OFFICE OF REGULATORY AFFAIRS – FIELD ACTIVITIES

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 President's Budget +/- FY 2017 CR
Office of Regulatory Affairs	**1,139,170**	**1,092,819**	**1,121,641**	**1,051,206**	**-70,435**
Budget Authority	***1,022,793***	***1,022,759***	***1,005,877***	***876,782***	***-129,095***
User Fees	***116,377***	***70,060***	***115,764***	***174,424***	***58,660***
Prescription Drug (PDUFA)	*14,360*	*9,814*	*12,725*	*42,702*	*29,977*
Medical Device (MDUFA)	*2,416*	*412*	*2,213*	*14,639*	*12,426*
Generic Drug (GDUFA)	*55,167*	*38,403*	*55,973*	*71,717*	*15,744*
Biosimilars (BsUFA)	*1,382*	*400*	*1,416*	*2,485*	*1,069*
Animal Drug (ADUFA)	*411*	*378*	*427*	*1,665*	*1,238*
Animal Generic Drug (AGDUFA)	*259*	*188*	*302*	*570*	*268*
Family Smoking Prevention and Tobacco Control Act	*16,663*	*9,749*	*16,631*	*14,550*	*-2,081*
Mammography Quality Standards Act (MQSA)	*13,612*	*10,322*	*13,892*	*13,892*	*---*
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*	*1,141*	*---*
Outsourcing Facility	*264*	*394*	*342*	*361*	*19*
FTE	**5,003**	**5,003**	**5,134**	**4,894**	**-240**

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, allergenics, cellular and gene therapy

products, tissue and tissue products, medical devices, cosmetics, dietary supplements, tobacco products, and products that emit 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
- executing recalls and other enforcement activities, including responding to consumer complaints and emergencies
- developing and fostering state and local partnerships.

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, perform analyses, 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 unify international standards and leverage resources. FDA introduced several programs to involve international stakeholders in the regulation of the global supply chain.

Strategic Coordinated Oversight of Recall Execution (SCORE)
To facilitate FDA's response when regulated foods are associated with real and potential public health risks, the Agency recently established a new process to streamline and strengthen decisions about compliance and enforcement actions. The Strategic Coordinated Oversight of Recall Execution (SCORE) team, a decision-making body of key senior leaders, was established in April 2016 to specifically address challenging food safety situations.

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, 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. The measures create a comprehensive regulatory framework for prevention and strengthen 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 on its on-site inspections of the highest risk facilities and industries both domestically and abroad. In addition, ORA actively advocate 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 products 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.

To speed its response when there are foods on the market presenting a real or potential danger to consumers' health, FDA created the SCORE team. The team consists of key senior leaders who engage in the most challenging recall situations, those complicated by such issues as the nature of the product, the scope of available evidence, and the company's response. The team supports the FDA's field staff across the country by evaluating the whole range of options for the use of the FDA's compliance and enforcement authorities, and making swift decisions about the best course of action to take. In 2016, SCORE reviewed and directed operations in cases that include flour contaminated with peanut protein, (a major food allergen), facilities contaminated with Listeria monocytogenes, pistachios in which Salmonella was detected, suspension of registration of a ready to eat manufacturer, and baby food that was not manufactured in compliance with infant formula regulations. All of these cases resulted in recalls and announcements issued by the firms and FDA.

NIFSS and Program Standardization

FDA prioritizes its inspectional efforts in coverage of the highest risk products, facilities, and global marketplace. Therefore, it must rely on the strength and capability of federal, state, local, tribal, and territorial public health regulatory partners through contracts, grants, and cooperative agreements 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. This domestic network of regulators is used to enhance FDA's own coverage of the domestic inventory and better protect the American food supply. However, there must be steps taken to ensure uniformity in the regulation and approach taken by each of the FDA partners. 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

- promote the National Integrated Food Safety System.

To meet the responsibilities specified by FSMA, FDA has made significant investments in the development of 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 national curriculum standard framework will continue to grow and will be evaluated and enhanced through training and continual improvement.

In FY 2016, FDA continued its strong partnerships with State manufactured food regulatory programs and promoted widespread participation in the national regulatory program standards. FDA currently has food safety inspection contracts with 47 regulatory agencies in 43 States and Puerto Rico. Manufactured Food Regulatory Program Standards (MFRPS) are implemented nationally with the goal of creating an integrated, risk-based, food safety system focused on protecting public health. The vast majority (91 percent) of States with food safety inspection contracts are enrolled in the MFRPS. In partnership with the Association of Food and Drug Officials, a Manufactured Food Regulatory Program Alliance (MFRPA) has been implemented to provide recommendations for improving and maintaining the MFRPS and manufactured food regulatory programs within an integrated food safety system. The MFRPA also hosts annual meetings, workgroups, and other forums to promote conformance with MFRPS.

Additionally, similar cooperative agreement programs are conducted to promote implementation of the Animal Feed Regulatory Program Standards and Voluntary National Retail Food Regulatory Program Standards. FDA also administered a cooperative agreement with a national agricultural association to facilitate long-term improvements to the national food safety system by providing states with information to aid in the research and identification of resources and changes needed to enforce the requirements of state laws and regulations related to Food for Animals that are modeled after FDA's Current Good Manufacturing Practices (cGMP), Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals rule.

FDA is enhancing produce safety through advancing and implementing the Produce Safety Rule by awarding $21.8 million in cooperative agreements to 42 states to enhance their capacity, coordination, and training efforts; and by administering a $1 million cooperative agreement with the National Association of State Departments of Agriculture to assist with national collaborative produce efforts and the development and dissemination of best produce practices.

Further, ORA advanced efforts to improve the national egg safety programs through a cooperative agreement with two state agencies designed to conduct egg regulatory program self-assessments of state egg laws and regulations in comparison to the current federal egg safety laws and regulations; develop and implement an agreement and protocol for sharing egg regulatory inspections and information between states and the FDA; and identify gaps and areas of improvement between Federal and State egg programs.

Import Operations

IMPORT LINES BY PROGRAM AREA
FY 2012 - FY 2018 (Est.)

Program Area	2012	2013	2014	2015	2016	2016 Percent Growth*	2016 Percent of Total Lines	Estimate 2017	Estimate 2018
Foods	10,805,094	11,502,065	12,180,223	13,080,429	13,952,537	5%	37.70%	14,643,462	15,368,602
Cosmetics	2,349,615	2,433,747	2,596,057	2,930,682	2,939,034	4%	7.94%	3,064,891	3,196,137
Human Drugs	592,591	590,079	641,908	688,208	739,309	4%	2.00%	770,786	803,603
Animal Drugs & Feeds	331,505	368,447	391,388	416,860	434,384	5%	1.17%	457,000	480,794
Biologics	65,469	74,402	82,710	150,673	151,911	14%	0.41%	172,563	196,021
Medical Devices & Rad Health	13,651,985	14,320,961	16,668,422	17,252,283	18,757,725	6%	50.69%	19,889,362	21,089,270
Tobacco Products	17,757	19,316	20,161	16,680	32,972	8%	0.09%	35,663	38,573
Total	27,814,016	29,309,017	32,580,869	34,535,815	37,007,872	5%	100.00%	39,033,727	41,173,000

*Percentage growth based off a 5 year average (FY 2012 - FY 2016)

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 to expedite the release of compliant products. COAC is a 20 member council that meets quarterly and is chartered to provide advice to the Secretaries of the Department of the Treasury and the Department of Homeland Security 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
- customs broker regulations
- trade enforcement
- U.S. government approach to trade and safety of imports
- protection of intellectual property rights.

FDA has collaborated with CBP and the International Trade Data System (ITDS) Board of Directors to transition to the Automated Commercial Environment (ACE) as the "single-window portal" through which to import goods into the United States. To facilitate entry via ACE, FDA developed "FDA Supplemental Guidance for the Automated Commercial Environment/ International Trade Data System" which identifies commodity-specific data elements needed to submit FDA-regulated products for import into the United States. Import entries submitted through ACE continue to increase along with filers, products, and expansion of ports.

FDA is also implementing a rule for FDA Safety and Innovation Act Section 708 in International Mail Facilities nationwide which will institute the "Administrative Destruction of Certain Drugs Refused Admission to the United States." 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. In FY 2016, ORA successfully piloted new processes for our Administrative Destruction authority in two international mail facilities. Regulatory procedures have been developed and finalized, training for field staff has been developed and is scheduled. Full national implementation is planned for FY 2017.

ORA continues to work to implement 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 Federal Food, Drug, and Cosmetic Act (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 2016 ORA established a team dedicated entirely to the stand-up of FSVP. Team members are currently working with other components of FDA in various activities, including development of a list of FSVP firms and identifying investigators who will attend training, such as Alliance Training, Train the Trainer, and Regulator Training during FY 2017.

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA is responsible to receive and review food defense risks prior notice for all food and animal feed imported or offered for import. ORA's Division of Food Defense Targeting (DFDT) was established to meet the Agency's responsibilities under this Act. In an effort to enhance operations, the DFDT developed and implemented a new IT system, the Prior Notice (PN) Manager. The PN Manager has fundamentally changed and improved how ORA targets, processes and responds to prior notice submissions, enhancing operations and providing more efficient work processes. It has allowed for enhanced prior notice targeting rules including a rules based food defense targeting platform with automated review status transmission to CBP via the ACE/ITDS portal.

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.

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 (EU). To date, ORA participated in 14 European assessments organized by the European Medicines Agency in support of Mutual Reliance efforts. The Mutual Reliance efforts enable sharing of inspection data and outcomes so that inspectional resources of all parties can be shifted to higher-risk work.

ORA is continuing to participate in the Medical Device Single Audit Program Pilot with four foreign regulatory authorities. This program includes the use of third party auditors to provide FDA with additional information related to the status of manufacturers, thus expanding FDA's knowledge of regulated industry. ORA also conducted 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.

ORA is actively engaged in the Center for Food Safety and Applied Nutrition's (CFSAN) efforts to expand the Agency's international arrangements under the Systems Recognition program. Under this program, the Agency works with more developed countries on a process by which FDA will assess if the country's food and feed safety system provides protections comparable to those in the United States. This approach allows FDA to focus import screening efforts on areas of higher risk. To date, FDA has entered into System Recognition arrangements with New Zealand and Canada and is exploring additional opportunities.

ORA is participating in the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS). CCFICS develops principles and guidelines related to food import and export inspection and certification systems with a view to harmonizing methods and procedures which protect the health of consumers, ensure fair trading practices, and contribute to facilitating international trade in food stuffs. Covering 99 percent of the world's population, the committee has seen several standards endorsed and adopted into the international food code including standards on guidelines for food import control systems, guidelines for national food control systems, and principles for food import and export inspection and certification.

To ensure continued global trade of domestically produced food commodities, ORA participated in audit activities throughout the year, hosting several foreign regulatory delegations to ensure appropriate regulatory oversight and safe manufacturing practices. In one audit, focused on U.S. facilities that export seafood to Europe, FDA hosted the European Union's Directorate General for Health and Food Safety (DG Sante). Visits were made to several domestic fishery facilities and ORA played a key role providing information, oversight, and guidance to FDA's EU counterparts. Other key audits included dairy and gelatin audits by the Taiwanese government.

Leveraging Laboratory Capabilities

ORA provides oversight of regulatory science standards in laboratories through the use of programs, systems, and cooperative agreements. FDA works collaboratively with external partners, including states, foreign government regulatory authorities, and industry, to allow these stakeholders to provide input on 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 participate in developing assignments.

ORA funds and manages 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. FDA currently funds 34 FERN network laboratories, including 15 microbiological, 14 chemical, and five radiological laboratories. Throughout FY 2016, 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. This ongoing work has found several contaminated samples collected at the retail level.

ORA's Winchester Engineering and Analytical Center (WEAC) and FERN National Program Office (NPO) have successfully started a FERN Radiological Proficiency Test (PT) program. Laboratory comparison studies have allowed FERN NPO and WEAC to gain information regarding the proficiencies of the five FERN Radiological Cooperative Agreement Program (CAP) laboratories, as well as other non-CAP network Radiological laboratories. PT studies have helped identify analytical gaps or needs to be addressed to be prepared to respond in a coordinated fashion to any radiological emergencies. As of November 2016, WEAC and FERN NPO have successfully completed five PTs with a total of 23 labs participating. This Radiological PT program will continue to prepare an average of two studies a year.

A separation lab at ORA Forensic Chemistry Center in Cincinnati, OH. Here analysts prepare samples and subject them to chromatographic analysis to detect contaminants, impurities, or to perform identity testing.

Currently, specialized ORA labs are standing up advanced pharmaceutical testing research programs to develop regulatory methods to evaluate new biotech drugs dominating the cancer and auto-immune therapy sectors. ORA is standing up two groups at Pacific Regional Lab Southwest and New York Regional Labs specialized in pharmaceutical testing. Advanced instrument platforms such as Nuclear Magnetic Resonance Spectroscopy and Mass Spectrometry systems are being acquired for these laboratories to be able to effectively probe the critical quality attributes of protein-based or nanoparticle-based drugs. Following the advent of innovator drugs incorporating protein/nanoparticle moieties, biosimilars are gaining market share especially in the areas of oncology and rheumatoid arthritis. As of April 20, 2017, FDA has approved four biosimilar drugs to be used in the United States.

In addition to equipment investment, personnel with specific skill sets have been identified to spearhead the research projects. ORA strategic research plan in this area includes first bringing online heparin testing using the nuclear magnetic resonance (NMR) platform. Heparin, an injectable blood thinner used to treat and prevent deep vein thrombosis and pulmonary embolism, is prone to adulteration with other compounds. In 2008, a case of heparin being adulterated with oversulfated chondroitin caused a large number of serious injuries. Therefore, heparin lots are now tested by the FDA Center for Drug Evaluation and Research (CDER) lab for purity and this testing will be turned over to ORA to be performed on its new NMR platform.

On the mass spectrometry (MS) platform, ORA strategic research will focus on developing characterization methods on a spectrum of drug compounds spanning from small (simple compound as the active pharmaceutical ingredient) to large formulations (active compounds encapsulated within antibodies, nanoparticles as the active pharmaceutical ingredient).

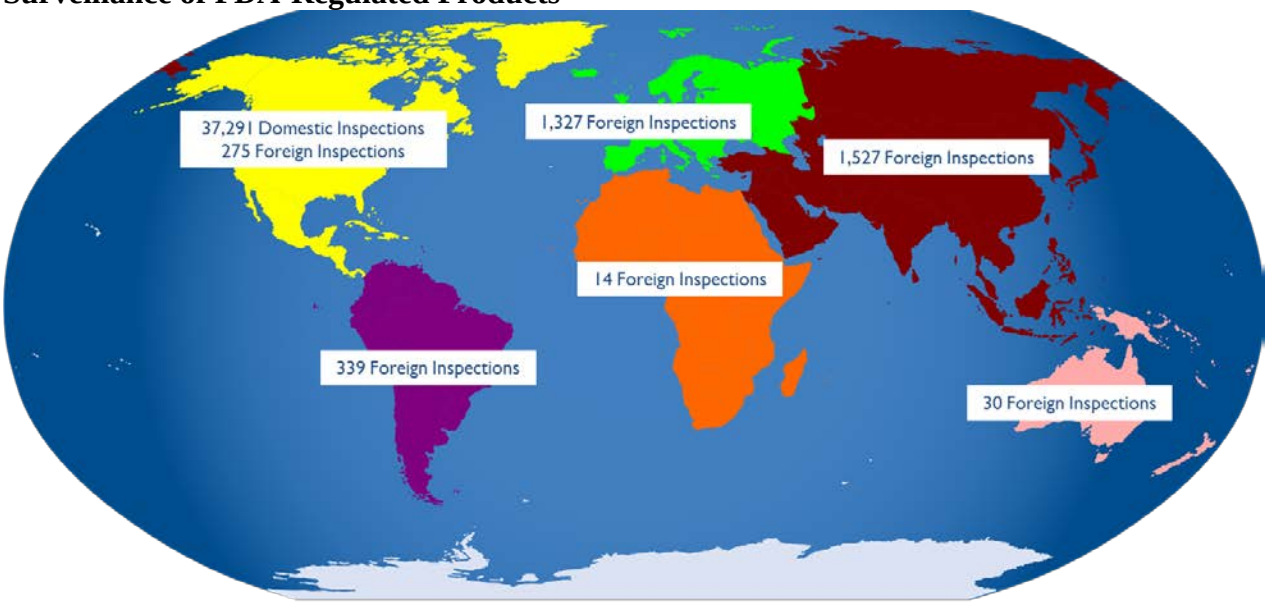
On the regulatory pharmaceutical testing front, ORA laboratories have provided analytical support to a large-scale assignment issued by CDER involving products manufactured in India. The Domestic-Import India-Origin Solid Oral Generic Dosage Forms and Control Samples (Tier 1) Survey Assignment was issued April 2015 and targeted domestic-import samples manufactured in India. Samples targeted for this assignment were identified by CDER as high-risk (Tier 1) based on factors such as historical quality data, increased sales volume, and recently reported cGMP violations by India manufacturers. ORA pharmaceutical labs collected and analyzed comparable drug products manufactured outside of India (control samples). Along with assessing product quality, results obtained from the India drug products and control drug products will serve as effective benchmarks for quality and surveillance purposes. In FY 2015, approximately 250 samples were collected and ORA labs completed testing for approximately 131 drug products. The assignment was extended through FY 2016 with additional sampling and testing (Tier 2).

ORA continues to expand its analytical repertoire by developing and utilizing methods using cutting-edge technology to respond to public health needs. Utilizing a newly integrated technology called Whole Genome Sequencing (WGS) to perform sub-species level microbial identification of the organisms found in the samples, an ORA lab contributed to the first recall in FDA history that was primarily based on WGS results. 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. In order to promote this technology further, ORA continues to work with State regulatory partners to initiate and utilize WGS in state laboratories on a national level.

To increase capabilities to screen imported commodities for chemical and biological contaminants, FDA implemented the first Analytical Screening Station at the Port of Everglades. These capabilities enhance FDA's presence at U.S. Ports of Entry with real-time analytical tools to stop adulterated products from coming into the U.S. market. These screening stations serve to increase product surveillance and promote FSMA with a proactive approach to providing analytical support for imported products.

ORA provides ISO/IEC 17025:2005 cooperative agreements to assist human and animal food testing laboratories in obtaining and maintaining accreditation to the ISO standard, and currently funds 36 state laboratories in furtherance of this goal. The intended outcome of this program is for microbiological and chemical food analyses performed on behalf of State manufactured human and animal food regulatory programs to be conducted within the scope of an ISO/IEC 17025:2005 laboratory, thus advancing the NIFSS.

Surveillance of FDA-Regulated Products



FY 2016 FDA Inspections by Continent
*Numbers as of December 2016.

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.

Under the Generic Drug User Fee Act (GDUFA), FDA committed to conducting risk-adjusted biennial current cGMP surveillance inspections of human generic Active Pharmaceutical Ingredients and finished dose form manufacturers, with the goal of achieving risk adjusted parity in domestic and foreign inspections by 2017. The Food and Drug Administration Safety and Innovation Act (FDASIA) Section 705 requires FDA to replace the previous two-year drug inspectional frequency requirement with a risk-based inspection schedule for domestic and foreign drug facilities. To accomplish this goal, FDA has employed a site selection surveillance inspection model that runs annually on all facilities in the FDA's inventory.

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.

ORA made significant advancements to its foreign workplanning process through the development and implementation of a new IT system. The Workplanning, Inspection, and Tracking System (WITS) captures and tracks the entire foreign food inspection planning and scheduling process in real-time and includes GIS mapping technology that identifies facilities specific locations. WITS has allowed ORA to streamline the foreign food inspection program, automating the creation of documents, removing duplicative steps in the process and capturing

the facility verification process through use of an intelligent questionnaire. This system has greatly improved ORA-Center coordination, collaboration, communication, and data integrity. ORA is currently working to deploy WITS beyond food commodities to include all foreign inspections and is evaluating its potential use for domestic inspections as well.

The Agency continues to leverage the work of its dedicated foreign inspections cadre, 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 responses 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.

ORA has expanded its assistance to state agencies regarding the capacity of inspection of medical devices with the addition of the California Department of Public Health to the FDA's Medical Device Contractual Inspection Program.

ORA is heavily involved in many critical aspects of FDA's human drug compounding program, including inspections and enforcement, policy development and implementation, state collaboration and coordination, and stakeholder outreach. In FY 2016 alone, ORA conducted 135 inspections of compounders, many of which belong to the category of compounders called outsourcing facilities that was created by the Drug Quality and Security Act of 2013.

Enforcement of FDA Authorities

In 2016, the criminal investigative work of ORA's Office of Criminal Investigations (OCI) resulted in 257 arrests, 274 convictions, and over $374.5 million in forfeiture, fines, and restitution. Many of these cases involved the distribution and sale of substandard and falsified products manufactured outside of the United States.

In continuing efforts to combat transnational criminal networks threatening public health, OCI increased its international presence through the assignment of Special Agents overseas. Since FY 2014, an OCI Special Agent has been stationed at Europol, in the Netherlands, and in FY 2016, OCI assigned a Special Agent at the Interpol Global Complex for Innovation (IGCI) in Singapore to work with Interpol's Global Health and Safety Sub-directorate. The IGCI is a cutting-edge research and development facility used for the international identification of crimes and criminals, innovative training, and operational support and partnerships.

Each year, OCI participates in Operation Opson, an Europol - Interpol joint operation targeting counterfeit and substandard food and beverages. Run from November 2015 through February 2016 and across 57 countries, Operation Opson V resulted in the seizure of 11,131.18 tons, 1,449,056.40 liters, and 5,549,328 units of counterfeit or substandard food and beverages.

OCI's Cybercrime Investigations Unit (CcIU) is on the leading edge of combating the global trafficking of substandard and falsified FDA-regulated products on the internet. Each year, CcIU agents team-up with internal and external partners as part of Interpol's annual Operation Pangea. FDA's collaborative efforts under Operation Pangea have resulted in more than 2,400 illegal

online pharmacy websites being taken offline and the seizure of over $81 million worth of potential dangerous illegal medicines and medical devices worldwide.

Through FY 2016, OCI has conducted training sessions on cybercrime, counterfeit drugs, and drug diversion for foreign criminal law enforcement agencies in Mexico, Canada, Central and South America, Africa, Asia, Australia, the Middle East, and Europe.

In 2014, OCI entered into a Letter of Intent Agreement with the French National Gendarmerie to combat counterfeit drugs and other transnational crimes affecting public health. In 2016, as part of the agreement, an officer of the National Gendarmerie attended OCI's Special Agent Training Program at the Federal Law Enforcement Training Center in Charleston, South Carolina.

FDASIA Section 706 allows FDA to obtain certain records from a drug manufacturer in lieu of or in advance of an inspection. In FY 2016, ORA initiated a time-limited six-month use of this authority in advance of already-planned cGMP surveillance inspections of foreign drug establishments. This program allowed ORA to garner data and qualitative feedback from ORA investigators and establishments regarding the appropriate scope and volume of records to request, the burden of producing and reviewing those records, and the process for requesting and confirming receipt of records. Investigators provided input on the usefulness of particular records for planning and targeting their on-site inspection time. In FY 2017, ORA will complete and analyze the results of this initial use of the authority, and accordingly plan to expand its use.

In FY 2016, ORA's Florida District Office used the authority under 706 for the first time to obtain records in advance of an inspection at a firm involved with the manufacturing and processing of prescription drugs after reports of an associated *Burkholderica cepacia* outbreak.

In FY 2016, FDA successfully enjoined 16 firms and executed four seizures of goods at facilities for violations to the FD&C Act and promulgated regulations.

FDA also utilized administrative authorities under FSMA. Specifically, FDA hand-delivered a Suspension of Registration order to a seafood manufacturer in New York. The firm was a processor and manufacturer of ready-to-eat (RTE) seafood products found to contain Listeria monocytogenes. Some of the strains had a pattern combination that was seen previously; some coming from clinical samples.

Improve and Safeguard Access

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

Premarket Activities

Implementation of GDUFA 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 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. ORA continues to conduct pre-approval and Bioresearch Monitoring (BIMO) inspections to support original and prior approval supplements to meet the GDUFA commitment goals.

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. To that end, ORA has launched several efforts intended to strengthen the core underpinnings of the organization: grade parity and career ladders, workforce development, and organizational culture and values.

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.

Throughout the implementation of FSMA, the Agency has looked for various new and innovative ways to train ORA and Center staff for these new rules. For the seven new FSMA rules, FDA has worked closely with industry, academia, and other stakeholders to develop training which will be comprehensive and helpful to all concerned. For some programs, the training curriculum for the rules involved two different parts: training that regulators and other stakeholders attend together, allowing for an open exchange of ideas and flow of information; and training specifically for regulators to learn how to implement the new rules. The training has been developed as a cooperative effort between FDA, industry and academia.

Throughout the year, ORA served as expert participants with the CFSAN and Center for Veterinary Medicine (CVM) counterparts to develop and complete several information webinars dubbed "FSMA Chats." During these chats, which started in FY 2016, FDA experts provide updated information regarding particular FSMA programs and answer questions from FDA staff, key stakeholders and regulated industry. This has allowed interaction between stakeholders in a new and innovative manner that allows for an open exchange of ideas outside of the normal regulatory pathways.

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 exploring 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, Low Acid Canned Foods/Acidified Foods (LACF/AF), 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. ORA's MLDP launched several new FY 2016 initiatives that provided further

opportunity to enhance ORA's leadership culture including partnering and collaborating with the FDA Alumni Association to create a mentoring program partnering current ORA managers with rehired annuitants to expand leadership competencies. The FDA Alumni Advisory Program is the recipient of the 2016 FDA Honors Innovator Award. Continuing ORA's Resilient Leadership Training Program helps leaders to lead with calm, clarity, and conviction.

Values Initiative
ORA recently launched an initiative that sought to capture stakeholder's thoughts about ORA's core values and the values that best reflect today's environment. This initiative included surveys and stakeholder engagement at every level of the organization, and resulted in a new set of values for ORA including: Accountability, Commitment to Public Health, Communication, Diversity and Inclusion, Integrity and Respect, and Quality.

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 which will allow FDA to have more commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, well-designed and coordinated implementation, and a de-layered management structure. Full implementation of program alignment is expected in FY 2017.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actual	$1,092,819,000	$1,022,759,000	$70,060,000
FY 2017 Annualized CR	$1,121,641,000	$1,005,877,000	$115,764,000
FY 2018 President's Budget	$1,051,206,000	$876,782,000	$174,424,000

BUDGET REQUEST

The FY 2018 budget request is $1,051,206,000, of which $876,782,000 is budget authority and $174,424,000 is user fees. Budget authority decreases by $129,095,000 compared to the FY 2017 Annualized CR budget and user fees increase by $58,660,000.

The FY 2018 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.

BUDGET AUTHORITY

Reductions (-$68.1 million)

Food Safety: -$53.7 million
In order to continue operations under the FY 2018 request level, ORA will apply the necessary program reductions to areas such as partnerships, training, IT and lab equipment, and across all program office operating budgets. While every effort will be made to protect resources for priorities including inspections and compliance activities, some reductions may occur due solely to reduced staff. ORA will reduce existing workforce levels through attrition, and will work to minimize the impact related to field exams, import entry review, investigations, sample analysis, and inspections for surveillance, compliance, and follow up activities, both domestically and abroad. It is FDA's goal to minimize the impact of these reductions on FDA's core mission activities.

ORA will reduce several state cooperative agreements. This impact includes reductions to the cooperative agreements supporting:

- the Food Emergency Response Network (FERN), a network able to respond to biological, chemical, or radiological food contamination emergencies
- the International Standards Organization (ISO) accreditation which supports non-FDA laboratories in achieving and maintaining this accreditation
- the Manufactured Food Regulatory Program Standards (MFRPS), which help develop and implement standards for federal and state programs to better direct regulatory activities toward reducing foodborne illness
- the Animal Feed Regulatory Program Standards (AFRPS), which help ensure a uniform and consistent approach to feed regulation
- the retail food protection standardization program, which helps prevent foodborne illness associated with the preparation, service, and sale of foods in food service and retail establishments.

Medical Product Safety & Availability: -$14.4 million
ORA will apply strategic reductions to its programs in order to preserve the highest priority activities and operations in support of protecting public health. ORA will reduce existing workforce levels through attrition.

In order to continue operations under the FY 2018 request levels, ORA will apply the necessary program reductions to areas such as training, IT and lab equipment, and across all program office operating budgets, while protecting resources for inspections and compliance activities.

Medical Product User Fee Recalibration (+$60.7 million)

The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees.

USER FEES

Medical Product User Fee Recalibration (+$60.7 million)

The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees.

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 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
214212: Percentage of planned import food field exams (approximately 160,000 in total). *(Output)*	FY 2016: 172,449 Target: 160,158 (Target Exceeded)	99%	99%	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2016: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain
214209: As required by the FSMA Legislation, cover all of the High Risk domestic inventory (approximately 19,000 firms) every three years. *(Output)*	FY 2016: 99.8% Target: 100% (Target Not Met)	33%	66%	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2016: 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
224211: Percentage of planned foreign and domestic high-risk human drug inspections (approximately 560 in total). *(Output)*	FY 2016: 698 Target: 560 (Target Exceeded)	64%	64%	Maintain
234212: Percentage of registered domestic blood bank and biologics manufacturing inventory inspected (approximately 900 in total). *(Output)*	FY 2016: 992 Target: 900 (Target Exceeded)	99%	99%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
234213: Percentage of planned human foreign and domestic tissue establishment inspections (approximately 570 in total). *(Output)*	FY 2016: 703 Target: 570 (Target Exceeded)	82%	82%	Maintain
244212: Percentage of domestic and foreign high-risk animal drug and feed inventory inspected (approximately 225 in total). *(Output)*	FY 2016: 248 Target: 225 (Target Exceeded)	99%	99%	Maintain
244203: Percentage of planned targeted prohibited material BSE inspections (approximately 477 in total). *(Output)*	FY 2016: 100% Target: 100% (Target Met)	99%	99%	Maintain
253211: Percentage of planned Medical Device Bioresearch Monitoring (BIMO) inspections (approximately 300 in total). *(Output)*	FY 2016: 309 Target: 300 (Target Exceeded)	91%	91%	Maintain
254211: Percentage of planned domestic and foreign Class II and Class III device inspections (approximately 1,600 in total). *(Output)*	FY 2016: 2,075 Target: 1,600 (Target Exceeded)	57%	57%	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 recognizes the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting the entire high-risk domestic inventory every three years. This goal serves to cumulatively track the progress over the three-year period as the coverage of the high-risk domestic inventory approaches the FSMA-driven goal of 100 percent. FY 2016 marked the final year of a three-year cycle.

The identified inventory to be inspected at the beginning of the FY 2014 to F 2016 cycle was approximately 19,000 firms; however this inventory number does not remain static over the course of the inspection cycle. Therefore as the inventory changes over the three-year period, FDA must make adjustments to work plans to meet the 100 percent target. Upon completion of FY 2016, the cumulative percentage reached 99.8 percent, very nearly achieving the 100 percent

target. This high level of accomplishment was achieved despite the dynamic and uncertain conditions facing FDA. For example, given that this goal tracks the inspections of the high-risk inventory there are more likely to be issues uncovered during these inspections. This requires ORA to redirect resources to conduct follow-up actions and reinspections, which use resources that otherwise would be deployed for inspecting the rest of the required inventory. The near-miss of the 100 percent target in FY 2016 resulted from a combination of changes in the inventory and utilization of resources for follow up or reinspections conducted within the domestic foods high-risk inventory that count as inspections but do not count toward additional coverage of the inventory, as these are inspections conducted at the same firm more than once.

FY 2017 marks the beginning of a new cycle and the target returns to 33 percent to signify that FDA is targeting the first third of the inventory for the new three-year cycle. FDA came very close to meeting our FY 2016 goal of 100 percent, and most of the remaining FSMA high risk firm inspections were completed in early FY 2017.

Moving from Numbers to Percentages for Field Targets

ORA is in the process of improving the field performance measures to make the measures more outcome oriented and better aligned with ORA's Program Alignment initiative. Several ORA performance goals will now be targeting either a percentage of the number specified in the work plan or a percentage of total inventories. Reporting a percentage rather than a number will clarify that these goals are intended to align with the public health priorities reflected in the work planning and inventory coverage. This also allows FDA the flexibility to respond dynamically to changing circumstances during the year, as work plans are revised to reflect emerging risks and evolving public health priorities. While the reporting format will change from numbers to percentages, the underlying level of activities for inspections and import field exams will be maintained from FY 2016 through FY 2017 and FY 2018.

PROGRAM ACTIVITY DATA TABLES

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,933***	***8,000***	***8,000***
Domestic Food Safety Program Inspections	5,783	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	182		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	249		
Domestic Fish & Fishery Products (HACCP) Inspections	716		
Import (Seafood Program Including HACCP) Inspections	321		
Juice HACCP Inspection Program (HACCP)	161		
Interstate Travel Sanitation (ITS) Inspections	922		
Domestic Field Exams/Tests	2,398	2,500	2,500
Domestic Laboratory Samples Analyzed	16,927	13,000	13,000
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,269***	***1,400***	***1,400***
All Foreign Inspections	1,269	1,400	1,400
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,202***	***9,400***	***9,400***
IMPORTS			
Import Field Exams/Tests	252,766	168,200	168,200
Import Laboratory Samples Analyzed	23,736	35,300	35,300
Import Physical Exam Subtotal	**276,502**	**203,500**	**203,500**
Import Line Decisions	13,952,537	14,650,164	15,382,672
Percent of Import Lines Physically Examined	1.98%	1.39%	1.32%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	87,817	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,952***	***9,088***	***9,088***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***676***	***100***	***100***
State Contract Food Safety (Non HACCP) Inspections	7,897	8,000	8,000
State Contract Domestic Seafood HACCP Inspections	964	1,000	1,000
State Contract Juice HACCP	91	100	100
State Contract LACF	110	100	100
State Partnership Inspections	676	100	100
State Contract Foods Funding	$13,283,752	$13,682,265	$14,092,732
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$19,038,534	$17,705,837	$16,466,428
Total State & Annual FERN Funding	**$32,322,286**	**$31,388,101**	**$30,559,161**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,830***	***18,588***	***18,588***

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***133***	***100***	***100***
Domestic Inspections	133	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***3***	***0***	***0***
Foreign Inspections	3	0	0
IMPORTS			
Import Field Exams/Tests	12,036	1,600	1,600
Import Laboratory Samples Analyzed	393	400	400
Import Physical Exam Subtotal	**12,429**	**2,000**	**2,000**
Import Line Decisions	2,939,034	3,085,986	3,240,285
Percent of Import Lines Physically Examined	0.42%	0.06%	0.06%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***136***	***100***	***100***

[1] The FY 2016 actual unique count of foreign inspections includes 178 OIP inspections (147 for China, 9 for India, & 22 for Latin America).

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,846***	***1,767***	***1,767***
Pre-Approval Inspections (NDA)	88	135	135
Pre-Approval Inspections (ANDA)	92	215	215
Bioresearch Monitoring Program Inspections	616	550	550
Drug Processing (GMP) Program Inspections	805	650	650
Compressed Medical Gas Manufacturers Inspections	97	50	50
Adverse Drug Events Project Inspections	88	88	88
OTC Monograph Project and Health Fraud Project Inspections	51	70	70
Compounding Inspections[1]	135	130	130
Domestic Laboratory Samples Analyzed	1,301	1,300	1,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1231***	***1275***	***1275***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	100	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	173	190	190
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	214	255	255
Foreign Drug Processing (GMP) Program Inspections	909	900	900
Foreign Adverse Drug Events Project Inspections	7	10	10
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***3,077***	***3,042***	***3,042***
IMPORTS			
Import Field Exams/Tests	10,053	10,000	10,000
Import Laboratory Samples Analyzed	1,009	620	620
Import Physical Exam Subtotal	**11,062**	**10,620**	**10,620**
Import Line Decisions	739,309	776,274	815,088
Percent of Import Lines Physically Examined	1.50%	1.37%	1.30%
STATE WORK			
UNIQUE COUNT OF STATE PARTNERSHIP HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***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	***3,077***	***3,042***	***3,042***

[1] The number of compounding inspections includes inspections of compounders that are and are not registered with FDA as outsourcing facilities.

[2] The FY 2016 actual unique count of foreign inspections includes 82 OIP inspections (41 for China, 35 for India, & 6 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 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,875***	***1,909***	***1,909***
Bioresearch Monitoring Program Inspections	80	100	100
Blood Bank Inspections	895	900	900
Source Plasma Inspections	180	190	190
Pre-License, Pre-Market Inspections	61	55	55
GMP Inspections	38	28	28
GMP (Device) Inspections	4	7	7
Human Tissue Inspections	638	650	650
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***68***	***47***	***47***
Bioresearch Monitoring Program Inspections	17	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	7	7	7
Pre-License, Pre-market Inspections	7	7	7
GMP Inspections (Biologics & Device)	34	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,943***	***1,956***	***1,956***
IMPORTS			
Import Field Exams/Tests	155	45	45
Import Line Decisions	151,911	162,545	173,923
Percent of Import Lines Physically Examined	0.10%	0.03%	0.03%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,943***	***1,956***	***1,956***

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2016 Actuals			FY 2017 Annualized CR			FY 2018 President's Budget		
	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	***1,822***	***255***	***1,589***	***1,664***	***298***	***1,398***	***1,664***	***298***	***1,398***
Pre-Approval /BIMO Inspections	39	39	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	221	221	0	175	175	0	175	175	0
BSE Inspections	1,341	0	1,341	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	13	0	13	25	0	25	25	0	25
Illegal Residue Program Inspections	397	0	397	450	0	450	450	0	450
Feed Manufacturing Program Inspections	250	0	250	200	0	200	200	0	200
Domestic Laboratory Samples Analyzed	1,555	8	1,547	1,560	20	1,540	1,560	20	1,540
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***126***	***118***	***8***	***76***	***71***	***5***	***76***	***71***	***5***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	13	13	0	40	40	0	40	40	0
Foreign Drug Processing and New ADF Program Inspections	109	109	0	33	33	0	33	33	0
Foreign Feed Inspections	7	0	7	5	0	5	5	0	5
BSE Inspections	5	0	5	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,948***	***373***	***1,597***	***1,740***	***369***	***1,403***	***1,740***	***369***	***1,403***
IMPORTS									
Import Field Exams/Tests	7,935	796	7,139	3,795	495	3,300	3,300	495	3,300
Import Laboratory Samples Analyzed	894	4	890	867	2	865	867	2	865
Import Physical Exam Subtotal	**8,829**	**800**	**8,029**	**4,662**	**497**	**4,165**	**4,167**	**497**	**4,165**
Import Line Decisions	446,903	48,661	385,723	469,248			492,711		
Percent of Import Lines Physically Examined	1.98%	1.64%	2.08%	0.99%			0.85%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***3,702***	***0***	***3,702***	***3,832***	***0***	***3,832***	***3,832***	***0***	***3,832***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [1]	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [2]	***2***	***0***	***2***	***0***	***0***	***0***	***0***	***0***	***0***
State Contract Inspections: BSE	3,694	0	3,694	3,500	0	3,500	3,500	0	3,500
State Contract Inspections: Feed Manufacturers	623	0	623	620	0	620	620	0	620
State Contract Inspections: Illegal Tissue Residue	134	0	134	130	0	130	130	0	130
State Partnership Inspections: BSE and Other	0	0	0	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	2	0	2	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$3,073,399	0	$3,073,399	$3,165,601	0	$3,165,601	$3,260,569	0	$3,260,569
BSE Cooperative Agreement Funding	$0	0	$0	$0	0	$0	$0	0	$0
State Contract Tissue Residue Funding	$456,317	0	$456,317	$442,627	0	$442,627	$429,348	0	$429,348
Total State Funding	**$3,529,716**	**$0**	**$3,529,716**	**$3,608,228**	**$0**	**$3,608,228**	**$3,689,917**	**$0**	**$3,689,917**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,652***	***373***	***5,301***	***5,572***	***369***	***5,235***	***5,572***	***369***	***5,235***

[1] The FY 2016 actual unique count of foreign inspections includes 12 OIP inspections (11 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 Partnership inspections.

[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 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,499***	***2,492***	***2,492***
Bioresearch Monitoring Program Inspections	272	300	300
Pre-Market Inspections	61	60	60
Post-Market Audit Inspections	69	60	60
GMP Inspections	1,420	1,400	1,400
Inspections (MQSA) FDA Domestic (non-VHA)	704	700	700
Inspections (MQSA) FDA Domestic (VHA)	54	50	50
Domestic Radiological Health Inspections	47	50	50
Domestic Field Exams/Tests	15	100	100
Domestic Laboratory Samples Analyzed	255	170	170
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS	***603***	***595***	***595***
Foreign Bioresearch Monitoring Inspections	15	14	14
Foreign Pre-Market Inspections	26	30	30
Foreign Post-Market Audit Inspections	30	20	20
Foreign GMP Inspections	728	550	550
Foreign MQSA Inspections	13	14	14
Foreign Radiological Health Inspections	78	50	50
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,102***	***3,087***	***3,087***
IMPORTS			
Import Field Exams/Tests	29,992	19,800	19,800
Import Laboratory Samples Analyzed	577	670	670
Import Physical Exam Subtotal	**30,569**	**20,470**	**20,470**
Import Line Decisions	18,757,725	20,070,766	21,475,719
Percent of Import Lines Physically Examined	0.16%	0.10%	0.10%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,803***	***7,880***	***7,880***
UNIQUE COUNT OF STATE PARTNERSHIPS DEVICE ESTABLISHMENT INSPECTIONS [1]	***0***	***0***	***0***
Inspections (MQSA) by State Contract	6,716	6,800	6,800
Inspections (MQSA) by State non-Contract	1,044	1,060	1,060
GMP Inspections by State Contract	43	20	20
State Partnership GMP Inspections	0	0	0
State Contract Devices Funding	$267,249	$275,266	$283,524
State Contract Mammography Funding	$9,720,997	$9,957,944	$10,157,103
Total State Funding	**$9,988,246**	**$10,233,210**	**$10,440,627**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,905***	***10,967***	***10,967***

[1] The FY 2016 actual unique count of foreign inspections includes 12 OIP inspections (8 for China and 4 for India).

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