDA will continue to identify and assess new scientific methods and considerations for clinical testing of cold and cough medicines in children to develop this rule.

[60] Hampton LM, Nguyen DB, Edwards JR, Budnitz DS. Cough and cold medication adverse events after market withdrawal and labeling revision. Pediatrics 132:1047-54, 2013.

9. Drug Shortages

The Committee is aware that shortages of critical drugs persist following the 2012 enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA). 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. Therefore, within the funding provided, 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

Mitigating and preventing drug shortages remains a top FDA priority. Our staff is making every effort to help ensure patients have access to critical and life-saving drugs – and the results are illustrated by declining numbers of new drug shortages year over year. Shortages, however, remain a significant concern impacting patient care.

In 2014, FDA:

- deployed a number of strategies to prevent specific shortages, these included working with manufacturers to resolve quality issues, expediting review of new applications, asking other manufacturers to increase production, and identifying products from alternate sources
- launched a new data tracking system to enhance the efficiency and consistency of drug shortage data
- revised internal policies and procedures to assure the utmost transparency in how FDA mitigates and prevents shortages
- developed an FDA Drug Shortage Assistance Award to provide public recognition to drug companies and manufacturers who have demonstrated a commitment to preventing or alleviating drug shortages of medically necessary drugs
- enhanced public communications about shortages on the FDA website with a Drug Shortage Searchable Database

Recognizing that drug shortages are a global challenge, FDA continues to work closely with other national regulatory authorities. We have initiated regularly scheduled calls with our international counterparts to share information about drug shortage management and mitigation strategies and specific shortages impacting patients in our respective countries. FDA has also been working with the Biomedical Advanced Research and Development Authority, as well as the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services to explore new methods to assist with critical and imminent drug shortages. Finally, FDA continues to build alliances and enhance our communications with a variety of healthcare professional organizations, patient advocacy groups, and industry-related organizations.

All of our actions are consistent with FDA's Strategic Plan for Preventing and Mitigating Drug Shortages released in October, 2013. The plan contains details on the origin of drug shortages, FDA's processes and procedures for helping to prevent or mitigate shortages, and FDA's strategy for strengthening those processes and procedures. The plan also outlines recommendations for actions other stakeholders can consider to help prevent shortages. The plan can be reviewed at: http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

10. Seafood Advisory

The Committee is concerned that after many years, FDA has not published updated advice on seafood consumption for pregnant women, mothers, and children. Seafood is an important part of a healthy diet which contains critical vitamins and nutrients, such as Omega 3s, which are essential during pregnancy to ensure optimal fetal and child development. The Committee directs FDA to publish final advice to pregnant women on seafood consumption in conjunction with all applicable parties as directed in House Report 112–101 and Senate Report 112–73 by June 30, 2014. FDA shall issue its final seafood risk benefits assessment at the same time as the seafood advice. The seafood advice shall be consistent with the latest science and contain a clear and actionable advice that will enable the public, medical, and scientific communities to make informed dietary decisions and recommendations. Finally, FDA shall provide a progress report to the Committee 30 days after the enactment of this Act and every 30 days thereafter until the advisory and seafood risk benefits assessment are published.

FDA Response

On June 10, 2014, FDA and EPA jointly issued a draft update to the seafood advice they last issued in 2004. The updated joint advice tracks the current recommendation in the Dietary Guidelines for Americans 2010, issued by the Departments of Agriculture and Health and Human Services, in that it advises pregnant women, women who may become pregnant, and nursing women eat at least 8 and up to 12 ounces per week of a variety of fish lower in mercury in order to optimize the developmental benefits that fish could provide. The two agencies announced that there would be at least one public meeting on the advice, to be held by the FDA Risk Communication Advisory Committee (RCAC). For that reason, the public comment period, which opened on June 11, was indefinite until such time as that meeting, and any other meeting, could be held. Specifically, FDA and EPA announced that the comment period will be open until 30 days after the last transcript from the advisory meeting and any other meetings that the agencies hold on this subject becomes available. The Risk Communication Advisory Committee met on the fish consumer advice on November 3-4 and the transcript from that meeting has recently become available. Since no other public meetings are planned, FDA and EPA will soon announce a date for the closing of the comment period by publishing a notice in the Federal Register. Once the comment period closes, the agencies will study the public comments, make whatever modifications to the advice are appropriate, and publish the updated advice. We expect this process to be completed in 2015.

11. ANDA Review Prioritization

In its Generic Drug User Fee Act commitment letter, FDA affirmed that in order to provide more certainty to the generic drug industry, it would expedite the review of Paragraph IV applications that become eligible for approval during the review period and other applications that have the potential to be the first generics to market. Within 45 days of enactment of this Act, the Committee directs FDA to report to the Committee how it has prioritized its abbreviated new drug application review process to ensure first generics are approved on the earliest possible date.

FDA Response

Expediting the review of Abbreviated New Drug Applications (ANDAs) for potential first generic products is crucial for ensuring timely access to low cost, high quality generic drugs.

In November, 2014, FDA published proposed criteria for “first generic” abbreviated new drug application submissions in the Federal Register. The criteria are consistent with two recently

issued Manuals of Policy and Procedure[61] designed to clarify how ANDA reviews will be prioritized, minimize confusion, and improve consistency. The agency has opened a public docket for stakeholders to share their feedback on the proposed criteria.

We believe that the proposed criteria appropriately focus FDA's resources on approving as quickly as possible, new safe and effective generic drug products for patient use. The Agency also believes that these criteria are consistent with the broad scope of the GDUFA Commitment Letter, and generally reflect industry intent. Finally, these criteria enable FDA to prioritize review of a *pending* ANDA when the date on which the ANDA can be approved alters due to changes in the patent or exclusivity landscape.

FDA looks forward to continued engagement with a broad range of stakeholders to inform the development of clear policies that will ensure the timely approval of first generics.

12. Mammography Quality Assurance Advisory Committee

The Committee urges FDA to quickly 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 lay report and physician report.

FDA Response
FDA has reviewed available evidence and drafted regulation amendments that will address the breast density issue. The amendments are currently under internal review and we plan to publish them in 2015.

13. Accelerated Approval

The Committee is concerned that FDA has underutilized the accelerated approval authority codified in FDASIA. Congress created this authority to facilitate review and approval of drugs to treat patients with rare, life-ending diseases that cannot reasonably be pursued through the standard FDA approval process. The Committee directs FDA to report on the way it has used this authority since 2012, its plans to use it in the future, and a justification for using this authority for diseases that are not life-ending.

FDA Response
For over 20 years FDA has utilized the accelerated approval pathway to speed treatments to patients suffering from a number of life-threatening diseases such as cancers and HIV/AIDS, and also for serious, non-fatal diseases including orthostatic hypotension and a number of rare, debilitating diseases.

Accelerated approval is based on a surrogate endpoint or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is "reasonably likely…to predict clinical benefit." FDA recognizes that patients and physicians are willing to accept greater risks, both of safety and uncertainty of benefit, for drugs treating life-threatening and severely debilitating illnesses with no good, available therapy. The reliance on "reasonably likely" surrogates and the smaller databases typical in accelerated approval reflect this recognition.

[61] MAPP 5240.3 Rev. I: Prioritization of the Review of Original ANDAs, Amendments, and Supplements and MAPP 5200.4: Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements.

An updated list of accelerated approvals from January, 2012 – December, 2014 is attached. A complete listing of accelerated approvals is updated semiannually at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/ucm373430.htm

If a surrogate endpoint becomes well established and known to predict clinical benefit, it can be used as a basis for traditional approvals -- speeding delivery of new treatments and saving sponsors time and money that would have been required for post-approval studies under the Accelerated Approval pathway. Indeed, 45 percent of the new drugs approved between 2010 and 2012 were approved on the basis of a surrogate endpoint.

In addition to accelerated approval, the Agency oversees other programs that expedite the availability of new drugs and biologics for patients with serious conditions. These include Breakthrough, Fast Track, and Priority Review. Last year, almost half of the new molecular entities approved by FDA were designated in one or more of these categories.

The Committee's request that FDA provide a justification for using accelerated approval authority to approve drugs intended to treat diseases that are not life ending is not clear to us. Since 1992, accelerated approval regulations have stated that the program applies to drugs intended to treat serious or life-threatening illnesses.

As a society, we are generally willing to accept greater risks and side effects from treatments for life-threatening and severely debilitating diseases than we would for less serious diseases. In the case of accelerated approval, these greater risks include a degree of uncertainty about clinical benefit, and potential, undiscovered adverse events that are more likely to be identified after approval given the smaller and generally shorter duration of accelerated approval safety data. Following accelerated approval, confirmatory studies are necessary to verify clinical benefits. The principal risk of this approach is the possibility that patients will be exposed to a drug that ultimately will not be shown to provide an actual clinical benefit, but which carries risk.

While accelerated approval is an invaluable tool to speed development of certain products to treat many serious diseases, it is not appropriate for others. Accelerated approval is inappropriate for fundamentally healthy individuals taking medication, for example, to treat conditions such as seasonal allergies or migraines. According to the results of the National Health and Nutrition Examination Survey, 48 percent of Americans took at least one prescription drug in the past month. This includes 1 out of every 5 children and 9 out of 10 older Americans. Almost a third reported taking two or more prescription drugs in the past month. Granting accelerated approval for non-serious conditions could subject millions of Americans to greater risk of exposure to adverse side effects over a long period of time – with more limited benefits.

FDA remains committed to utilizing the Accelerated Approval pathway in situations where it is appropriate and encourages sponsors seeking to develop drugs for serious diseases to engage in discussions with FDA early in development to explore whether this pathway would be appropriate.

14. Duchenne Muscular Dystrophy

The Committee commends the collaboration between FDA and the Duchenne Muscular Dystrophy community to advance useful regulatory tools for benefit-risk considerations in this disease population and drug development guidance. The Committee supports the agency's

engagement with the patient population for these purposes and to enable the appropriate use of regulatory flexibility as provided in FDASIA.

FDA Response
We recognize that there are substantial unmet needs for patients afflicted with Duchenne Muscular Dystrophy (DMD). FDA is fully committed to making safe and effective drugs available for patients with this life-threatening disease as soon as possible, is actively engaged with new drug sponsors and the patient community, and is prepared to apply considerable flexibility in this situation including considering accelerated approval for drugs to treat DMD. We have also committed to issuing a guidance for industry in 2015 on development of drugs to treat DMD and other similar diseases – and appreciate the hard work of the Parent Project Muscular Dystrophy in advancing these efforts.

15. Special Protocol Assessment Agreements

The Committee is concerned about questions that have arisen in connection with the rescission of a Special Protocol Assessment Agreement (SPA), including fundamental questions concerning FDA's adherence to the statutory and regulatory guidelines that apply to the SPA process as well as to questions concerning fairness to the sponsors. The Committee would like to reiterate that FDA is expected to adhere to the established standard as informed by the *Congressional Record* and the 1997 PDUFA Goals Letter. The Committee is aware of FDA's ability to rescind a SPA agreement reached under section 505(b)(5)(C)(ii) of the Food, Drug, and Cosmetic Act only if it demonstrates that ''a substantial scientific issue essential to determining the safety or efficacy of the product has been identified after the testing has begun.'' This standard is informed by the *Congressional Record* and the 1997 PDUFA Goals Letter. The Congressional report explains that Congress intended ''that such agreements should be binding on both parties'' except when ''a substantial scientific issue has come to light after an agreement has been reached and testing has begun, which has a direct bearing on the safety or effectiveness of the product.'' The Committee also expects that, as a matter of public policy and fundamental fairness to the sponsor, FDA should be accountable for continued diligence in identifying issues that bear on the continued enforceability of a SPA agreement and in notifying the sponsor of such issues within a reasonable period of time after FDA becomes aware. To ensure agreement over the standard to rescind a SPA, the Committee directs FDA to report to the Committees on Appropriations of the House and Senate within 60 days of enactment of this Act regarding the standard by which FDA would rescind a SPA. Lastly, to ensure agreement over the standard to rescind a SPA, the Committee directs FDA to revise and re-issue, after public comment, its existing guidance regarding SPA agreements to clarify the agency's interpretation of the statutory standard regarding SPA agreements and the rescission of such agreements.

FDA Response
The statute permits an SPA agreement to be rescinded if "a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the [clinical trial] has begun."[62] FDA takes SPA agreements seriously and has rarely rescinded an SPA agreement. Since FDAMA was enacted in 1997, CDER has issued over 1000 SPA agreements. Fewer than 1 percent have been rescinded. SPA rescission decisions are made on a case-by-case basis after careful review of the circumstances to determine whether the statutory standards have been met.

[62] 21 USC 355(b)(5)(C)

FDA is working to revise the *Guidance for Industry: Special Protocol Assessment* to clarify which protocols qualify for review under SPA, clarify the SPA process, provide sponsor options after receipt of a Non Agreement Letter, and add a new section that describes rescission of an SPA, including the opportunity for the sponsor to meet with FDA prior to rescission. We anticipate publication of the revised draft guidance by the end of calendar year 2015.

16. Blood Plasma Products

The Committee notes that the FDA Circular of Information for the Use of Human Blood and Blood Components states that plasma from different sources has identical clinical indications. Plasma from manual donation may be transfused and if not needed for that indication, may be sent for further manufacture into biologics such as immunoglobulin, clotting factor concentrates, and albumin. However, plasma from automated donation may be transfused but cannot be shipped for further manufacture until approximately one year after the donation. At that point the plasma is too old to be manufactured into other biologics and is destroyed and wasted. This seems illogical since there is a shortage of these biologic products in the United States. The Committee directs FDA to report back within 60 days of enactment of this Act on the scientific or medical justification for the different post-donation manufacturing policies and under what circumstances those policies might be adjusted to allow for the more timely use of plasma from automated donations into other biologics.

FDA Response

The Committee report notes that there is a shortage of products manufactured from plasma in the United States. FDA has seen no evidence of such a shortage, and in fact, collections of Source Plasma have increased substantially over the past decade. The United States even contributes a significant amount of Source Plasma for further manufacture to meet global needs. .The Committee report also states that plasma stored beyond its one-year expiration as a product for direct transfusion cannot be further manufactured into biologics and must be "destroyed or wasted." However, if the plasma is frozen and stored according to certain standards, it is suitable for use in the manufacture of plasma derivatives after its one year expiration and is referred to as recovered plasma at that time. FDA is not aware of any commercial plasma fractionators who are unwilling to use one year old plasma for further manufacture, provided that donor testing meets all requirements.

As noted in the Committee report, plasma made by separation from a collection of whole blood and intended for direct transfusion may not always be needed for direct transfusion. It can be relabeled and sold at any time for further manufacture, mainly fractionation into plasma derivatives such as clotting factors and immune globulins. This plasma is called recovered plasma. Based upon the policies in place at blood collection establishments in the United States, it is collected from volunteer donors who receive no payment. In contrast, Source Plasma is apheresis plasma that, at the time of collection, is intended to be used solely for further manufacturing, which is mainly for fractionation into plasma derivatives such as clotting factors and immune globulins. Source Plasma is collected predominantly from paid donors in the United States, and the regulations limit it use to further manufacture. A distinction between Source Plasma and recovered plasma is maintained for several reasons, including the paid versus unpaid volunteer donor characteristics, and the requirement that Source Plasma be frozen immediately after collection to maximize the recovery of labile proteins.

Blood collectors have the option to collect Source Plasma by implementing Source Plasma standards and procedures and by applying for a Source Plasma license, but they have generally

opted not to do so. Instead, blood establishments have been permitted to sell apheresis plasma as recovered plasma for further manufacturing after outdate, when it is no longer suitable for transfusion. This policy assured that plasma collected from unpaid volunteer donors was not collected with an actual intent of sale for further manufacturing, potentially creating a source of revenue for blood collection establishments at the expense of the good will of unpaid voluntary blood donors. Blood collection establishments that collect plasma for transfusion are presently seeking to convert and sell apheresis plasma at an earlier date, prior to expiration, to help maintain the pool of voluntary donors, to ease the logistics of inventory management, and to avoid the costly storage of apheresis plasma for one year. FDA understands the concerns of the blood collection establishments and is currently exploring the development of a pathway that could address these concerns by allowing a portion of apheresis plasma to be used for further manufacturing within a certain timeframe after collection (e.g., a few weeks after collection), provided certain criteria distinguishing it from Source Plasma are met.

17. Sunscreen Ingredient Review

The Committee is extremely concerned that another year has passed without FDA completing its review of the pending Time and Extent Applications (TEAs) and the OTC Monograph rulemakings on sunscreens. Immediate action on sunscreens should be a priority since the need for sunscreens is evidenced by the nearly one million people that are currently living with skin cancer and the fact that melanoma is the fifth leading cause of cancer in the U.S. this year. FDA has listed actions related to sunscreen as a high priority in the Unified Agenda since 2008. While the Committee is encouraged that FDA has issued two sunscreen final rules and feedback letters to some sunscreen TEA applicants, significantly more work remains to protect Americans from developing skin cancer. The Committee directs FDA to complete its review by December 2014 of the remaining safety and effectiveness submissions already submitted for sunscreen active ingredients that have been found eligible for potential inclusion in the sunscreen monograph via TEAs and to work expeditiously on completing the OTC monograph rulemakings. The Committee is also encouraged that FDA is seeking input from stakeholders on how to modernize the OTC Drug Review, including the TEA process, and directs FDA to continue to work with stakeholders through the process and explore ways to improve the OTC Drug Review more broadly.

FDA Response

We share Congress' commitment, expressed in the recently enacted Sunscreen Innovation Act (SIA), to ensure that sunscreens meet modern standards for safety and effectiveness. Over the past year, we have been working diligently to outline the criteria for industry that FDA will use to determine whether new, active sunscreen ingredients are Generally Recognized as Safe and Effective (GRASE). While substantial progress has been made, FDA continues its work. The SIA requires FDA to issue regulations on the sunscreen monograph, including SPF and dosage forms, within 5 years of enactment, and to establish the criteria for the remaining sunscreen Time and Extent (TEA) applications within 90 days of enactment. We intend to meet this requirement. It also sets up a timeline for FDA review once required data are submitted by industry. The timing for final decisions permitting marketing of these ingredients will depend on when additional required data are submitted by industry.

We also agree with Congress that a more efficient and streamlined system for regulating OTC monograph drugs generally is essential. Such a system, accompanied by relevant resources, is needed to ensure that OTC drugs are regulated in a manner that employs modern scientific and

medical standards to meet the needs of health management and preventive care by consumers, and to balance priorities for expediting the review and market entry of new monograph ingredients with addressing known and emerging safety issues in a timely manner. To this end, FDA held a public hearing to obtain input on the OTC Drug Review process in March 2014, and reopened the comment period after this meeting to obtain further feedback. FDA is currently reviewing the comments from this meeting and is considering options for broader monograph reform efforts.

18. Import Clearance Process

The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, should consider reprioritizing existing funding to ensure sufficient FDA personnel are available to clear shipments expeditiously at the time of their arrival at the port of entry including outside normal working hours and on holidays. The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall develop a Trusted Trader Program designed to allow shipments from highly compliant importers to be released with minimal documentation or additional information being provided. This program should be designed in a way as to not jeopardize the safety of food and medical products under the agency's jurisdiction. Recognizing that FDA has a responsibility to ensure legitimate trade is cleared rapidly and that compliant shipments are not unduly detained, the agency will provide a report to relevant Committees of Congress on two statistics that measure the effectiveness of its targeting rules twice each year, beginning six months after the passage of this measure, and again after one year. This report will contain: (1) the number of shipments being identified for FDA examination as a percentage of all shipments subject to FDA regulatory review, and (2) the number of violative products detained as a percentage of those being held.

FDA Response

FDA will provide the report the Committee has requested, as well as updates on its import processes. To date, FDA has worked with U.S. Customs and Border Protection (CBP) to expedite clearance at the port of entry and has made progress in development of the Trusted Trader Program. On June 16, 2014, a Federal Register Notice was issued by CBP to publicly notify the trade community regarding a test of the Trusted Trader Program. FDA and CBP have since reviewed the applicants and identified nine participants for a pilot test, which will begin after the participants are notified and CBP receives confirmation of their intent to participate.

19. Deeming Regulations

The Committee is encouraged that FDA has provided options for a way forward on distinguishing between premium cigars and other tobacco products in its recently proposed rule ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Docket No. FDA–2014–N–0189). In particular, the Committee notes that FDA is considering excluding premium cigars from the scope of this proposed rule through Option 2. The Committee believes this could be a viable solution, given that the Family Smoking Prevention and Tobacco Control Act makes little mention of cigars throughout the legislation, and there is even less evidence that Congress intended to focus on the unique subset of premium cigars. The Committee notes that premium cigars are shown to be distinct from other tobacco products in their effects on youth initiation, the frequency of their use by youth and young adults, and other such behavioral and economic factors.

FDA Response
FDA proposed in the "deeming rule" two options for the scope of the rule. Option 1 would extend FDA's regulatory authority to all products meeting the statutory definition of tobacco product, including small, large, and premium cigars. Option 2 would exclude from the scope of the rule certain cigars, referred to as "premium cigars," with a set of characteristics including retail price of over $10, not having non tobacco characterizing flavors, wrapped in whole tobacco leaf, etc.

By proposing two options, FDA sought comment on whether all cigars should be subject to deeming and what additional restriction(s) may or may not be appropriate for different kinds of cigars. In particular, FDA sought comment on the relative merits of Option 1 versus Option 2, taking into account what is best to protect the public health, including possible benefits to the public health or possible negative public health consequences of adopting one option or the other.

Although all cigars are harmful and potentially addictive, it has been suggested that different kinds of cigars including small cigars, cigarillos, large cigars, premium cigars, may have the potential for varying effects on public health, if there are differences in their effects on youth initiation, the frequency of their use by youth and young adults, and other factors.

However, while much of the cigar smoking by youth appears to be of non-premium products, premium cigars are in fact smoked by youth. Analyses from the 2010 and 2011 National Survey of Drug Use and Health (NSDUH) found that while most adolescent cigar smokers aged 12-17 preferred Black and Mild brand cigars, 3.5 percent of these adolescents identified their usual brand as a premium cigar brand (Delnevo et al. Preference for flavored cigar brands among youth, young adults, and adults in the USA. Tobacco Control. In Press). Further, the 2012-13 National Adult Tobacco Survey found 16.3 percent of young adults aged 18-29 reporting current cigar smoking (Coleman et al. Poster Presentation. Society for Nicotine and Tobacco Research. Feb. 2014); among those young adults more than one in seven reported their usual cigar was a premium product (Corey et al.).

We published our proposal with both options for public comment to solicit information, such as on disease risk, nicotine addiction, how premium cigars are used, and an appropriate definition for premium cigars. FDA received over 135,000 comments during the comment period, and FDA intends to examine all of the available information in order to make the best-informed decision.

20. Artificial Pancreas

The Committee commends FDA for taking critical steps in advancing artificial pancreas systems, including its recent approval of the threshold suspend system. The Committee encourages FDA to continue collaboration with key stakeholders to ensure that artificial pancreas systems are further developed, tested, and approved, ensuring timely access to safe and effective systems for patients with type 1 diabetes.

FDA Response
FDA has made substantial progress in advancing the development of safe and effective artificial pancreas device systems. Our proactive role in Artificial Pancreas development has been widely appreciated by the diabetes community. In 2014, we reviewed and approved approximately 30 experimental Artificial Pancreas systems investigational protocols. We continue to collaborate with stakeholders, including researchers, clinicians, manufacturers, investors, policymakers, and patient advocates to help clarify expectations, solve challenges as they arise, and encourage the development of Artificial Pancreas systems for people with type 1diabetes. We are working closely with Artificial Pancreas device sponsors to balance premarket and postmarket studies with

the goal of significantly reducing the time to market. With these efforts, we strongly believe that an Artificial Pancreas is within technological reach and fully expect the first approved closed-loop artificial pancreas device in the United States in the next few years.

21. Natural Claims

The Committee requests that the Commissioner submit to the Committees on Appropriations of both Houses of Congress a detailed document describing the agency's current policy with respect to natural claims on food products within 90 days of enactment of this Act.

FDA Response
FDA will provide the report as requested by the Committee.

22. Regulation of Tree Nuts

The Committee urges FDA to consider the exemption of tree nut producers from regulation under section 419 of the Federal Food, Drug, and Cosmetic Act if such tree nuts meet the criteria for "rarely consumed raw" and the recipient of the produce performs commercial processing that adequately reduces pathogens as described in the proposed regulation "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule".

FDA Response
As currently proposed, tree nuts that meet the criteria of "rarely consumed raw" and those that receive commercial processing that adequately reduces pathogens would not be subject to the provisions of section 419. By way of background, FDA tentatively concluded that an approach that considers both the risk associated with the commodity and that associated with the agricultural practices applied to the crop under the conditions in which it is grown would provide the most appropriate balance between public health protection, flexibility, and appropriate management of different levels of risk. Under this approach, we considered available information on outbreaks and contamination as well as existing evidence on characteristics of the commodity (such as whether the commodity grows on trees or has a smooth rind). This evidence informed the proposed requirements, but we have tentatively concluded that limiting the scope of this proposed regulation, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," based on outbreak data or on the levels of frequency of pathogen detection alone would not adequately address the risk of serious adverse health consequences or death. Therefore, we proposed to cover tree nuts in the aforementioned proposed regulation.

Because the scope and stringency of the regulatory requirements depend on the types of practices employed within operations of producers of different tree nut commodities, all producers may not be subject to all controls and restrictions.

While we proposed to cover tree nuts that do not meet the criteria we propose for ''rarely consumed raw'' in this proposed rule, such as walnuts and almonds, we recognize that many of these tree nuts receive commercial processing to adequately reduce pathogens, and thus, may be eligible for an exemption under proposed § 112.2(b). Our main food safety concerns relevant to on-farm growing, harvesting, packing, and holding of tree nuts pertain to those tree nuts that would be sold raw and untreated.

23. Generic Drug Labeling

The Committee is deeply concerned with FDA's proposed rule regarding "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products" that would change longstanding policy and allow generics to alter their label without FDA's prior approval. Ironically, FDA published this proposed rule after the agency's recent success in launching the Sentinel Initiative. This initiative helps to electronically track the safety of drugs once they reach the market, especially in terms of identifying drug safety communications. The Committee is unaware of evidence of a need to change existing regulations. The proposed rule has the potential to threaten public health by creating unprecedented patient and provider confusion by having multiple labels for the same product, therefore undermining the longstanding policy of sameness. The Committee urges FDA to maintain a system where prescription drug labels on the market are FDA-approved, grounded in scientific evidence, and present no opportunity for mismatched dispensing or use information between the name brand drug and the generic version drug. Additionally, sufficient evidence is lacking on how FDA derived such a low cost estimate for this proposed rule. Under the proposed rule, generic and brand manufacturers could assume additional obligations and possible liability, which may drive smaller companies from the market, increase the cost of generic medications, and lead to additional drug shortages. FDA's cost impact analysis has not accounted for or addressed these or other unintended consequences, and further the Committee is concerned about the resources necessary to carry out such a significant policy change FDA must clear up any potential confusion that will likely be created in going forward with the currently proposed regulation. The agency must also justify the cost of such a regulation that fails to provide a net health benefit to consumers and providers. The Committee directs the agency to complete a new economic analysis of the rule, paying particular attention to the cost of pharmaceutical products, before FDA finalizes the rule and report back to the Committee on Appropriations of both Houses of Congress within 90 days of enactment of this Act.

FDA Response

FDA's proposed rule, if finalized, is intended to improve the communication of important drug safety information to health professionals and the public by providing quicker access to important new safety-related information about generic drugs. It would create parity between brand and generic drug manufacturers by allowing generic drug manufacturers to independently update product labeling with newly acquired safety information and distribute the revised labeling, before FDA reviews or approves the labeling change – just as brand manufacturers currently do. Generic manufacturers would also be required to inform the brand name manufacturer about the change.

Currently, more than 80 percent of drugs dispensed are generic and some brand drug manufacturers may discontinue marketing after generic drug entry. Yet generic manufacturers must wait to update safety information in generic drug labeling until after FDA has approved a change to the corresponding brand drug labeling.

Brand drug manufacturers are allowed to independently update and promptly distribute updated safety information by submitting a "changes being effected" (CBE-0) supplement to FDA. Currently, if a generic manufacturer believes that newly acquired safety information should be added to drug labeling, it must notify FDA, and wait for FDA to determine whether labeling for both the brand and generic drugs should be revised, which may result in a delay in getting new information to health care professionals and patients.

To enhance transparency while FDA is reviewing the CBE-0 supplement and to make safety-related changes to drug labeling quickly available to health care professionals and the public, FDA proposes to create a web page where safety-related changes proposed by all drug manufacturers would be posted. Members of the public could subscribe to receive updates.

The proposed rule would be expected to reduce the variation between brand and generic drug labeling. FDA would make an approval decision on proposed labeling changes for the generic drug and the corresponding brand drug at the same time, so that brand and generic drug products have the same FDA-approved labeling. Generic drug manufacturers would be required to submit conforming labeling changes within a 30-day time frame after FDA approval of a change to the corresponding brand drug labeling.

The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from various stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

FDA is carefully reviewing comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), health care associations, drug and pharmacy associations, brand and generic drug companies, law firms, state governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment. FDA will determine next steps based on our analysis of the comments.

A new economic analysis will accompany the final rule. The analysis cannot be completed until substantive decisions on the provisions of the final rule are concluded.

FDA is proceeding in accordance with the Administrative Procedure Act, which ensures that FDA will evaluate and address the comments on the proposed rule submitted to the public docket, that FDA will take those comments into account in determining whether and how to finalize the rule, and that any final rule that is adopted will reflect FDA's consideration of public comments.

24. National Antimicrobial Response Monitoring System (NARMS)

The Committee expects FDA to provide funding for the National Antimicrobial Response Monitoring System at $7,800,000 and urges FDA to consider providing additional funding for this program if warranted. The Committee encourages FDA to utilize NARMS as part of the strategy to preserve the effectiveness of antibiotics. The agency should continue to use the NARMS data for evaluating new food animal antibiotics, guiding policy and regulations on the use of antibiotics, conducting risk assessments, and tracking changes in resistance to identify potential human and animal health problems.

FDA Response
FDA will provide funding as requested by the Committee along with the additional funds appropriated for NARMS in FY 2015.

25. FDA User Fee Collections/Obligations

The Committee continues to be concerned about the financial management of FDA's user fee programs. The Committee directs that not later than November 1, 2014, and each month thereafter through the months covered by this 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 Act. 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 2015 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 the Committee requested.

26. Finalization of the Veterinary Feed Directive

The Committee directs the Secretary of Health and Human Services to require FDA to finalize the Veterinary Feed Directive regulation by December 2014.

FDA Response
The comment period for the proposed changes to the existing Veterinary Feed Directive (VFD) rule ended March 12, 2014, and FDA received over 2000 comments. FDA has completed analysis of these comments and is now focused on drafting the final regulation, which is currently targeted for publication in May 2015.

27. 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 National Agriculture and Food Defense Strategy (NAFDS - Section 108 of Public Law 111–353) details specific food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders plan to accomplish to meet the objectives outlined within the Food Safety Modernization Act (FSMA - Section 108). The NAFDS charts a direction for how the federal agencies, in cooperation with Federal, State, local, tribal, and territorial (SLTT) governments and private sector partners, protect the nation's food supply against intentional contamination. Within NAFDS, the Coordinated Research Agenda (Appendix B) documents ongoing and future research activities across the federal government. FDA continue to review advancements in research and technology with portable and technologically advanced testing platforms needed to effectively enhance monitoring and protecting against intentional adulteration; and, promote food safety, including those applicable and/or specific to seafood.

28. Cosmetics and Colors

The Committee directs the Office of Cosmetics and Colors (OCAC) to respond by March 15, 2015, to a citizen petition setting safety levels for trace amounts of lead in cosmetics. The Committee notes that every year since FY 2012, it has repeatedly requested that OCAC respond to this petition. The Committee urges OCAC to make this a priority.

FDA Response
As noted in our response to the Committee last year, although the data currently 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. FDA expects to meet the March 2015 due date for response to the citizen petition.

29. 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 FSMA-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.

30. Concerns with Opioid Application Approvals

The Committee is alarmed by a growing trend of prescription drug and opioid abuse. The Committee notes that FDA has taken a number of positive steps in recent years to address this complex challenge. However, the Committee is discouraged by FDA's 2013 approval of a New Drug Application for Zohydro, a high-dose undiluted painkiller containing hydrocodone. While the United States makes up only 4.6 percent of the world's population, its residents consume 99 percent of the world's supply of hydrocodone. These drugs are now the most widely prescribed painkillers in the U.S., and emergency room visits involving hydrocodone rose from 38,000 in 2004 to more than 115,000 in 2010. Approving this powerful narcotic without any abuse deterrent formulation, despite the strong opposition of the relevant FDA expert Advisory Panel, seems counter to the assertion that "the prevention of prescription opioid abuse is of the highest priority for the FDA." The DEA Administrator indicated to the Committee that the agency is spending considerable resources to educating agents, diversion investigators, and tactical diversion squads about the approval of this medication that "frightens us all." In addition to strong concerns that the drug is ripe for misuse and addiction, the Committee is concerned that approving new applications without abuse deterrent properties will stifle innovation in this newly emerging field of scientific research. The Committee therefore requests that FDA provide a report within 60 days of enactment, including a detailed accounting of FDA's methodology for postmarket tracking of Zohydro and findings to date. In addition, the Committee encourages FDA to continue its outreach to the medical community and provide data about the utilization of REMS-compliant training programs by prescribers. Lastly, the Committee includes bill language that prevents FDA from obligating $20,000,000 of its discretionary funding for the Office of the Commissioner unless the agency finalizes the draft guidance entitled "Industry Guidance: Abuse-Deterrent Opioids—Evaluation and Labeling." If by June 30, 2015, FDA does not complete this guidance, the $20,000,000 will be used by the Office of Criminal Investigation to assist in the prevention of opioid drug abuse.

FDA Response
FDA carefully assesses the risks and benefits of all proposed prescription drug products. This includes, in the case of opioids, the risk of abuse by patients and non-patients and the consequences of that abuse. We concluded that the benefits of Zohydro ER outweighed its risks

despite its lack of abuse-deterrent properties. At the time of its approval, Zohydro ER was the first extended-release (long-acting) hydrocodone product and the first single-entity hydrocodone product; all previously-approved hydrocodone products (e.g., Vicodin) were short-acting and contained acetaminophen, which is associated with liver toxicity risks.

FDA has worked to facilitate the introduction of opioid drug products that can be expected to deter abuse. The latest such product to be approved, Hysingla ER, is, like Zohydro ER, a single-entity extended-release hydrocodone product. Hysingla ER's sponsor is required to study the impact of that product's abuse-deterrent properties on actual abuse as a condition of approval, and FDA will assess the benefits and risks of other hydrocodone-containing drug products, including Zohydro ER, in light of that information as it becomes available. FDA will also continue to carefully scrutinize all available information concerning prescribing patterns and abuse of Zohydro ER, as it has done since that product's approval.

FDA shares your concerns about prescription opioid drug abuse and strongly believes that abuse-deterrent formulations can play a role in curbing that abuse. We believe, though, that concerns about abuse should not focus on specific products, but rather the entire class of opioid products. This is especially true in the case of products like Zohydro ER that account for only a tiny fraction of the prescription opioid market.[63] A report that focuses on Zohydro alone is unlikely to yield meaningful information.

FDA believes that it is critical to focus on changing clinical and patient behaviors that contribute to opioid-related morbidity and mortality. The Agency is attempting to do that through its REMS for all extended-release and long-acting opioids, which requires sponsors to provide opioid prescriber training, data about utilization of REMS-compliant training programs by prescribers, and patient education materials. Zohydro ER and Hysingla ER are part of that REMS.

FDA is in the process of revising the abuse-deterrent opioids guidance and is committed to publishing it in final form soon. We believe the basic framework laid out in the 2013 draft guidance is sound. FDA has approved four opioid product labels with abuse deterrence claims since the draft guidance issued. Publishing a final version will be helpful, but it is important to note that the fact that this guidance is not yet final has not prevented and will not prevent FDA from evaluating proposals to include abuse-deterrence language in the labeling of specific products.

The Agency is also working on the appropriate testing protocols and evaluation standards for generic versions of opioids with potentially abuse-deterrent properties, and plans to publish guidance on that topic in the near future as well. More generally, FDA is committed to making progress on setting and applying appropriate regulatory incentives and expectations regarding abuse-deterrent opioids, and will continue to prioritize this effort.

[63] The Committee is correct that hydrocodone-containing products are widely prescribed, but these products overwhelmingly consist of short-acting combination products like Vicodin, not long-acting products like Zohydro ER and Hysingla ER that are indicated only for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate.

31. Tobacco Product Smuggling

The Committee understands that nearly one in four packs of cigarettes consumed in Texas is smuggled in from Mexico and more than half of the cigarettes consumed in New York are the result of interstate smuggling operations. In addition, an average of one out of every five packs of cigarettes consumed in California, Arizona, and New Mexico are the result of smuggling operations. FDA's regulation over tobacco products provides the agency with unique expertise and intelligence in the area of tobacco sales and market dynamics. The Committee recommends FDA's Office of Criminal Investigations assist Federal, state, and local agencies in targeting the highest-level criminal tobacco trafficking organizations by gathering intelligence and disseminating leads with their partner organizations to help address this illicit activity.

FDA Response
The Food and Drug Administration's Office of Criminal Investigation (FDA-OCI) combats the smuggling of illicit goods, including regulated tobacco products, in a variety of ways. FDA-OCI gathers and analyzes intelligence from domestic and foreign governments and other public and private sources to identify individuals and organizations involved in illicit activity. FDA-OCI also partners with local, state, and federal agencies to combat the illicit trade of violative FDA-regulated tobacco products.

32. Spending Plan

Not later than 30 days after the date of enactment of this Act, the Secretary of Agriculture, the Commissioner of the Food and Drug Administration, and the Chairman of the Farm Credit Administration shall submit to the Committees on Appropriations of the House of Representatives and the Senate a detailed spending plan by program, project, and activity for all the funds made available under this Act including appropriated user fees, as defined in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act).

FDA Response
FDA provided the report that the Committee requested.

33. Compassionate Use

The Committee is concerned with a lack of useful data regarding the number of Expanded Access (sometimes called compassionate use) requests made on behalf of patients that are denied by sponsors of investigational products. In order to obtain an accurate understanding of the scope of this problem, the Committee requests that GAO conduct a review of how FDA is working with all stakeholders to accelerate the approval of innovative, safe, and effective medicines and how FDA takes into account safety and efficacy data from Expanded Access programs.

FDA Response
This is a challenging and complex issue and we welcome thoughtful efforts to improve existing programs. FDA is willing to work with sponsors of investigational products to explore avenues for appropriate expanded access to drugs to treat serious and life-threatening diseases.

SENATE APPROPRIATIONS COMMITTEES SIGNIFICANT ITEMS

SENATE COMMITTEE REPORT 113-164

1. Abuse Deterrent Drug Development

The Committee urges FDA to make faster progress on setting and applying appropriate regulatory incentives and expectations regarding abuse-deterrent opioids. This includes finalizing the January 2013 draft guidance on evaluation and labeling of abuse-deterrent opioids and publishing draft guidance on the assessment of generic versions of such products. The draft guidance on generics should include a discussion of whether and in what circumstances human abuse liability studies will be needed, and if so, how applicants can ensure that such studies are acceptable for review by FDA. The Committee further urges FDA to include, where appropriate, descriptions of studies of a product's abuse-deterrent properties when a sponsor has not yet established a claim of abuse deterrence.

FDA Response
FDA believes it has made substantial progress on this important topic but agrees that more work remains to be done. Thus far, four opioid product labels have been approved with abuse deterrence claims consistent with the 2013 draft guidance. FDA is in the process of revising and finalizing this guidance. However, the fact that this guidance is not yet final has not and will not prevent FDA from evaluating proposals to include abuse-deterrence language in the labeling of specific products.

FDA is also working on the appropriate testing protocols and evaluation standards for generic versions of opioids with potentially abuse-deterrent properties and plans to publish guidance on that topic in the near future. FDA expects that the issues concerning human abuse liability studies raised in the Committee's report will be addressed in the latter document.

2. Antibiotics

The Commissioner is urged to devise a strategy to help ensure the use of medically important antibiotics in food animals for disease prevention, as defined in guidance for Industry No. 213, that is judicious and appropriate. Additionally, the Commissioner is directed to finalize a Veterinary Feed Directive rule prior to April 1, 2015, and is encouraged to include provisions that provide adequate assurance that licensed veterinarians will be familiar with the animals and premises where they are kept when prescribing medically important antibiotics for use in food animals.

FDA Response
FDA's GFI #213 will eliminate the use of medically important antimicrobials for production uses, and require veterinary oversight of the remaining therapeutic uses (for treatment, control, or prevention of disease) of these products in the feed or water of food-producing animals. While these represent significant changes in the way these products have been used it animal agriculture for decades, FDA acknowledges that they may not address all concerns. Once GFI #213 is fully implemented FDA will continue to engage in this issue to ensure that public health and animal health needs are addressed.

FDA has completed analysis of over 2000 public comments received regarding proposed changes to the Veterinary Feed Directive (VFD) rule, including several that relate to the issue raised about

the adequacy of veterinary oversight. FDA is considering all such comments while drafting the final regulation, which is currently targeted for publication in May 2015.

3. Artificial Pancreas

The Committee commends the FDA for taking critical steps in advancing artificial pancreas systems, including its recent approval of the threshold suspend system. The Committee encourages the FDA to continue collaboration with key stakeholders to ensure that artificial pancreas systems are further developed, tested and approved, ensuring timely access to safe and effective systems for patients with type I diabetes.

FDA Response
FDA has made substantial progress in advancing the development of safe and effective artificial pancreas device systems. Our proactive role in Artificial Pancreas development has been widely appreciated by the diabetes community. In 2014, we reviewed and approved approximately 30 experimental Artificial Pancreas systems investigational protocols. We continue to collaborate with stakeholders, including researchers, clinicians, manufacturers, investors, policymakers, and patient advocates to help clarify expectations, solve challenges as they arise, and encourage the development of Artificial Pancreas systems for people with type 1 diabetes. We are working closely with Artificial Pancreas device sponsors to balance premarket and postmarket studies with the goal of significantly reducing the time to market. With these efforts, we strongly believe that an Artificial Pancreas is within technological reach and fully expect the first approved closed-loop artificial pancreas device in the United States in the next few years.

4. Compounding Guidance Documents

The Committee notes that the Food and Drug Administration has begun implementing the Compounding Quality Act by releasing guidances and working to appoint members to the Pharmacy Compounding Advisory Committee. The Committee is concerned that the Food and Drug Administration is not meeting with any stakeholders before publicly releasing further guidance for public comment. The Committee directs the Food and Drug Administration to meet with stakeholders to help inform the implementation of the Compounding Quality Act to ensure continued access to safe compounded drugs for which there is a clinical need.

FDA Response
FDA recognizes the Committee's concern and recommendation, and notes that we have in fact met with many key stakeholders and are considering their views as we implement sections 503A and 503B of the FD&C Act. In addition to the 50-state meeting held on March 20-21, 2014, in May, 2014, we met with several Federal agencies that handle or reimburse for compounded drugs, and during June, July, and September, 2014, FDA held listening sessions with over 40 stakeholder organizations, including pharmacy groups, hospital associations, consumer groups, and medical practice groups. We obtained a lot of information during these sessions, which we are considering as we develop additional regulations and guidances.

We also note that we have heard from numerous stakeholders, including Congress, about the need to expeditiously issue guidance with regard to the requirements for facilities registering as outsourcing facilities under section 503B, as well as on various topics regarding implementation of section 503A. FDA has indicated to all stakeholders who have requested meetings its willingness to entertain written submissions from them concerning their views, and in two cases, groups of stakeholders have provided FDA with suggested draft guidance. Other stakeholders have provided their views on a variety of topics in comments submitted in response to the draft

guidances published in the Federal Register after the DQSA was enacted, and FDA is considering those comments. FDA believes that stakeholders can provide more meaningful input on a topic after they see FDA's proposed approach as described in a draft guidance or a proposed regulation. As we did with the six draft guidances issued since the enactment of the DQSA, FDA intends to continue to issue guidances in draft for public comment in accordance with its Good Guidance Practices regulations (21 CFR 10.115), and to engage in notice and comment rulemaking. For example, in July, 2014, FDA published a proposed rule to update the list of drugs that may not be compounded under section 503A or section 503B because they have been withdrawn or removed from the market because they have been found to be unsafe or ineffective. FDA will consider comments received on the proposed rule and on any draft guidances and issue final regulations or guidance, respectively. To date, FDA has issued final versions of three guidance documents previously issued in draft, taking into consideration the public comments that we received. Delaying all guidance until after FDA has met with all stakeholders would unnecessarily delay issuance of guidance necessary to help achieve the public health protections that led to the enactment of the DQSA.

5. Comprehensive Device Review Assessment

FDA is directed to participate in a comprehensive assessment of the process for the review of device applications conducted by an independent entity capable of performing technical analysis, management assessment, and program evaluation for the device review program. In consultation with FDA and industry, the assessment should include, but is not limited to, an identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards; analysis of elements of the review process to facilitate a more efficient process; assessment of FDA methods and controls for collecting and reporting information on premarket review process resource use and performance; assessment of the effectiveness of FDA's Reviewer Training Program implementation; and recommendations for ongoing periodic assessments and any additional, more detailed or focused program assessments. Following this assessment, FDA is directed to report to the Committee, within 120 days of the enactment of this act, on the findings of the assessment and the agency's plan to incorporate those findings and recommendations, as appropriate, into its management of the premarket review program.

FDA Response

FDA agreed to participate with the medical device industry in a comprehensive assessment of the process for the review of device applications. A two-phase assessment was conducted by a private, independent consulting firm. The first phase of the analysis involved an assessment of the medical device submission review process. The MDUFA III Commitment Letter specified that the independent assessment identify process improvements and best practices (i.e., those likely to have a significant impact on review times). The Letter also specifies that FDA publish an implementation plan for each set of recommendations, within six months of receipt of the recommendations.

On December 11, 2013, Booz Allen Hamilton (BAH), the independent contractor, issued a report on the priority recommendations, "http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf" The report identified four priority recommendations. Each intended to improve the efficiency and review time of medical device submission review:

- Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process.
- Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews.
- Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes.
- Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews.

On June 11, 2014, FDA issued a plan of action (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM400674.pdf) outlining the actions it intends to implement based on the four identified priority recommendations. In December 2014 FDA issued another plan of action (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM426392.pdf) in response to BAH's final report on findings and recommendations. It includes revisions to address additional information and outlines the actions FDA plans to implement in response to the additional seven recommendations identified in the final report. FDA's approach to addressing the recommendations remain the same; recognizing that the recommendations can be expanded to further enhance the efficiency of our processes.

6. Counterfeit Products

The Committee recommendation includes an increase of $4,820,000 to provide FDA with additional resources to investigate counterfeit drugs both within the United States and internationally. These funds will be used to complete undercover purchases of suspected counterfeit products for testing; to remove counterfeit products from the market; and to prosecute criminal actors. The Committee believes that the growing marketplace for counterfeit drugs available on the Internet is particularly concerning, and these funds will allow FDA to enhance its cybercrime program, which will ultimately allow FDA to seek appropriate criminal fines and forfeitures, and to protect the public health.

FDA Response
FDA shares the Committee's concern about the threat posed by counterfeit products and appreciates the vital, additional resources it has provided for enhanced enforcement efforts.

7. Fixed Dose Combination Drugs

The Committee applauds the agency's issuance of draft guidance to promote the development of fixed combination drug products for critical diseases like cancer, HIV, global diseases like malaria and tuberculosis, and against health threats like drug-resistant infections. The Committee encourages the FDA to finalize the guidance by the end of this calendar year to facilitate development of new treatments against serious and life-threatening diseases.

FDA Response
On October 10, 2014, FDA published the final guidance titled, "New Chemical Entity Exclusivity Determinations for Certain Fixed-Dose Combination Drug Products." Combination therapy is emerging as the standard of care in certain disease settings, such as cancer, cardiovascular disease, and infectious diseases like HIV and AIDS. FDA recognizes the importance of such combination therapies and has aligned its policy to encourage their development. The final guidance recommends 5-year exclusivity for fixed-dose combination drugs containing a single, new active

drug substance. This policy will be applied to new drug applications approved on or after the publication of this final guidance.

8. Food Safety Modernization Act

The Committee notes that FDA has stated its intent to re-propose certain sections of the Food Safety Modernization Act proposed rules for produce safety and preventive controls for human food and animal food because significant changes are warranted. The Committee is concerned that the agency only intends to address discrete portions of these proposed rules. FDA is reminded that the activities covered by the proposed rules are complex and interrelated and that the concerns raised by the rules are broader than the handful of items FDA has announced that it will address. The agency shall ensure that all Food Safety Modernization Act regulations are science-based, risk-based, and flexible, taking into account the different risks posed by different commodities. For example, the secondary market for spent grains and byproduct from human food manufacturing and agricultural practices is an important part of the supply chain for agricultural producers that reduces waste and produces safe, cost effective animal feed. FDA should reconsider how its proposed preventive controls for animal food rule will affect this relationship and the environment. Additionally, FDA should take into account the diversity of many integrated livestock and poultry feeding arrangements, and aquaculture feeding arrangements, when promulgating the final rule. Further, FDA is directed to ensure that the public has an opportunity to review and comment on all preventive controls for human food requirements, accompanied by an economic analysis, including such elements as supplier verification, environmental monitoring, and verification testing of products in the form of a proposed rule, not an interim final or final rule. FDA should allow flexibility in the location and frequency of verification testing. The Committee strongly encourages the agency to re-propose the produce safety and preventive controls for human and animal food rules in their entirety so stakeholders may comment on the agency's proposals as a whole.

FDA Response

FDA published four supplemental notices of proposed rulemakings on September 29, 2014, including: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food); and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls for Animal Food). One of the issues addressed in the supplemental notices, for public comment, was the treatment of human food byproducts, including spent grains, when used as animal food. In the supplemental notice for Preventive Controls for Animal Food, FDA also discussed and specifically asked for comment on feed mills associated with contract or vertically integrated farming. Further, the supplemental proposals on Preventive Controls for Human Food and Preventive Controls for Animal Food included regulatory language for potential requirements for supplier verification, product testing, and environmental monitoring for public review and comment. The proposed regulatory language would provide flexibility for product testing and environmental monitoring, to be performed as appropriate to the facility, the food, and the nature of the preventive control. FDA is committed to ensuring that our implementation of FSMA is science-based, risk-based, and flexible, as appropriate.

The comment periods for the original proposed rules were 120 days and were each extended in response to requests by the public. The comment periods for the Produce Safety proposed rule and the Preventive Controls for Human Food rule were extended three times: on April 26, 2013,

the comment periods were extended an additional 120 days (78 FR 24691 and 78 FR 24692); on August 9, 2013, the comment periods were extended another 60 days (78 FR 48636 and 78 FR 48637), and on November 20, 2013, the comment periods were extended a final 7 days (78 FR 69604 and 78 FR 69605). The comment periods for these two proposed rules, originally published on January 16, 2013, did not end until November 22, 2013. The comment period for the animal preventive controls rule was extended on February 3, 2014, to March 31, 2014 (79 FR 61111). Finally, FDA provided a 75 day comment period for the supplemental notices of proposed rulemaking. We note that we have conducted throughout this process, even before the first original proposals were published in January 2013, extensive outreach to our stakeholders to seek their input and engage them in the rulemaking process.

FDA is currently under a consent decree issued by the Federal District Court for the Northern District of California Oakland Division dated February 25, 2014 (Case No. 12-cv-04529-PJH), to issue the final rules on Preventive Controls for Human Food and Preventive Controls for Animal Food by August 30, 2015, and the final rule on Produce Safety by October 31, 2015. This is an extremely tight timeframe for all the work that is needed to review, analyze, and respond to the comments received, draft the final rules, and move the rules forward through clearance to publish by the court ordered deadlines. Reproposing the rules in their entirety would make it impossible to meet these deadlines.

9. Food Safety Outreach and Technical Assistance

As FDA implements the requirements of the Food Safety Modernization Act [FSMA], it is critical that the agency work with USDA to perform outreach and technical assistance to farmers and small businesses to help them understand FSMA requirements and resources available to help with FSMA compliance as rules are developed and implemented. The Committee recommendation includes $2,500,000 for the National Institute of Food and Agriculture to conduct extension activities related to FSMA, as requested in the budget.

FDA Response
FDA intends to continue this activity.

10. Global Drug Supply Chain

FDA is directed to ensure that adequate resources are dedicated to the Office Global Regulatory Operations and Policy and the Center for Drug Evaluation and Research to advance the agency's strategic priority of strengthening the safety and integrity of the global drug supply chain. In order to advance this initiative, resources should be dedicated to FDA's international leadership to combat threats to global health and the global drug supply chain from counterfeit medicines; promote regulatory convergence and the harmonization of international standards that will strengthen global drug supply chain security; and build upon and achieve key goals as articulated in FDA's reports on Global Engagement and the Pathway to Global Product Safety and Quality. As part of this effort, funding and personnel should be dedicated to advance the success of key efforts, including the FDA-championed Global Road Map on Medical Product Quality and Supply Chain Integrity under the Asia Pacific Economic Cooperation Regulatory Harmonization Steering Committee which will require FDA's continued leadership to ensure its success and tangible outcomes. In addition, adequate resources should be dedicated to FDA's work to improve policy, international cooperation, and enforcement collaboration related to the Internet and the unprecedented growth in illegal drug sales via the Internet, including the online trade of counterfeit, adulterated, misbranded, and unapproved drugs.

FDA Response
FDA shares the Committee's priority to protect the safety and security of the global drug supply chain in an increasingly complex and interconnected world and appreciates the appropriation of additional resources to assist in such efforts. We intend to bolster and strengthen our active engagement with government regulatory counterparts in other nations, as well as with industry regional and international organizations, to enhance oversight of safety and quality throughout the supply chain. The foundation for these efforts is built on information-sharing, data-driven risk analytics, enhanced intelligence, and the smart allocation of collaborative resources.

11. Import Shipments

The Commissioner is encouraged to ensure that sufficient FDA personnel are available to clear shipments expeditiously at the time of their arrival at the port of entry, including outside normal working hours and on holidays. The Commissioner is further encouraged to work to develop a process by which shipments from highly compliant importers may be released with minimal administrative disruption. Recognizing that FDA has a responsibility to ensure legitimate trade is cleared rapidly and that compliant shipments are not unduly detained, FDA is directed to provide two reports to the Committees on Appropriations, the first 6 months after the enactment of this act, and the second in 6 additional months. These reports shall provide information on the number of shipments being identified for FDA examination as a percentage of all shipments subject to FDA regulatory review and the number of violative products detained as a percentage of those being held.

FDA Response
FDA will provide the reports the Committee has requested, as well as updates on its process to clear shipments by highly compliant importers. Currently, FDA is still in the process of developing the rules for the Voluntary Qualified Importer Program (VQIP), which is designed to expedite the review and entry of food. The deadline for the agency to submit rules to the Federal Register is October 31, 2015.

12. Inclusion in Clinical Trials

Research has shown that gender differences, as well as differences based on age, race, or other factors, may contribute to differences in the safety and efficacy of drugs, biologics, and devices. The Committee directs FDA to encourages diverse participation, including women, racial and ethnic minorities, and the elderly, to help assure that clinical trials are representative of those individuals who ultimately will use these medical products, and that the products will be safe and effective for people in these demographic subgroups. The Committee urges the FDA to issue the Action Plan required by section 907 of the Food and Drug Administration Safety and Innovation Act and provide a timeline for implementation of the actions FDA will take, in cooperation with industry stakeholders, to ensure that women, minorities, and others are appropriately represented in clinical research, that meaningful subgroup analyses of clinical trials are conducted, and that subgroup specific clinical trial results are made publically available in an accessible and timely manner.

FDA Response
FDA shares the Committee's commitment to encourage diversity in clinical trials among all demographic subgroups including women and minorities. Following extensive consultation with stakeholders, FDA released its *Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data* in August, 2014. The Plan includes specific action items to improve

the quality of demographic subgroup reporting and analysis, encourage greater subgroup participation, and enhance the availability of data. The Agency's scientific reviewers are actively encouraging drug sponsors to conduct trials in a broad population that closely resembles their products' intended audience. They evaluate proposed clinical trial exclusions with a critical lens – and recommend modifications during early drug development interactions with sponsors. Such efforts are guided by a Good Review Practice Manual of Policies and Procedures (Clinical Review of Investigational New Drug Applications) published in December 2013 that emphasizes that clinical trial inclusion needs to become a regular part of our assessment of individual trials and overall development plans. Further, as part of FDA's commitment to transparency of clinical trial data, it has created a new website called Drug Trials Snapshot. Six recently approved new drugs have been posted with subgroup analyses by sex, race, and age. The FDA is asking for public comments on these postings and plans to post demographic data of all new drugs approved beginning in 2015.

Achieving clinical trial inclusion goals will require FDA's active engagement and that of many of our stakeholders including federal partners, industry, health care professionals, patient advocacy groups, and community-based organizations. Some of the action items identified in FDA's Action Plan can be accomplished quickly. Others will require more time and resources. We look forward to collaborating and advancing our common goal -- improving the safety and efficacy of all medical products.

13. Mammography Quality Standards Act

The Committee recommendation includes full funding as requested for implementation of the Mammography Quality Standards Act. This program sets national quality standards for mammography facilities, equipment, personnel, and operating procedures, and has improved the quality of mammography and made mammograms a more reliable tool to detect breast cancers.

FDA Response
More than 8,700 FDA-certified facilities nationwide work to uphold the goal of the Mammography Quality Standards Act; FDA will continue to set national quality standards for mammography facilities to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages.

14. Nanotechnology

The Committee recognizes the increased capabilities that FDA has developed to study environment, health, and safety of nanomaterials within FDA's Jefferson Laboratory Campus, including the National Center for Toxicological Research, and its consolidated headquarters at White Oak, Maryland. The Committee expects FDA to continue 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.

FDA Response
The FDA Collaborative Nanotechnology Grants (CORES) program has funded 18 research projects since 2011 and plans to award six projects in 2015. These projects align with the National Nanotechnology Initiative Environment, Health, and Safety Research Strategy as well as the activities listed in Section 1126 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144). These projects have increased FDA knowledge on nanotechnology and led to the development of vital regulatory science tools, such as assays, assessment

methodologies, and test protocols FDA uses to evaluate nanotechnology in FDA-regulated products.

Through these projects, FDA staff developed working knowledge of nanotechnology which they shared with the scientific community through peer-reviewed journal articles and presentations at FDA and scientific conferences. These projects increased collaboration across FDA and strengthened the agency's relationship with academia and across the US Government.

Finally, the research findings from these projects proved vital in drafting regulatory guidance to industry and in providing sound and scientifically based responses to inquiries from stakeholders.

Together, the CORES projects along with the development of core facilities at Jefferson Laboratories and White Oak campus, regulatory science focused research projects within the FDA, and training through multiple modalities have enhanced FDA's ability to understand and regulate nanotechnology-based products. FDA will continue 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.

15. Office of Cosmetics and Colors

The Committee recommendation includes 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 notes that every year since fiscal year 2012, it has requested that OCAC respond to a citizen petition setting safety levels for trace amount of lead in cosmetics. The Committee is disappointed that OCAC has not responded to these requests and urges OCAC to make this a priority. Therefore, the Committee directs the Office of Colors and Cosmetics to respond to the petition by March 15, 2015. Additionally, in light of China's importance to U.S.-based manufacturers and consumers, the Committee directs FDA establish a bilateral technical dialogue with Chinese regulators. The Committee directs FDA to promote international regulatory harmonization and trade in cosmetic products by supporting international trade negotiations on cosmetics in bilateral and multilateral trade agreements.

FDA Response

OCAC will use FY 2015 funding for direct support of the operation, staffing, compliance, research, and international activities performed by the office. As noted in our response to the Committee last year, although the data currently 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. FDA expects to meet the March, 2015 due date for response to the citizen petition.

FDA has established a collaborative relationship with Chinese regulators on cosmetic safety issues and continues to maintain an interactive dialogue. A bilateral forum with the Chinese regulators is anticipated to occur in 2015. FDA also actively participates in various international trade negotiations on cosmetics (e.g., the Transatlantic Trade Investment Partnership or TTIP with the European Union).

16. Pediatric Device Consortia Grants

The Committee is pleased that the nine FDA-funded Pediatric Device Consortia have assisted in advancing the development of 324 proposed pediatric medical devices since its inception in 2009, as well as promoting job-growth in the healthcare sector, and as such, continues to support this critical effort. 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 currently available on the market. However, the Committee remains concerned that children's medical devices continue to lag behind those manufactured for adults and directs the FDA to fund the program at the levels authorized by the Food and Drug Safety and Innovation Act of 2012 (Public Law 112–144).

FDA Response
FDA continues to support this important pediatric program which supports eight consortia across the United States. The consortia funded by this program have assisted in the evaluation and/ or development of over 440 potential pediatric devices since the program's inception. One hundred and forty-six of these proposed devices continue to receive input from the consortia as active projects. Note that if the program were to be funded at the levels authorized by the Food and Drug Safety and Innovation Act of 2012 (Public Law 112-144), it would adversely impact CDRH's ability to meet other mandates, unless additional appropriations were provided for this specific purpose.

17. Prescription Drug Inserts

The Committee is aware that FDA is considering regulatory changes that could eliminate printed professional inserts for prescription drugs. A July 2013 GAO report on the topic concluded that while there were potential public health benefits associated with electronic drug labeling, relying exclusively on electronic labeling could disadvantage physicians, pharmacists, other healthcare providers, and ultimately patients, potentially adversely impacting public health. Therefore, the Committee directs FDA to ensure that any proposed regulation regarding electronic inserts of drug labeling does not come in lieu of paper inserts.

FDA Response
On December 18, 2014, FDA issued a proposed rule entitled "Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products." This proposed rule addresses the Committee's concerns and the findings from the GAO report about exclusive reliance on electronic inserts in lieu of paper inserts, while at the same time ensuring that the most up-to-date prescribing information is available for use by health care providers.

The rule, if finalized as proposed, would require that prescribing information be distributed, in most cases, electronically rather than in paper form. However, the proposed rule allows for drugs to be exempted from electronic-only distribution if electronic-only distribution could adversely affect the safety, effectiveness, purity, or potency of the drug, is not technologically feasible, or is otherwise inappropriate. Examples of circumstances where it may be appropriate to exempt a product from the requirements for electronic distribution of prescribing information include a product which requires multiple steps for reconstitution, a product that is intended for use in an emergency room, or a product that may be stockpiled for use during an emergency.

In addition, if the Internet is not available, under the proposal, a health care provider may request a copy of the prescribing information from the manufacturer. FDA is proposing to require that manufacturers provide a toll-free telephone number (printed in the statement appearing on the

immediate container label and outer container) that the health care provider can call to request that the manufacturer provide the most current prescribing information by FAX, email, or mail. The manufacturer would be required to ensure that the toll-free telephone number is current, fully-functioning, and maintained so that there is always an alternate method to obtain the current prescribing information if the requestor cannot access the FDA's labeling repository web site. The toll-free telephone number would be required to be available 24 hours a day, 7 days a week. The manufacturer would be required to take adequate steps to ensure that it provides the requested prescribing information promptly.

FDA believes that electronic drug labeling offers significant benefits over a paper based system. It ensures that the most current prescribing information, reflecting newly identified safety risks, newly approved uses for a drug already on the market, and other current information about the drug, will be available and readily accessible at the time of clinical decision-making and dispensing. It also delivers content in a more user-friendly format.

For the Agency to better understand the impact of the proposed regulation on the various stakeholders, in the preamble to the rule, we have specifically requested comment related to electronic distribution of professional prescribing information, and we will consider all comments prior to issuance of a final regulation.

18. Seafood Advisory

The Committee is concerned that after many years, the FDA has not published an updated advice on seafood consumption for pregnant women, mothers, and children. The Committee directs the FDA to publish final advice to pregnant women on seafood consumption in conjunction with all applicable parties as directed in House Report 112–101 and Senate Report 112–73 by June 30, 2014.

FDA Response

On June 10, 2014, FDA and EPA jointly issued a draft update to the seafood advice they last issued in 2004. The updated joint advice tracks the current recommendation in the Dietary Guidelines for Americans 2010, issued by the Departments of Agriculture and Health and Human Services, in that it advises pregnant women, women who may become pregnant, and nursing women eat at least 8 and up to 12 ounces per week of a variety of fish lower in mercury in order to optimize the developmental benefits that fish could provide. The two agencies announced that there would be at least one public meeting on the advice, to be held by the FDA Risk Communication Advisory Committee (RCAC). For that reason, the public comment period, which opened on June 11, was indefinite until such time as that meeting, and any other meeting, could be held. Specifically, FDA and EPA announced that the comment period will be open until 30 days after the last transcript from the advisory meeting and any other meetings that the agencies hold on this subject becomes available. The Risk Communication Advisory Committee met on the fish consumer advice on November 3-4 and the transcript from that meeting has recently become available. Since no other public meetings are planned, FDA and EPA will soon announce a date for the closing of the comment period by publishing a notice in the Federal Register. Once the comment period closes, the agencies will study the public comments, make whatever modifications to the advice are appropriate, and publish the updated advice. We expect this process to be completed in 2015.

19. Seafood Economic Integrity

The Committee recognizes the importance of seafood to a healthy diet, but is concerned that the FDA does not focus sufficient attention on economic integrity issues, particularly with respect to mislabeling of species, weights, and treatment. The Committee encourages the FDA to work with States 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 our 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 is preparing to expand its DNA capabilities by releasing new test methodologies for detecting crustacean DNA, allowing for species substitution analysis of shrimp, crab and lobster. FDA works toward implementing better-targeted and more efficient sampling strategies to identify seafood misbranding and adulteration and is currently conducting an evaluation of retail seafood counter substitution with the assistance of multiple states and their respective inspection agencies. FDA is currently a part of the new Presidential Task Force established to combat IUU Fishing and Seafood Fraud; and as such works closely with several agencies such as DOC-NOAA and DHS-CBP to help better target fraudulent activities.

20. Shellfish Embargo

As a result of a dispute over sanitation protocols, the European Union imposed a retaliatory ban on U.S. shellfish in July 2010, depriving U.S. shellfish growers of a lucrative market. The Committee is concerned that, in nearly 4 years, a resolution has not been achieved. The Committee recommends that the FDA continue its ongoing consultation with the U.S. Trade Representative [USTR] to address the issue as expeditiously as possible. The FDA is also directed to provide a report to the Committee on this issue within 100 days.

FDA Response
The FDA is committed to working with the EU on a two-way equivalence determination between the US and the EU (Netherlands and Spain) for trade of molluscan shellfish. Current discussions are focused on the remaining issues of additional controls that The Netherlands and Spain have agreed to put into place in certain growing areas and production controls to satisfy US requirements and EU concerns with biotoxin control procedures used by the US. Both sides will audit conditions in the other's territory to confirm that required controls have been implemented effectively. The EU will audit the United States first with tentative dates in March 2015 and the FDA will follow thereafter with audits of the Netherlands and Spain. FDA continues to consult with USTR to address this issue.

21. Special Protocol Assessment

The Committee is aware that questions have arisen in connection with the rescission of a Special Protocol Assessment [SPA] Agreement. While FDA can rescind a SPA agreement reached under section 505(b)(5)(C) of the Food, Drug, and Cosmetic Act if certain requirements are met, the Committee expects that FDA should be accountable for continued diligence in in identifying issues that bear on a SPA agreement and in notifying the sponsor of such issues within a reasonable period of time after FDA becomes aware. To ensure clarity over the standard to rescind a SPA agreement, the Committee encourages FDA to revise and re-issue, after public

comment, its existing guidance regarding SPA agreements, including the statutory standards associated with the rescission of such agreements.

FDA Response
The statute permits an SPA agreement to be rescinded if "a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the [clinical trial] has begun."[64] FDA takes SPA agreements seriously and has rarely rescinded an SPA agreement. Since FDAMA was enacted in 1997, CDER has issued over 1000 SPA agreements. Fewer than 1 percent have been rescinded. SPA rescission decisions are made on a case-by-case basis after careful review of the circumstances to determine whether the statutory standards have been met.

FDA is working to revise the *Guidance for Industry: Special Protocol Assessment* to clarify which protocols qualify for review under SPA, clarify the SPA process, provide sponsor options after receipt of a Non Agreement Letter, and add a new section that describes rescission of an SPA, including the opportunity for the sponsor to meet with FDA prior to rescission. We anticipate publication of the revised draft guidance by the end of calendar year 2015.

22. Sunscreen Labeling Regulations

The Committee is pleased that FDA finalized regulations establishing significant new labeling and testing requirements for products marketed under FDA's monograph for over-the-counter sunscreen drug products. The Committee directs the FDA to finalize its proposed rule limiting the maximum Sun Protection Factor [SPF] to "50" or "50+" and issue a proposed rule to establish testing and labeling standards for sunscreen sprays.

FDA Response
We share Congress' commitment, expressed in the recently enacted Sunscreen Innovation Act (SIA), to ensure that sunscreens meet modern standards for safety and effectiveness. The SIA requires FDA to issue regulations on the sunscreen monograph, including SPF and dosage forms, within 5 years of enactment. In addition, the SIA requires FDA to establish the criteria the Agency will use to determine whether new, active sunscreen ingredients are Generally Recognized as Safe and Effective (GRASE) for the remaining sunscreen Time and Extent (TEA) applications within 90 days of enactment. We intend to meet this requirement.

23. User Fees

The Committee notes that the restoration in fiscal year 2014 of user fees sequestered in fiscal year 2013 was to be used by FDA to mitigate the impact of the sequester on the user fee programs. This includes the hiring of new staff, and FDA initiatives supported by PDUFA user fees, including the regulatory science activities as outlined in sections IX, X, and XI of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017. The Committee requests that FDA provide a detailed financial summary for the restored fiscal year 2013 PDUFA user fees; identify funding spent to date; and a detailed plan for the allocation of the remaining funds. Specifically, the Committee requests that FDA identify and report to the Committee an itemized accounting of any and all funds expended for each of the regulatory science activities as outlined in sections IX, X, and XI of the PDUFA V Performance Goals and provide a plan for how the PDUFA user fees will be allocated for each such activity through fiscal year 2017.

[64] 21 USC 355(b)(5)(C)

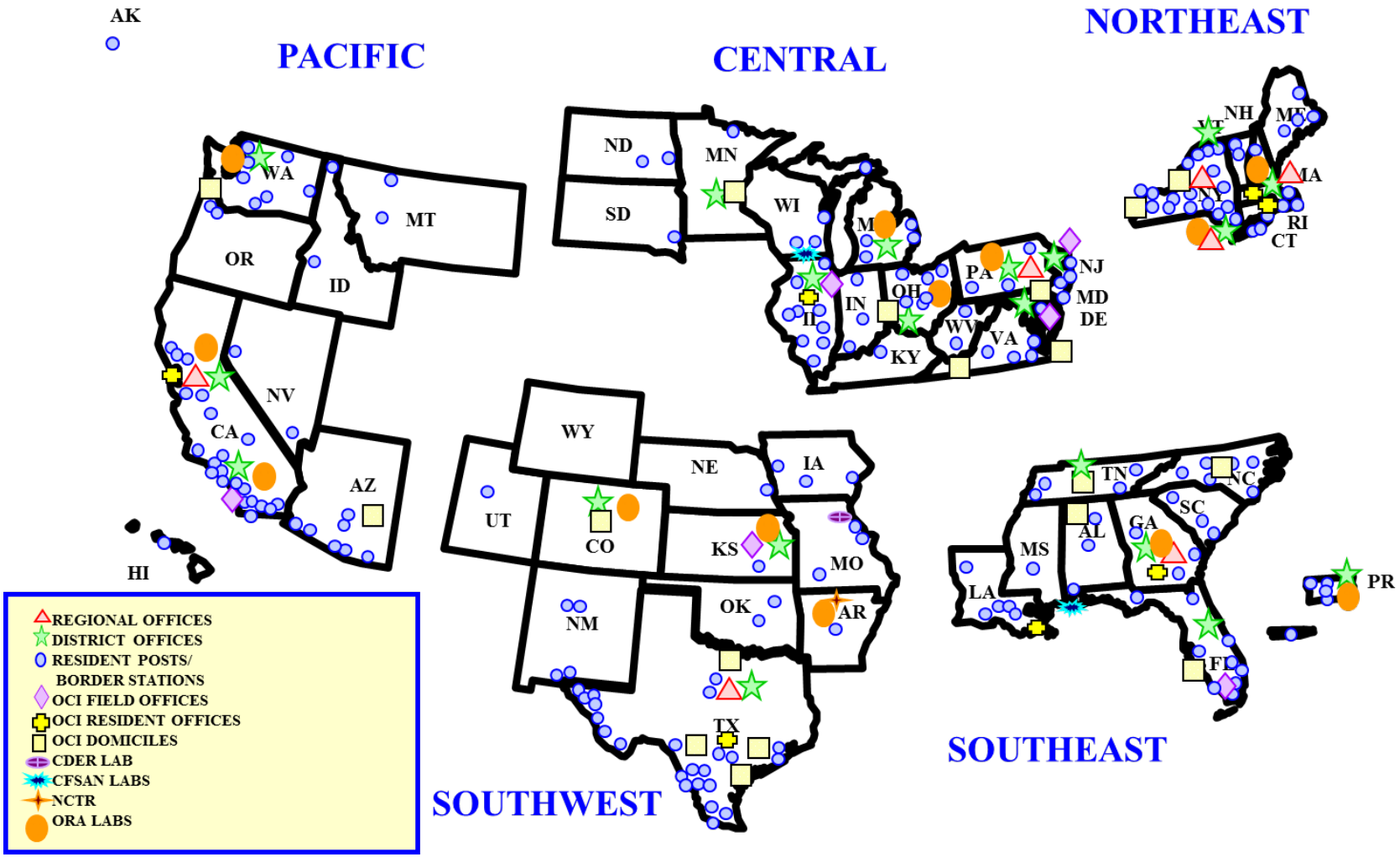
FDA Response
FDA will provide the report that the Committee requested.

24. White Oak Consolidation

The Commissioner is directed to identify in FDA's fiscal year 2016 budget justification the funding level that is necessary to complete Phase II and Phase III of the White Oak Consolidation. Additionally, the Committee expects FDA to provide a justification and spending plan in subsequent budget requests for completion of both Phase II and Phase III of the White Oak Consolidation.

FDA Response
In FY 2016, the Budget includes $5 million to work with GSA to update the Master Plan for White Oak to ensure it identifies the most cost effective way to house FDA's current and projected personnel, to include Phase III buildings to further consolidate FDA staff at White Oak. In the following fiscal years and in concert with GSA funding for design and construction of Phases II and III buildings, FDA will provide necessary funding for miscellaneous items including furniture, IT infrastructure, security, and relocation of staff and associated costs for these phases. It is currently estimated by GSA that completion of Phase II construction will cost $201 million (GSA appropriation) and Phase III will cost $396 million (GSA appropriation). FDA's estimated costs to support construction and occupancy of Phase II and III buildings are $85 million and $115 million, respectively. These FDA estimated costs do not include ongoing and increasing costs for Campus operations. All estimates are subject to change based on delays in receiving funds, including escalation costs, as well as the outcome of the Master Plan update.

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES



HIV/AIDS FUNCTIONAL TABLE

(Dollars in Thousands)

Program	FY 2012 Actual	FY 2013 Actual	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Human Drugs	$32,243	$31,658	$39,455	$39,455	$39,455
Biologics	34,122	32,852	33,596	33,596	33,596
Medical Devices	1,721	1,088	353	353	353
Field Activity	37,720	37,887	35,280	36,750	36,750
Toxological	---	---	---	---	---
Other Activities	3,476	3,410	3,491	3,491	3,491
Total HIV/AIDS	**$109,282**	**$106,895**	**$112,175**	**$113,645**	**$113,645**

CROSSCUTS

(dollars in thousands)	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Antimicrobial Resistance	**26,812**	**32,489**	**47,321**
Budget Authority (non-add)	*25,005*	*30,504*	*45,336*
Behavioral Health	**35,490**	**33,821**	**33,068**
Budget Authority (non-add)	*13,626*	*14,081*	*12,939*
Bioterrorism	**242,118**	**242,118**	**242,118**
Food Defense (non-add)	217,489	217,490	217,490
Medical Countermeasures Initiative (MCMi) (non-add)	*24,552*	*24,552*	*24,552*
Physical Security (non-add)	6,971	6,970	6,970
Life Sciences-Biodefense Complex (non-add)	17,658	17,658	17,658
Drug Abuse	**11,203**	**9,353**	**8,952**
Budget Authority (non-add)	*3,292*	*3,873*	*3,364*
Food Safety	**1,195,171**	**1,228,893**	**1,530,133**
Budget Authority (non-add)	*1,195,171*	*1,214,478*	*1,323,936*
Global Health	**161,327**	**181,636**	**184,123**
Budget Authority (non-add)	*94,870*	*102,767*	*102,442*
Pandemic Influenza	**38,307**	**38,267**	**37,950**
Budget Authority (non-add)	*30,391*	*30,330*	*29,999*
Patient Safety	**395,839**	**420,158**	**431,174**
Budget Authority (non-add)	*193,795*	*202,034*	*199,766*
Pediatric Drugs	**13,240**	**14,767**	**12,529**
Budget Authority (non-add)	*5,549*	*6,766*	*4,428*
Prevention	**3,967,720**	**4,318,505**	**4,382,255**
Budget Authority (non-add)	*2,257,111*	*2,289,707*	*2,344,707*
Precision Medicine	**---**	**---**	**9,704**
Budget Authority (non-add)	---	---	*9,704*
Quality Improvement	**20,465**	**20,818**	**20,992**
Budget Authority (non-add)	*10,867*	*10,967*	*10,967*
Tobacco	**593,192**	**566,000**	**599,000**
Budget Authority (non-add)	---	---	---
Women's Health	**98,659**	**105,722**	**105,962**
Budget Authority (non-add)	*48,660*	*50,116*	*49,429*
Office of Women's Health (non-add)	*4,442*	*4,442*	*4,442*
Breast Cancer (MQSA) (non-add)	*29,413*	*34,047*	*34,486*

CENTRAL ACCOUNTS

Program (dollars in thousands)	FY 2014 Actuals		FY 2015 Estimates		FY 2016 Estimates	
	BA	UF	BA	UF	BA	UF
Foods	**16,263**	**---**	**16,257**	**---**	**16,589**	**---**
Center	5,125	-	5,125	-	5,228	-
Field	11,138	-	11,131	-	11,361	-
Human Drugs	**19,125**	**40,581**	**19,103**	**44,489**	**19,508**	**44,477**
Center	16,184	39,083	16,184	42,547	16,507	42,547
Field	2,942	1,497	2,920	1,942	3,001	1,930
Biologics	**10,022**	**6,810**	**10,033**	**7,132**	**10,222**	**7,128**
Center	9,121	6,299	9,121	6,483	9,303	6,483
Field	901	511	912	649	919	645
Animal Drugs and Feeds	**3,207**	**1,721**	**3,209**	**1,762**	**3,271**	**1,762**
Center	1,931	1,675	1,931	1,715	1,970	1,715
Field	1,276	46	1,277	47	1,301	47
Devices and Radiological Health	**7,680**	**6,257**	**7,696**	**7,574**	**7,834**	**7,574**
Center	5,689	5,469	5,689	6,499	5,803	6,499
Field	1,991	788	2,007	1,075	2,031	1,075
National Center for Toxicological Research	**854**	**-**	**854**	**-**	**871**	**-**
FDA Headquarters	**12,404**	**5,796**	**12,404**	**5,489**	**12,652**	**5,489**
Total	**69,555**	**61,165**	**69,555**	**66,446**	**70,946**	**66,431**

HHS Charges and Assessments

Assessments	**$1,671,603**
NIH eRA Grants Management System Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System	$169,638
Office of Commissioned Corps Force Management SGLI reimbursement	$30,330
Department Ethics Program The Office of General Counsel provides legal and related support services to FDA	$1,470,496
Federal Audit Clearinghouse	$1,139
Fee For Service	**$32,257,550**
Program Support Center/ Office of the Secretary Provides various services to the FDA, including some Information and Systems Management Services	**$12,715,848**
Financial Management Services (FMS)	$645,682
Strategic Acquisition Service	$1,101,668
Administrative Operations Service Includes costs for security, building operations, shredding, storage, graphics, property disposal, trans-share, mail and payroll services	$6,833,698
Facilities and Logistics Service Includes building operations, shredding, storage, and property disposal	$4,134,800
Federal Occupational Health (FOH) FDA agency health units and services	**$2,153,131**
Information & System Management Services	**$15,028,969**
Freedom of Information (FOIA)	$301,480
Unified Financial Management Systems (UFMS)	$6,366,000
The Program Support Center delivers and manages O&M Services for UFMS by supporting daily operations.	
HCAS Operations and Maintenance HCAS O&M services provide support for daily operations of the HCAS application.	$2,229,000
Telecommunication Services Telecommunications team offers expertise on technical design & support for customer systems	$446,022
HHS NET	$907,113
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	$4,779,354
Human Resource Center – Rockville, Maryland	**$2,359,602**

Jointly Funded Projects	**$4,764,717**
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.	$1,644,990
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
Other Jointly Funded Projects	**$1,971,389**
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 (DHHS) contracted and monitored by Office of the Inspector General (OIG) and its components, and related services.	$405,800
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	$147,999
Intra-department Council on Native American Affairs IAG with DHHS, 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	$6,000
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 This needs to be linked into the table of contents.	$68,671

HHS Charges and Assessments

Activity	FY 2014 Actual	FY 2015 Estimate	FY 2016 Estimate
Assessments	**$ 1,671,603**	**$ 1,849,740**	**$ 1,916,831**
Fee for Service	**$ 32,257,550**	**$ 34,472,637**	**$ 47,431,000**
Program Support Center/OS	$ 12,715,848	$ 12,852,057	$ 25,128,000
Federal Occupational Health	$ 2,153,131	$ 2,781,149	$ 2,812,000
Information System Management Service	$ 15,028,969	$ 16,345,523	$ 16,058,000
Human Resource Center – Rockville, Maryland	$ 2,359,602	$ 2,493,908	$ 3,433,000
Jointly Funded Services	**$ 4,764,717**	**$ 4,478,035**	**$ 4,170,286**
Enterprise Information Management	$ 1,644,990	$ 1,239,804	$ 776,000
International Health - Bilateral Agreement	$ 1,148,338	$ 1,231,159	$ 1,319,953
Other Jointly Funded Projects	$ 1,971,389	$ 2,007,072	$ 2,074,333
Total	**$ 38,693,870**	**$ 40,800,412**	**$ 53,518,117**

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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
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
CARB	Combating Antibiotic Resistant Bacteria
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
DOJ	Department of Justice
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
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)
SE	Substantial Equivalence
SEQC	Sequencing Quality Control
SLEP	Shelf Life Extension Program
SNS	Strategic National Stockpile
SP	Strategic Priority
SRL	Southeast Regional Laboratory (SRL)
SW	Southwest
TB	Tuberculosis
TCORS	Tobacco Centers of Regulatory Science
TIMS	Tobacco Inspection Management System
TPMP	Tobacco Product Manufacturing Practice
TPSAC	Tobacco Product Scientific Advisory Committee
UDI	Unique Device Identification
UESC	Utility Energy Service Contract
UF	User Fee
UN	United Nations
USAMRIID	United States Army Medical Research Institute for Infectious Diseases
USC	United States Code
USDA	United States Department of Agriculture
USP	U.S. Pharmacopoeia
VAERS	Vaccine Adverse Event Reporting System
VICH	Veterinary International Conference on Harmonization
VKA	Vitamin K Antagonist
WD	Withdrawn
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization

GLOSSARY OF TABLES

All-Purpose Table (APT)	Provides comprehensive financial information on the budget at the program, project, and activity (PPA) levels.
Amounts Available for Obligation	Lists the base appropriations followed by any rescissions, supplemental funding, transfers, and any other adjustments to provide a total obligation level for that Fiscal Year.
Appropriations History	Lists the ten year history of appropriations and estimates for FDA's Salary and Expenses and Building and Facilities appropriations, excluding indefinite user fees.
Budget Authority By Activity	Provides budget authority and FTE for three years: FY 2014 FY 2015 and FY 2016.
Budget Authority Crosswalks	Highlights absorptions, reductions, and increases by program line and major initiative for a given fiscal year − for example Food Safety, Medical Product Safety, Pay Inflation Cost, Rent and Infrastructure Budget Authority By Activity − starting from the prior budget year.
Crosscuts	Shows programs that are crosscutting throughout FDA. Each crosscut program line in the table shows a "snapshot" of the funding that is targeted toward a specific area in each fiscal year and provides an indication of resource trends.
Detail of Full-Time Equivalent Employment (FTE)	Provides FTE data by FDA organizational component − such as CFSAN, CDER, CBER, etc. − for each of the three fiscal years included in the CJ (Prior Year, Current Year, and Budget Year) as well as a five-year history of the average General Schedule (GS) grade.
Detail of Positions	Provides information on the number of General Schedule (GS), Executive Level (EX), Executive Service (ES), Commissioned Corps (CC), Administratively Determined (AD), and other positions − including Administrative Law Judges (AL), Wage Grade − across FDA, including a three year history of the average GS levels and salaries.
HIV/AIDS Functional Table	Shows a "snapshot" of the funding in FDA targeted toward HIV/AIDS related programs and activities for five fiscal years and provides a breakout of the funding by program line.
Major Activities Table	Provides an overview of the FDA budget by program and major activities: Food Safety, Medical Product Safety, and Medical Countermeasures, including absorptions, reductions, and increases.
Object Classification Tables	Provides information by object class for budget authority, user fees, and total program level − which is a combination of both budget authority and user fees. Object classes are categories that present obligations by the items or services purchased by the Federal Government.

Physicians' Comparability Allowance (PCA)	Provides information on physicians' comparability allowances that are paid to eligible Government physicians (including dentists) in order to recruit and retain them. The PCA is paid only to physicians serving in positions for which there is a significant recruitment and retention problem.
Salaries and Expenses	Breakdowns all salaries and expenses incurred by FDA by object class. The totals for each object class match the object classification tables for budget authority, user fees, and total program level. This table excludes object classes 31.0 to 43.0, when compared to the Object Classification tables.
Summary of Changes	Summarizes the changes in estimates from FY 2015 to FY 2016 and explains those changes on an item-by-item basis by budget authority, user fees, program level, and FTE.