OFFICE OF REGULATORY AFFAIRS – FIELD ACTIVITIES

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Office of Regulatory Affairs	**1,049,021**	**998,913**	**1,124,401**	**1,274,999**	**150,598**
Budget Authority	***934,454***	***934,393***	***1,008,024***	***1,033,739***	***25,715***
User Fees	***114,567***	***64,520***	***116,377***	***241,260***	***124,883***
Prescription Drug (PDUFA)	*16,263*	*8,612*	*14,360*	*14,584*	*224*
Medical Device (MDUFA)	*2,105*	*2,142*	*2,416*	*2,553*	*137*
Generic Drug (GDUFA)	*54,083*	*34,180*	*55,167*	*56,158*	*991*
Biosimilars (BsUFA)	*1,348*	---	*1,382*	*1,416*	*34*
Animal Drug (ADUFA)	*404*	*31*	*411*	*414*	*3*
Animal Generic Drug (AGDUFA)	*186*	---	*259*	*277*	*18*
Family Smoking Prevention and Tobacco Control Act	*15,887*	*9,470*	*16,663*	*14,900*	*-1,763*
Mammography Quality Standards Act (MQSA)	*13,339*	*10,085*	*13,612*	*13,892*	*280*
Food and Feed Recall	*1,000*	---	*1,000*	*1,000*	---
Food Reinspection	*5,382*	---	*5,382*	*5,382*	---
Voluntary Qualified Importer Program	*4,320*	---	*4,320*	*4,320*	---
Third Party Auditor Program	---	---	*1,141*	*1,141*	---
Outsourcing Facility	*250*	---	*264*	*277*	*13*
Food Facility Registration and Inspection	---	---	---	*28,949*	*28,949*
Food Import	---	---	---	*86,122*	*86,122*
International Courier	---	---	---	*5,201*	*5,201*
Cosmetics	---	---	---	*4,674*	*4,674*
FTE	**4,807**	**4,776**	**5,005**	**5,137**	**132**

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) advances FDA's mission to protect public health by conducting field operational activities to ensure the safety, effectiveness, and quality of a wide range of products accounting for about 20 cents of every dollar consumers spend in the United States. These activities are conducted in support of each of the FDA Centers and help to provide

awareness, surveillance, and enforcement of FDA regulations related to our nation's food supply, human and veterinary drugs, vaccines, blood products, medical devices, cosmetics, dietary supplements, tobacco products, and products that give off radiation.

ORA is responsible for a wide range of mission critical activities involving FDA-regulated products and manufacturing facilities, including:

- inspections and investigations (including criminal investigations)
- sample collection and analyses
- screening FDA-regulated products offered for import into the United States
- responding to emergencies
- executing recalls and other enforcement activities
- responding to consumer complaints.

ORA has staff in 227 offices across 49 states, including the U.S. Virgin Islands and the Commonwealth of Puerto Rico and has staff both temporarily and permanently assigned to foreign posts. ORA manages 13 scientific laboratories that conduct applied research and perform highly specialized analyses of domestic and imported products. In addition, ORA also funds state, local, tribal, and territorial regulatory jurisdictions to conduct inspections, collect samples, advance conformance with national regulatory program standards, and enhance program capacity and infrastructure.

Recent Accomplishments

Three of ORA's most significant accomplishments from the past year are as follows.

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). The NIFSS is accomplished through the development and implementation of standards, and the use of contracts, grants, and cooperative agreements with key federal, state, local, tribal, and territorial regulatory and public health partners, as well as with key industry and state associations. ORA continues its involvement in developing and implementing the necessary rules, standards, outreach, and training to help ensure quality and consistency across the system.

Extending FDA's Global Presence

ORA maintains cadres of investigators to conduct foreign inspections in the food, drug, and device program areas. ORA collaborates with its international counterparts to converge international standards and leverage resources. FDA introduced several programs to involve international stakeholders in the regulation of the global supply chain.

Focus on Pharmacy Compounding

FDA is implementing the compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including those added by the Drug Quality and Security Act (DQSA). ORA increased inspections of compounders and takes regulatory action when warranted to prevent further potential outbreaks caused by contamination in the compounding process.

Enhance Oversight

Risk-Related Preventive Focus

ORA has strengthened the surveillance and compliance programs used to monitor FDA-regulated products by enhancing strategies that focus on high-risk products and by focusing on

preventive approaches with regulated industry. FSMA outlines this new approach to food safety that is risk-informed and preventive in focus. In partnership with the Office of Food and Veterinary Medicine (OFVM), ORA is building functional preventive measures across the food system platform, creating a comprehensive regulatory framework for prevention, and strengthening FDA's inspection, compliance, imports review, sampling, and outbreak response tools.

Working with the Centers, ORA uses the risk-based approach to target firms to inspect, enabling ORA to focus its on-site inspections of the highest-risk facilities and industries. ORA is actively advocating for enhanced partnerships with federal, state, local, tribal, and territorial public health regulatory partners. The strengthening of the domestic network of regulators permits ORA to apply its highly-skilled staff of investigators to focus on the areas of regulation that pose the highest risk to the American public, including the growing supply of products introduced into the United States from the global marketplace.

Sampling approaches have also changed to help the Agency to better understand risks, assess the value of strategies to control those risks, and prevent contaminated product from reaching consumers. FDA has created a new sampling approach that is not only surveillance or compliance based, but also serves as a mechanism to actively identify risks and when possible, identify areas where preventive controls should be put into place to better protect public health. As FDA increases its understanding of the sources of contamination in high-risk commodities and practices, it can more effectively allocate resources to address public health risks through targeted sampling and other risk mitigation strategies.

NIFSS and Program Standardization

FDA prioritizes its inspectional efforts in coverage of the highest-risk products, facilities, and global marketplace. Therefore, it must rely greatly on the strength and capability of federal, state, local, tribal, and territorial public health regulatory partners through contracts and grants to provide much of the domestic surveillance. This reliance allows FDA to share the responsibility and cost of protecting the American food supply with many of its domestic public health regulatory partners. However, there must be steps taken to ensure uniformity in the regulation and approach taken by each of the FDA's partners.

To meet the responsibilities enacted by FSMA, FDA has made significant investments in the development of NIFSS. In order to ensure successful implementation of the NIFSS, FDA has worked closely with its partners to develop guidance, rules, and standards which will help provide framework to the regulation these partners provide in FDA's stead. This framework will continue to grow and will be tested and enhanced through training and continual improvement.

In FY 2015, FDA expanded partnerships with several national public health regulatory organizations, and promoted widespread participation in the national regulatory program standards. Food contracts represent 98 percent of the domestic manufactured food regulatory program and Manufactured Food Regulatory Program Standards (MFRPS) have been instituted to refine the efforts conducted under this program. In partnership with the Association of Food and Drug Officials (AFDO), a MFRP Alliance has been implemented to provide recommendations for improving and maintaining the MFRPS and manufactured food regulatory programs within an integrated food safety system. Animal Feed Regulatory Program Standards (AFRPS) were released in 2014 in collaboration with the American Association of Feed Control Officials (AAFCO). ORA has since developed a cooperative agreement program to promote

state implementation of the AFRPS, resulting in 21 state programs enrolled. This development is significant since currently the state regulatory agencies complete approximately 80 percent of the FDA animal feed work plan. Additionally, Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) have been developed and ORA has steadily increased funding in this program resulting in 671 state, local, tribal, and territorial regulatory programs enrolled in the VNRFRPS as of October 2015.

ORA continues to build and enhance the capacity of state public health regulatory agencies to contribute to domestic oversight by funding their performance of surveillance inspections, including verification of compliance with hazard-based preventative controls and other applicable standards. FDA works with the Partnership for Food Protection (PFP) in a collaborative effort with fellow public health regulatory partners to:

- create national standards for inspections;
- improve coverage of domestic food facilities;
- develop training and certification programs;
- improve recall and response effectiveness;
- increase collaborative efforts; and
- promote the Integrated National Food Safety System.

Mitigating Significant Increases in Import Entry

IMPORT LINES BY PROGRAM AREA
FY2011-FY2017 (Est.)

Program Area	2011	2012	2013	2014	2015	2015 Percent Growth*	2015 Percent of Total Lines	Estimate 2016	Estimate 2017
Foods	10,167,887	10,805,094	11,502,065	12,180,223	13,080,429	5%	37.87%	13,718,926	14,388,591
Cosmetics	2,121,088	2,349,615	2,433,747	2,596,057	2,930,682	6%	8.49%	3,111,524	3,303,525
Human Drugs	477,818	592,591	590,079	641,908	688,208	7%	1.99%	734,654	784,234
Animal Drugs & Feeds	284,973	331,505	368,447	391,388	416,860	7%	1.21%	446,903	479,111
Biologics	53,731	65,469	74,402	82,710	150,673	17%	0.44%	176,313	206,317
Medical Devices & Rad Health	9,584,415	13,651,985	14,320,961	16,668,422	17,252,283	10%	49.95%	19,044,228	21,022,297
Tobacco Products	13,258	17,757	19,316	20,161	16,680	3%	0.05%	17,238	17,815
Total	22,703,170	27,814,016	29,309,017	32,580,869	34,535,815	8%	100.00%	37,249,787	40,201,890

Over the last decade, there has been a very significant increase in FDA-regulated products introduced for import into the U.S. market. While such vast growth has been difficult to match with available resources, FDA has made several advancements in how imported products are targeted and processed for entry.

ORA works in partnership with the U.S. Customs and Border Protection (CBP) and the Commercial Operations Advisory Committee (COAC) in an effort to improve and streamline the import process which will help to expedite the release of compliant products. COAC is a 20 member council that meets quarterly and advises government agencies on the commercial operations of CBP and related functions, taking into consideration issues such as:

- global supply chain security and facilitation
- CBP modernization and automation
- air cargo security
- customs broker regulations
- trade enforcement
- U.S. government approach to trade and safety of imports
- agriculture inspection
- protection of intellectual property rights.

FDA has collaborated with CBP and the International Trade Data System (ITDS) Board of Directors to establish a fully electronic Automated Commercial Environment (ACE) as the "single-window portal" through which to import goods into the U.S. To facilitate entry via ACE, FDA developed "FDA Supplemental Guidance for the Automated Commercial Environment/International Trade Data System Data" which provides commodity-specific data elements needed to submit entries for import into the U.S. To date there have been multiple entries filed through the ACE system. Import entries submitted through ACE continue to increase along with filers, products, and expansion of ports.

FDA has implemented line-level release in its automated import entry review system. An import entry may include one or more products and each product must be listed as a separate line item in the entry. Previously, if any one line of a multi-line entry was held for any reason, the entire entry would be held. By implementing line-level release, there has been a reduction of entry lines designated for review and enhanced processing of entries. An initial review of these results shows a dramatic shift reducing these entry lines designated for review on average by more than 31,000 lines per day allowing substantial resources to be directed to higher-risk work.

FDA is also implementing a rule in International Mail Facilities nationwide which will institute the "Administrative Destruction of Certain Drugs Refused Admission to the United States." On September 15, 2015, this final rule for FDA Safety and Innovation Act section 708 was published in the *Federal Register*. The authority under this rule allows FDA to destroy, without the opportunity for export, drugs refused for admission that are valued at $2,500 or less with due process prior to the destruction. ORA is developing the necessary operational and information technology system changes to fully implement this authority. This authority will help avoid the re-introduction of violative products and deter the entry of unsafe drugs going directly to consumers.

Cultivating a Global Regulatory Network

FDA continues to increase its regulatory presence globally to ensure that the food, feed, and medical products available in the United States meet U.S. regulatory requirements. FDA fosters 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 public health regulatory partners. FDA has formed partnerships with various stakeholders to leverage resources to oversee FDA-regulated products and has developed technologies that streamline redundant processes and enhance inspectional capacity.

Under FSMA, ORA is also working on the implementation of the Foreign Supplier Verification Program (FSVP) and the Voluntary Qualified Importer Program (VQIP). The FSVP regulation

specifically requires U.S. food importers to develop, maintain, and follow a program that verifies that their foreign suppliers have established adequate preventive controls and that the human and/or animal food(s) produced within the foreign supplier's facility are in compliance with the FD&C Act. VQIP is a formal voluntary program under which importers of food may submit evidence of regulatory compliance and safety controls in return for the facilitated entry of import entries into the United States.

During FY 2015, ORA collaborated with OFVM to finalize an important VQIP guidance document, "Draft Guidance for Industry: FDA's Voluntary Qualified Importer Program." This document provided guidance on the benefits VQIP importers can expect to receive, the eligibility criteria for VQIP participation, instructions for completing a VQIP application, conditions that may result in revocation of participation in VQIP, and criteria for VQIP reinstatement following revocation.

ORA is actively involved in the Office of Global Regulatory Operations and Policy's efforts to establish a Mutual Reliance agreement with members of the European Union. ORA assisted in auditing the European Medicines Agency assessments and re-assessments of certain members of the EU. The Mutual Reliance efforts would enable sharing of inspection data and outcomes so that the inspectional resources of all parties could be shifted to higher-risk work.

ORA is participating in the Medical Device Single Audit Program (MDSAP) Pilot alongside four other foreign regulatory authorities. This program includes the use of third party auditors to provide FDA with additional information related to the compliance status of manufacturers, thus expanding FDA's knowledge of regulated industry. During the pilot, FDA is accepting the MDSAP audit reports as a substitute for routine FDA inspections. In implementing and assessing this pilot, FDA aims to have increased information with which to perform its risk-based work planning, allow for greater efficiency in FDA's use of resources, and provide broader understanding of regulated industry.

FDA is partnering with CBP in developing a trusted Trader Program designed to facilitate the importation process for selected firms. CBP issued a *Federal Register* Notice announcing a test program on June 16, 2014. FDA has reviewed the applicants and nine participants have been selected to participate. The pilot will begin after the applicants have been notified and CBP receives confirmation of the intent to participate.

ORA has also initiated a Secure Supply Chain Pilot Program (SSCPP), designed to enhance the security of imported drugs. The SSCPP allows pre-qualified companies who have been designated to take part in this two-year program to have expedited entry for the importation of up to five selected drug products into the United States. If successful, the expansion of this program will help expedite the admissibility process for pharmaceuticals originating from known sources with a validated secure supply chain protocol and a demonstrated ability to maintain control of their drugs from the time of manufacture abroad through entry into the United States.

Leveraging Laboratory Capabilities

ORA provides oversight of regulatory science standards in laboratories through the use of programs, systems, and cooperative agreements. FDA worked collaboratively with external partners, including states, foreign government regulatory authorities, and industry, to allow these stakeholders to provide input on these laboratory standards and on the identification of sampling assignments. This strategy has strengthened the surveillance of FDA-regulated food products by

gaining cooperation up front and allowing stakeholders to take part in the development of the assignments.

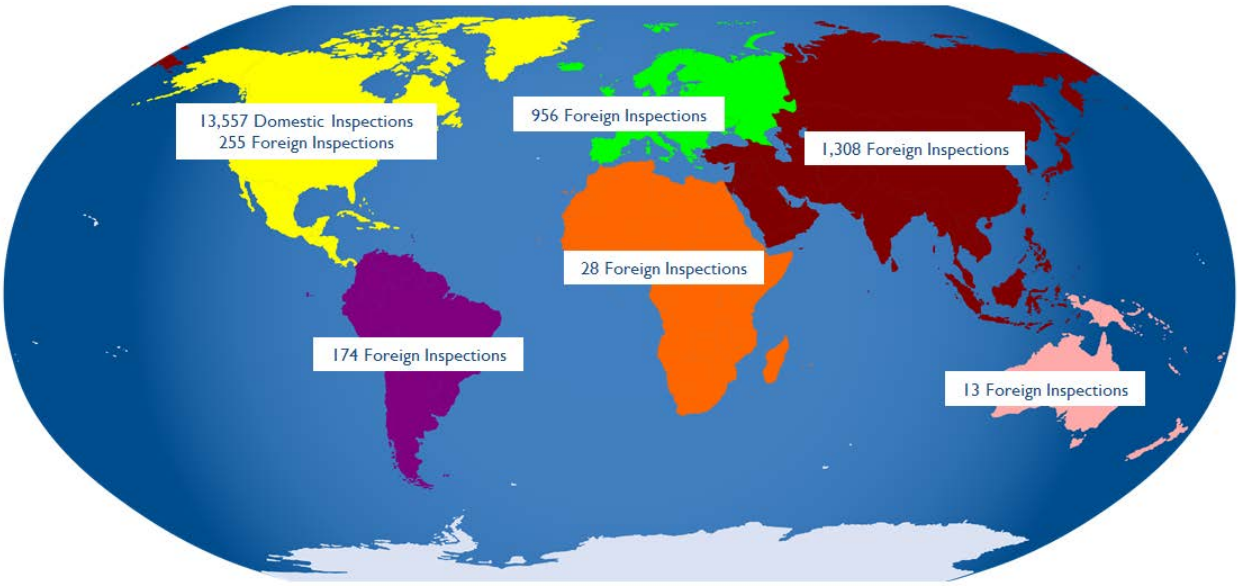
ORA also funds and manages Food Emergency Response Network (FERN) cooperative agreement programs designed to assist state laboratories with building their capability and capacity and demonstrating competency in FDA regulatory testing methodologies and reporting requirements. Throughout FY 2015, the FERN Microbiological Cooperative Agreement Program (mCAP) labs were involved in testing avocados for Salmonella and Listeria monocytogenes as part of a large-scale assignment. Positive results from FERN laboratories were shared with industry and as a result, recalls were conducted as appropriate.

ORA's Winchester Engineering and Analytical Center (WEAC) and FERN National Program Office (NPO) are also working together to start a FERN Radiological Proficiency Test program. This laboratory comparison study will allow FERN NPO and WEAC to gain information regarding the proficiencies of FERN Radiological CAP labs running various methodologies. This study will help to identify any analytical gaps or needs to be addressed before establishing a network of labs with a harmonized methodology base that can be prepared to respond in a coordinated fashion to any radiological emergency that occurs.

ORA is expanding its analytical repertoire by developing methods using cutting-edge technology to respond to public health needs. An outstanding example of ORA's scientific sophistication being leveraged to address an urgent public health issue is the response in FY 2014 and FY 2015 investigating the source of nontuberculous mycobacterium infections that were traced to a tattoo parlor. ORA worked with State regulatory partners to utilize a relatively newly integrated technology called Whole Genome Sequencing to perform sub-species level microbial identification of the organisms found in the samples. Working with State partners and exchanging genetic information, the cause of the infections was traced to inks used at the tattoo

parlor. The regulatory outcome was built on a solid scientific case that represented effective federal-state collaboration, communication, and utilization of new technology.

Surveillance of FDA-Regulated Products



FY 2014 FDA Inspections by Continent

ORA works with each Center to develop and implement a work plan that outlines assignments in more than 500 activity areas that span all of FDA's regulated commodities while maintaining flexibility to respond to unplanned activities, such as new product recalls, emergencies, and outbreaks that may arise, to ensure quick containment and mitigation. ORA accomplishes the FDA mission through a highly skilled professional and administrative staff including consumer safety officers (CSOs) or field investigators, compliance officers, laboratory analysts, recall staff, consumer complaint coordinators, criminal investigators, state cooperative program specialists, and many other critical staff functions nationwide.

FDA's foreign inspections are a critical component of protecting the health and safety of U.S. citizens. These inspections help to ensure 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.

The Agency continues to leverage the work of its dedicated foreign inspections cadre, FDA inspection staff located at FDA's foreign offices, and its domestic-based investigators to continue to enhance the overall coverage of the foreign establishment inventory. Through improvements to technology systems, FDA also continues to increase transparency and access to importers and other government agencies, helping to improve the efficiency of import entry reviews.

Protecting the U.S. food supply requires an integrated approach for identifying, investigating, and responding to foodborne illnesses and food-related incidents. This approach has improved response to mitigate the number of illnesses associated with incidents related to food products. ORA's investment in developing training and mobilization of joint ORA and state Rapid

Response Teams reduces exposure times, increases consumer protection, and minimizes the loss of consumer confidence, while lessening potential detrimental economic impact on industry.

In November 2013, President Obama signed the Drug Quality and Security Act (DQSA), legislation that contains important provisions relating to the oversight of compounding of human drugs. The DQSA created a new category of compounders called outsourcing facilities, which are subject to increased Federal oversight and quality standards, including inspections according to a risk-based schedule and current good manufacturing practice (CGMP) requirements. ORA is involved in the development and publication of several guidance documents to implement compounding provisions of the DQSA. In FY 2015, FDA estimates conducting 120 inspections, including 90 inspections of compounding pharmacies and 30 inspections of outsourcing facilities. In addition to the increased inspections of compounding pharmacies for cause, ORA leads the Compounding Training Subgroup.

Enforcement of FDA Authorities

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. Starting in FY 2014, OCI embedded an agent at Europol, located in the Netherlands, to assist with international FDA cases with a connection to any of Europol's 28 member states. In FY 2015, OCI began working with Interpol to assign a Special Agent as a liaison officer at The Interpol Global Complex for Innovation (IGIC) in Singapore, to work with Interpol's Medical Products and Counterfeiting and Pharmaceutical Crime sub-directorate. The IGIC is a cutting-edge research and development facility used for the identification of crimes and criminals, innovative training, operational support and partnerships.

As part of Interpol's annual Operation Pangea, OCI's Cybercrime Investigations Unit coordinated externally with other foreign and domestic agencies, and internally with the FDA Pangea working group members. FDA's focus during Pangea was websites illegally selling medical devices and illegal online pharmacies and resulted in more than 2,400 websites being taken offline and the seizure of $81 million worth of potential dangerous illegal medicines and medical devices worldwide.

In December 2014, OCI entered into a Letter of Intent Agreement with the French National Gendarmerie to combat counterfeit drugs and other transnational crimes that affect the public health. This agreement provides for stronger collaboration between the United States and France, as well as enhancing operational support and the exchange of investigative information.

For the month of June 2015, OCI and the UK Medicines and Healthcare Products Regulatory Authority exchanged agents on detail to each other's headquarters units to promote education of agency missions and enhance coordination on current and future joint investigations.

Through FY 2015, OCI conducted several training sessions on cybercrime, counterfeit drugs, and drug diversion for foreign criminal law enforcement agencies in Canada, New Zealand, Mexico, Latin America, Central America, France, and Turkey.

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 Activities
Implementation of the Generic Drug User Fee Act (GDUFA) program commits FDA to prioritizing inspections of establishments not previously inspected and those that are associated with Abbreviated New Drug Applications (ANDAs) that are otherwise approvable or eligible for tentative approval except for an outstanding inspection. ORA collaborates with the Center for Drug Evaluation and Research (CDER) in prioritizing ANDA inspections, targeting inspectional resources, and creating efficiency by identifying generic drug manufacturing facilities for inspection to coincide with Center reviews of applications.

FDA committed to conducting 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 risk adjusted parity in domestic and foreign inspections by 2017. ORA continues to increase pre-approval and surveillance inspections to meet the GDUFA goals by the 2017 commitment.

ORA conducts bioresearch monitoring (BIMO) inspections of scientific research studies in support of marketing applications. In FY 2015, the first domestic and foreign BIMO inspections in support of a Modified Risk Tobacco Product Application (MRTPA) and their corresponding premarket tobacco product applications (PMTA) were conducted. The inspectional focus was on the products for which the modified risk and premarket tobacco product applications were submitted.

ORA continues to conduct inspections of tobacco manufacturing establishments covering labeling, advertising, understanding the manufacturing methods and testing, and ensuring the marketing of products is not geared towards youth. In combination with the BIMO inspections, ORA conducted manufacturing inspections in order to confirm the accuracy of the data and information provided in the application regarding manufacturing methodology, specifications, processes, testing, and controls, and to determine whether the formulation of the products can be consistently reproduced with the firm's established manufacturing controls.

Strengthen Organizational Excellence

ORA enhances program integrity through its commitment to operational, workforce, and organizational excellence. This investment includes recruiting, training, developing, and retaining a diverse, world class workforce, and the creation of leadership roadmaps to support professional development.

Workforce Development
FDA employees must be highly skilled and meet professional standards to carry out their responsibilities. ORA and key training partners 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.

ORA has developed plans for continuous improvement of training in alignment with Job Task Analysis results. Outcomes of these reviews include a major curriculum revamp for each program area, incorporating a blended learning approach and providing quality training in an efficient, timely and cost-effective manner. This training includes increased incorporation of web modules, webinars, and on-the-job training at the student's locality.

FDA is establishing additional investigator and analyst certification programs to institute professional standards for regulatory employees who execute the authority of FDA as defined in the FD&C Act and related acts. Programs already exist for Seafood, Shellfish, Low Acid Canned Foods/Acidified Foods (LACF/AF), Milk, Retail Food, Drug, Import, Medical Device, Clinical BIMO, Blood Bank and Plasma Center certifications. These certification programs provide a foundation to ensure highly skilled individuals are available to carry out FDA's mission.

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 program is to provide a framework for moving forward with succession management in the effort to strengthen the leadership skills of employees at all levels.

Commitment to Quality
ORA is committed to quality and continual improvement. 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.

In order to keep pace with the acceleration of scientific innovation, globalization, and recent legislative authorities, pending approval, FDA will be implementing a Program Alignment initiative that will result in organizational and operational changes to ensure that FDA achieves its mission-critical objectives and optimizes the coordination of the work performed among the Centers and ORA. A key part of this process is to enhance the specialization of ORA investigators. This enhancement of specialization will allow FDA to have more commodity-based expertise, training, and better tools for ensuring that FDA's oversight is risk-based, efficient, effective, and results in consistent, public health focused decision making. Numerous transitional activities related to Program Alignment will be occurring during FY 2016, with full implementation, pending approval, expected in FY 2017.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$998,913,000	$934,393,000	$64,520 ,000
FY 2016 Enacted	$1,124,401,000	$1,008,024,000	$116,377,000
FY 2017 President's Budget	$1,274,999,000	$1,033,739,000	$241,260,000

BUDGET REQUEST

The FY 2017 Budget Request is $1,274,999,000, of which $1,033,739,000 is budget authority and $241,260,000 is user fees. The budget authority increases by $25,715,000 compared to the FY 2016 Enacted level and user fees increase by $124,883,000. The FY 2017 President's budget allows FDA to continue to ensure that food, feed, and medical products are available to the American public are safe and effective.

The FY 2017 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 collections
- lab analysis
- enforcement activities
- import operations to screen all FDA-regulated products offered for import into the United States.

These activities, in coordination with the efforts of the six Product Centers, help ensure the adherence to laws that protect and advance public health.

In FY 2017, ORA will continue to lead field activities in each of FDA's six product areas to uphold oversight of the safety and quality of FDA-regulated products and advance public health. ORA will maintain levels of operational activities to inspect regulated products and manufacturers, conduct sample analyses of regulated products, and reviews of imported products offered for entry into the United States. As part of an ongoing commitment to quality and continual improvement, ORA will further hone utilization of risk-based approaches of regulatory activities to make best use of available resources. Additionally, ORA will continue to work with its state, local, tribal, territorial, and foreign counterparts as applicable to further leverage, collaborate, and standardize the oversight of FDA-regulated products throughout the global marketplace.

In support of the Food and Veterinary Medicine programs, ORA will continue stewardship of its resources to institute smart regulation of food and animal feed products available for use by the American public. ORA will continue to conduct field operational activities on a surveillance and for-cause basis in oversight of these products offered from the domestic and global marketplace using proven standards and regulatory science to ensure safety and quality. ORA will continue to invest in state regulatory and public health systems through contracts, grants, cooperative agreements, and partnerships.

In support of the Medical Product programs, ORA will continue stewardship of its resources to institute smart regulation of human drug, animal drug, biologic, medical device, and radiological health products available for use by the American public. ORA will continue to conduct field operational activities on a surveillance and for-cause basis in oversight of these products offered from the domestic and global marketplace using proven standards and regulatory science to ensure safety and quality. Additionally, ORA will maintain regulatory activities instrumental to the review and approval of new medical products to safeguard the American public's improved access to innovative new products.

At the President's budget level, ORA will prioritize resources in order to protect consumers and enhance public health by maximizing compliance of FDA-regulated products and minimizing risk associated with these products. This focus will continue to best serve the advancement and protection of public health and allow ORA to respond to any public health emergencies or outbreaks that arise during the fiscal year by diverting resources from other regulatory activities that pose the lowest impact on risk to public health. However, without additional resources, it will be difficult for ORA to meet the challenges posed by the increasing globalization of the supply chain of FDA-regulated products as well as assume the new responsibilities and authorities in the public health arena, such as the Drug Quality and Security Act (DQSA); the FDA Safety and Innovation Act (FDASIA); and the FDA Food Safety Modernization Act (FSMA).

BUDGET AUTHORITY

Food Safety: $770.4 million (+ $25.3 million)

National Integrated Food Safety System (NIFSS): +$11.3 million
Foods: +$11.3 million

Building the NIFSS is a central element of FSMA's mandate to FDA and crucial to successful implementation of FSMA. The FY 2017 request will build on the FY 2016 investments in this area. The additional funds for NIFSS will contribute to the enhancement of ORA's ability to ensure that the NIFSS cooperative agreements and grants are continued and expanded, as well as provide additional investments in modernization of inspections and training of FDA investigators. In addition, the funds will build the state capacity to coordinate with FDA as a central tenet of FSMA by conducting:

- investigator training
- investigator certification programs
- state laboratory coordination
- and by increasing the capacity to share information with the states as it relates to FDA's new inspection and compliance approach.

Additional funding in these areas is essential to be successful in aligning state programs with FDA's new inspection and compliance approach.

The requested funding will also support states in carrying out facility inspections to implement the human and animal food preventive controls and produce rule. States currently conduct more than half of the domestic food and feed facility inspections required by FSMA. To ensure both effectiveness and efficiency, FDA expects that states will continue or increase the number of inspections they conduct as FDA transitions to prevention-oriented inspections or new oversight of produce operations to determine industry compliance with the new FSMA standards and rules.

Import Safety – Foreign Supplier Verification Program (FSVP) Implementation: +$14.0 million
Foods: +$14.0 million

The requested funds will enable FDA to implement the multifaceted new import safety system mandated by Congress.

FDA will continue implementing the FSVP rule. Under FSVP, importers must verify that food imported into the United States has been produced consistent with FSMA's new standards for

produce safety and preventive controls in food facilities. This preventive approach to import safety presents an enormous challenge for both FDA and food importers, given that approximately 90,000 consignees received food shipments in FY 2015.

Building on the FY 2016 investment, FSVP will require further investment to hire and train staff to perform FSVP inspections, provide extensive training and technical assistance for importers, and provide outreach to foreign firms and foreign government partners on the new FSVP requirements. To improve import safety, FDA will also expand its overseas presence, as mandated by FSMA. This expansion in FDA's international presence includes increasing and better targeting FDA inspections of foreign food facilities, as well as working with and assisting foreign governments in better ensuring the safety of food before it is exported to the United States.

ORA will further its work on the implementation of the FSVP 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. Implementation of FSVP requires a substantial regulatory development process involving staffing and training within FDA to enforce the regulation, and also 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 could become a major barrier to trade. Already, the agency receives thousands of inquiries each year from importers to resolve problems at the border ports, to which it cannot adequately respond. A poorly implemented FSVP regulation could be expected to expand that problem.

Medical Product Safety and Availability: $263.4 million (+$0.44 million)

Compounding: +0.44 million
Human Drugs: +$0.44

The requested FY 2017 funding will allow FDA to improve oversight of human drug compounding through increased inspection and enforcement activities, policy development and implementation, and state collaboration and coordination. Increased efforts in these areas will help to prevent outbreaks that could result in deaths of or injuries to patients who receive compounded drugs.

FDA will continue to support inspections of compounding pharmacies under section 503A of the Food, Drug, and Cosmetic Act, and outsourcing facilities under section 503B. FDA will require direct inspection resources as well as significant resources to support these inspections. FDA's budget request for compounding is critical to uphold its mission of promoting and protecting public health.

USER FEES

Current Law User Fees: -$0.06 million

The FY 2017 request includes a decrease of $0.06 million for current law user fees. The net decrease is due to an adjustment to projected Tobacco Control Act field activities. This decrease offsets the $1.7 million increase requested in the remaining current law user fees. FY 2017

current law user fees 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: +$125.0 million

Proposed Food Import Fee: +$86.1 million
Foods: +$86.1 million

The Field Foods Program request for the proposed Food Import Fee is $86,122,000. 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: +$29.0 million
Foods: +$27.9 million / Animal Drugs and Feeds: +$1.1 million

This user fee will allow FDA to continue development and implementation of 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. 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: +$4.7 million
Foods: +$4.7 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: +$5.2 million
Foods: +$0.8 million, Human Drugs: +$0.5, Devices +$3.9 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 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
214201: Number of prior notice import security reviews. *(Output)*	FY 2015: 80,990 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2015: 174,432 Target: 160,000 (Target Exceeded)	160,000	160,000	maintain
214203: Number of Filer Evaluations. (Output)	FY 2015: 1,212 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2015: 8,527 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2015: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	maintain
214209: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 19,500 firms) every three years. *(Output)*	FY 2015: 80% Target: 66% (Target Exceeded)	100%	33%	+33%
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2015: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	maintain
224201: Number of foreign and domestic high-risk human drug inspections. *(Output)*	FY 2015: 835 Target: 750 (Target Exceeded)	750	750	maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. *(Output)*	FY 2015: 957 Target: 900 (Target Exceeded)	900	900	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
234203: Number of human foreign and domestic tissue establishment inspections. *(Output)*	FY 2015: 656 Target: 570 (Target Exceeded)	570	570	maintain
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2015: 303 Target: 250 (Target Exceeded)	250	250	maintain
244203: Cover 100% of targeted prohibited material BSE actual inventory. *(Output)*	FY 2015: 100% Target: 100% (Target Met)	100%	100%	maintain
253201: Number of Medical Device Bioresearch Monitoring (BIMO) inspections. *(Output)*	FY 2015: 305 Target: 300 (Target Exceeded)	300	300	maintain
254201: Number of domestic and foreign Class II and Class III device inspections. *(Output)*	FY 2015: 2,080 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. FY 2015 marked year two of the three-year cycle, and ORA has made significant progress by inspecting 80% of the total cumulative high-risk domestic inventory. The FY 2016 target is set at 100% and closes the three year cycle. FY 2017 marks the beginning of the next three year cycle, and while the target returns to 33% to signify the first third of the inventory, the delta shows that it is still an increase of 33% because of the new three year cycle.

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.

Conduct Highest Risk BSE Inspections

Since establishing this performance goal, the aim has been to inspect 100% of the licensed and unlicensed feed mills, renderers and protein blenders that make or use prohibited materials in their feed manufacturing operation. However, the total inventory of these firms has been dropping for several years as firms are either combined through mergers or just stop using prohibited materials. ORA will continue to cover 100% of the targeted prohibited BSE inventory, even though we estimate a reduction of 35% of the BSE inventory over the next few years.

PROGRAM ACTIVITY DATA

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,334***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,078	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	220		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	325		
Domestic Fish & Fishery Products (HACCP) Inspections	979		
Import (Seafood Program Including HACCP) Inspections	331		
Juice HACCP Inspection Program (HACCP)	195		
Interstate Travel Sanitation (ITS) Inspections	897		
Domestic Field Exams/Tests	2,154	3,945	3,945
Domestic Laboratory Samples Analyzed	13,157	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,357***	***1,200***	***1,200***
All Foreign Inspections	1,357	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***8,691***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	245,804	160,200	160,200
Import Laboratory Samples Analyzed	21,128	35,300	35,300
Import Physical Exam Subtotal	**266,932**	**195,500**	**195,500**
Import Line Decisions	13,080,429	13,718,926	14,388,591
Percent of Import Lines Physically Examined	2.04%	1.43%	1.36%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	80,990	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,277***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***88***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,225	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	973	1,104	1,104
State Contract Juice HACCP	79	103	103
State Contract LACF	111	68	68
State Partnership Inspections	88	273	273
State Contract Foods Funding	$12,706,038	$13,087,219	$13,479,836
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$20,701,071	$21,322,103	$21,961,766
Total State & Annual FERN Funding	**$33,407,109**	**$34,409,322**	**$35,441,602**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,056***	***20,496***	***20,496***

[1] The FY 2015 actual unique count of foreign inspections includes 150 OIP inspections (65 for China, 65 for India, & 20 for Latin America).

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***88***	***100***	***100***
Domestic Inspections	88	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***3***	***0***	***0***
Foreign Inspections	3	0	0
IMPORTS			
Import Field Exams/Tests	17,133	1,600	1,600
Import Laboratory Samples Analyzed	488	500	500
Import Physical Exam Subtotal	**17,621**	**2,100**	**2,100**
Import Line Decisions	2,930,682	3,111,524	3,303,525
Percent of Import Lines Physically Examined	0.60%	0.07%	0.06%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***91***	***100***	***100***

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,775***	***1,856***	***1,856***
Pre-Approval Inspections (NDA)	112	171	171
Pre-Approval Inspections (ANDA)	122	216	216
Bioresearch Monitoring Program Inspections	573	563	563
Drug Processing (GMP) Program Inspections	713	591	591
Compressed Medical Gas Manufacturers Inspections	201	295	295
Adverse Drug Events Project Inspections	92	120	120
OTC Monograph Project and Health Fraud Project Inspections	42	79	79
Compounding Inspections[1]	115	130	130
Domestic Laboratory Samples Analyzed	1,450	1,450	1,450
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***1072***	***999***	***999***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	107	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	194	83	83
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	221	255	255
Foreign Drug Processing (GMP) Program Inspections	814	843	843
Foreign Adverse Drug Events Project Inspections	10	15	15
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,847***	***2,855***	***2,855***
IMPORTS			
Import Field Exams/Tests	8,437	7,200	7,200
Import Laboratory Samples Analyzed	586	490	490
Import Physical Exam Subtotal	**9,023**	**7,690**	**7,690**
Import Line Decisions	688,208	734,654	784,234
Percent of Import Lines Physically Examined	1.31%	1.05%	0.98%
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	***2,847***	***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 2015 actual unique count of foreign inspections includes 69 OIP inspections (24 for China, 36 for India, & 9 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 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,835***	***2,047***	***2,047***
Bioresearch Monitoring Program Inspections	97	100	100
Blood Bank Inspections	893	1,060	1,060
Source Plasma Inspections	175	194	194
Pre-License, Pre-Market Inspections	54	7	7
GMP Inspections	27	28	28
GMP (Device) Inspections	6	7	7
Human Tissue Inspections	600	661	661
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***67***	***47***	***47***
Bioresearch Monitoring Program Inspections	19	11	11
Foreign Human Tissue Inspections	1	0	0
Blood Bank Inspections	7	8	8
Pre-License, Pre-market Inspections	8	2	2
GMP Inspections (Biologics & Device)	32	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,902***	***2,094***	***2,094***
IMPORTS			
Import Field Exams/Tests	85	45	45
Import Line Decisions	150,673	176,313	206,317
Percent of Import Lines Physically Examined	0.06%	0.03%	0.02%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,902***	***2,094***	***2,094***

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2015 Actuals			FY 2016 Estimate			FY 2017 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	***1,565***	***226***	***1,356***	***1,565***	***299***	***1,524***	***1,565***	***299***	***1,524***
Pre-Approval /BIMO Inspections	39	39	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	189	189	0	222	222	0	222	222	0
BSE Inspections	1,163	0	1,163	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	24	0	24	25	0	25	25	0	25
Illegal Residue Program Inspections	424	0	424	473	0	473	473	0	473
Feed Manufacturing Program Inspections	178	0	178	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,650	4	1,646	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS [1]	***98***	***83***	***15***	***75***	***69***	***6***	***75***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	35	35	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	70	70	0	33	33	0	33	33	0
Foreign Feed Inspections	8	0	8	7	0	7	7	0	7
BSE Inspections	10	0	10	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,663***	***309***	***1,371***	***1,640***	***368***	***1,530***	***1,640***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	7,311	1,708	5,603	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	931	1	930	750	2	748	750	2	748
Import Physical Exam Subtotal	**8,242**	**1,709**	**6,533**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	416,860			446,903			479,111		
Percent of Import Lines Physically Examined	1.98%			0.97%			0.91%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***4,426***	***0***	***4,426***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [2]	***6***	***0***	***6***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [3]	***306***	***0***	***306***	***0***	***0***	***0***	***0***	***0***	***0***
State Contract Inspections: BSE	4,105	0	4,105	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	741	0	741	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	276	0	276	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	6	0	6	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	306	0	306	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$2,917,129	0	$2,917,129	$3,004,643	0	$3,004,643	$3,094,782	0	$3,094,782
BSE Cooperative Agreement Funding	$0	0	$0	$0	0	$0	$0	0	$0
State Contract Tissue Residue Funding	$469,072	0	$469,072	$483,144	0	$483,144	$497,638	0	$497,638
Total State Funding	**$3,386,201**	**$0**	**$3,386,201**	**$3,487,787**	**$0**	**$3,487,787**	**$3,592,420**	**$0**	**$3,592,420**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***6,401***	***309***	***6,109***	***6,685***	***368***	***6,575***	***6,685***	***368***	***6,575***

[1] The FY 2015 actual unique count of foreign inspections includes 7 OIP inspections (7 for China).

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

[3] The State cooperative agreement BSE inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number along with the funding for these inspections are expected to decrease in the future until there are no planned State Cooperative Agreement BSE inspections.

Field Devices and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,587***	***2,864***	***2,864***
Bioresearch Monitoring Program Inspections	296	300	300
Pre-Market Inspections	57	67	67
Post-Market Audit Inspections	34	34	34
GMP Inspections	1,555	1,594	1,594
Inspections (MQSA) FDA Domestic (non-VHA)	625	723	723
Inspections (MQSA) FDA Domestic (VHA)	53	43	43
Domestic Radiological Health Inspections	42	101	101
Domestic Field Exams/Tests	96	139	139
Domestic Laboratory Samples Analyzed	176	183	183
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS [1]	***729***	***603***	***603***
Foreign Bioresearch Monitoring Inspections	14	25	25
Foreign Pre-Market Inspections	42	31	31
Foreign Post-Market Audit Inspections	26	19	19
Foreign GMP Inspections	639	521	521
Foreign MQSA Inspections	14	15	15
Foreign Radiological Health Inspections	55	45	45
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,316***	***3,467***	***3,467***
IMPORTS			
Import Field Exams/Tests	26,654	18,821	18,821
Import Laboratory Samples Analyzed	658	1,123	1,123
Import Physical Exam Subtotal	**27,312**	**19,944**	**19,944**
Import Line Decisions	17,252,283	19,044,228	21,022,297
Percent of Import Lines Physically Examined	0.16%	0.10%	0.09%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,904***	***7,929***	***7,929***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS [2]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,809	6,800	6,800
Inspections (MQSA) by State non-Contract	1,075	1,110	1,110
GMP Inspections by State Contract	20	19	19
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$287,518	$296,144	$305,028
State Contract Mammography Funding	$9,317,189	$9,596,705	$9,884,606
Total State Funding	**$9,604,707**	**$9,892,849**	**$10,189,634**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***11,220***	***11,396***	***11,396***

[1] The FY 2015 actual unique count of foreign inspections includes 10 OIP inspections (9 for China and 1 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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