OFFICE OF REGULATORY AFFAIRS - FIELD ACTIVITIES

(Dollars in Thousands)	FY 2018 Enacted	FY 2018 Actuals	FY 2019 Annualized CR	FY 2020 President's Budget	FY 2020 (+/-) FY 2019 Annualized CR
Office of Regulatory Affairs	**1,171,116**	**1,152,189**	**1,173,404**	**1,223,992**	**50,588**
Budget Authority	***1,061,799***	***1,061,760***	***1,061,799***	***1,110,861***	***49,062***
User Fees	***109,317***	***90,429***	***111,605***	***113,131***	***1,526***
Prescription Drug (PDUFA)	*9,511*	*9,123*	*10,569*	*10,333*	*-236*
Medical Device (MDUFA)	*2,314*	*2,292*	*2,457*	*2,390*	*-67*
Generic Drug (GDUFA)	*55,915*	*55,355*	*56,808*	*57,430*	*622*
Biosimilars (BsUFA)	*1,150*	*1,158*	*1,100*	*1,363*	*263*
Animal Drug (ADUFA)	*310*	*36*	*431*	*440*	*9*
Animal Generic Drug (AGDUFA)	*238*	*3*	*335*	*216*	*-119*
Family Smoking Prevention and Tobacco Control Act	*14,684*	*10,612*	*14,684*	*14,684*	*---*
Mammography Quality Standards Act (MQSA)	*13,995*	*11,380*	*13,995*	*14,556*	*561*
Food And Feed Recall	*1,000*	*---*	*1,000*	*1,040*	*40*
Food Reinspection	*5,382*	*---*	*5,382*	*5,600*	*218*
Voluntary Qualified Importer Program	*4,320*	*---*	*4,320*	*4,495*	*175*
Third Party Auditor Program	*144*	*---*	*144*	*150*	*6*
Outsourcing Facility	*354*	*470*	*380*	*434*	*54*
FTE	**4,898**	**4,898**	**4,939**	**4,997**	**58**

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); Drug Quality and Security Act of 2013; Food and Drug Administration Reauthorization Act of 2017 (FDARA) (P.L. 115-52).

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 on FDA regulated products to ensure their safety,

effectiveness, and quality. As FDA's lead office for all agency field activities, ORA is responsible for a wide range of mission critical activities including:

- inspections and investigations (including criminal investigations)
- sample collection and analyses
- examination of FDA-regulated products offered for import into the United States
- oversight of recalls and execution of enforcement actions
- response to consumer complaints and emergencies
- development and promotion of state and local partnerships.

FDA regulated products account for about 20 cents of every dollar spent in the United States. ORA protects consumers and enhances public health by maximizing compliance and minimizing risk of all FDA-regulated products including:

- human and animal foods, cosmetics, and dietary supplements
- human and veterinary drugs
- vaccines, blood products, tissue, tissue products, allergenics, cellular and gene therapy products
- medical devices and products that emit radiation
- tobacco products.

ORA has staff in 227 offices across 49 states, including the U.S. Virgin Islands and the Commonwealth of Puerto Rico, with staff both temporarily and permanently assigned to foreign posts. ORA manages 13 scientific laboratories including two colocated medical product labs, and one tobacco lab that conducts applied research and performs highly specialized analyses of domestic and imported products. ORA also develops and maintains information technology systems used across FDA that support information sharing and risk-based decision making. In addition, ORA promotes an Integrated Food Safety System (IFSS) by providing resources to state, local, tribal, and territorial (SLTT) regulatory jurisdictions to conduct inspections, collect samples, and enhance program capacity and infrastructure by advancing conformance with national regulatory program standards.

Recent Accomplishments

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

Enhanced Presence at International Mail Facilities (IMFs)

In response to the current opioid crisis, ORA prioritized support to increase personnel and improve space and infrastructure at IMFs. In FY 2018, ORA increased our presence at the IMFs by hiring 40 import investigators, which resulted in an increase in examinations at the IMFs to 27,000, which was three times more than FY 2017 levels. In addition, ORA doubled the Office of Criminal Investigations(OCI) Port of Entry program staff by hiring 12 special agents and two senior operations managers to oversee the program, as well as 8 chemists to perform scientific testing and assist in the development of a standard set of tools to aid in investigations and parcel review. Improvements at IMFs will continue, as ORA implements new authorities included in the the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), signed into law on October 24, 2018. The SUPPORT Act will enhance ORA's ability to work in partnership with Customs and Border Protection (CBP) and U.S. Postal Service to prevent the importation of unsafe, unapproved, and

misbranded products by providing new enforcement tools and additional resources, equipment and analytical instrumentation for the IMFs.

Integrated Food Safety System (IFSS)

ORA continues to support a Food Safety Modernization Act (FSMA) mandate to strengthen the food safety capabilities of SLTT agencies that FDA relies on to meet the increased inspection mandate. ORA offers resources through contracts, grants, and cooperative agreements to promote the development of partnerships among other federal and SLTT agencies. In addition, to support the design and management of IFSS regulatory programs, FDA works with its SLTT agencies and association partners to develop and implement national standards.

European Union (EU) Mutual Recognition Agreement

The amended Pharmaceutical Annex of the 1998 U.S. – European Union (EU) Mutual Recognition Agreement (MRA) was implemented on November 1, 2017. The Mutual Recognition Agreement allows us to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. This collaborative effort increases efficiency across U.S. and EU regulatory systems by avoiding duplicative inspections, allowing the reallocation of resources to areas with higher public health risks, and thereby enabling greater market access and improving international harmonization.

ORA continues to work with the Centers on successful implementation and operationalization of the MRA by participating in European assessments organized by the European Medicines Agency. As of December 1, 2018, FDA has recognized 20 European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. To date, ORA has completed its review of 42 inspection reports from EU capable countries.

Strengthen Science and Efficient Risk-Based Decision Making

Surveillance of FDA-Regulated Products

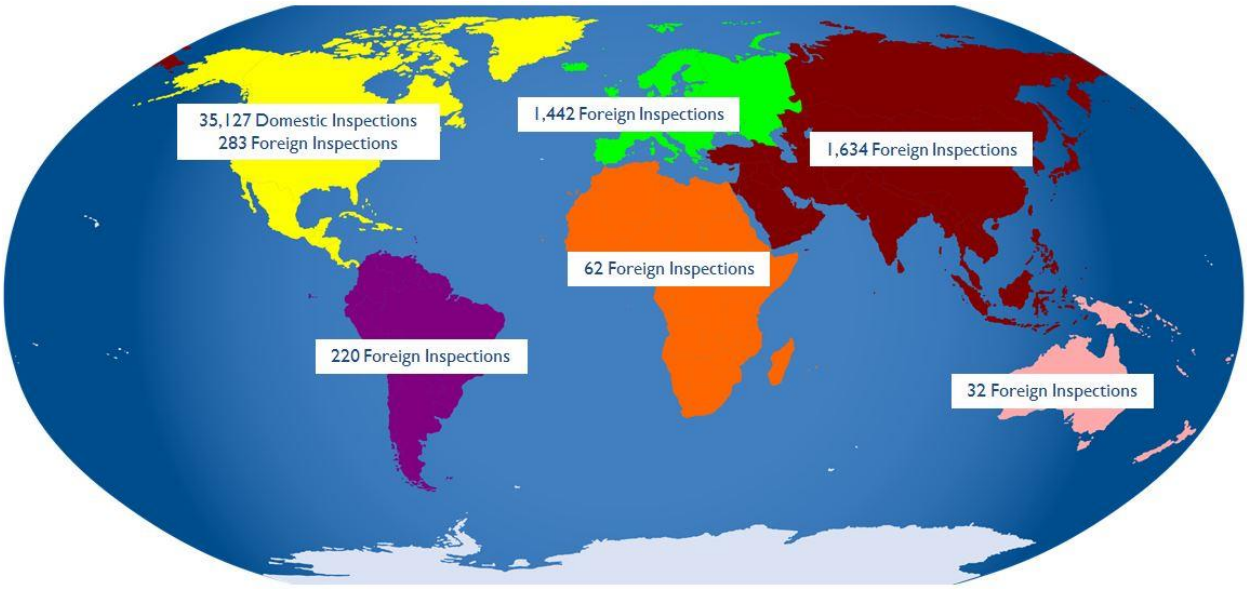

Figure 15 FY 2018 FDA Inspections by Continent. *Numbers as of December 2018

ORA works with each FDA Center to develop and implement a work plan that outlines assignments for over 500 activity areas across FDA's regulated commodities while maintaining flexibility to respond to unplanned activities, such as product recalls, emergencies, and outbreak investigations, to ensure quick containment and mitigation. ORA accomplishes the FDA mission through a highly skilled professional staff including:

- Consumer safety officers (CSOs)
- Compliance officers
- Laboratory analysts
- Recall coordinators
- Occupational Safety and Health Officers
- Consumer complaint coordinators
- Criminal investigators
- State cooperative program specialists

FDA's foreign inspections are a critical component of protecting the health and safety of U.S. citizens. These inspections ensure that products produced in foreign countries intended for the U.S. market meet the same regulatory standards as those manufactured domestically.

ORA enhances the overall coverage of the foreign establishment inventory by leveraging the work of its dedicated foreign inspections cadre, the inspection staff located at FDA's foreign offices, and domestic-based investigators. In addition, through enhancements to technology systems, FDA has increased transparency and access to importers and other government agencies to improve the efficiency of the review of products offered for entry into the U.S.

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 food products. ORA's investment in training and the mobilization of joint ORA and state Rapid Response Teams increases consumer protection, and minimizes the loss of consumer confidence, while lessening the economic impact on industry.

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
- stakeholder outreach.

In FY 2018 alone, ORA conducted 130 inspections of compounding facilities. Many belong to the category of compounders called outsourcing facilities created by the Drug Quality and Security Act of 2013. Outsourcing facilities are a new sector of drug compounder intended to provide a safe and reliable supply of compounded drugs needed by hospitals, clinics and other providers. ORA Occupational Safety and Health Officers have provided advisement and training to safely handle and ship active pharmaceutical ingredients.

The FDA Reauthorization Act of 2017 (FDARA) requires the Food and Drug Administration (FDA) to publicly report information related to inspections of facilities necessary for approval of a drug or a device. FDARA section 902 requires that the FDA make a report regarding facility

inspections related to drug and device approvals available on an annual basis through the Agency's website. The report contains data on inspections necessary for the approval of specified human drugs and medical devices. The inaugural report was published March 1, 2018. The information and metrics contained in this report provide benchmark data to industry stakeholders regarding inspections related to product application approvals.

Enforcement of FDA Authorities

ORA's Office of Criminal Investigations (OCI) has the primary responsibility for criminal investigations conducted by FDA and for all law enforcement and intelligence issues pertaining to threats against FDA-regulated products. Through July of FY 2018, the criminal investigative work of OCI resulted in:

- 283 domestic arrests
- 34 foreign arrests
- 215 convictions
- Approximately $2.3 billion in forfeiture, fines, and restitutions.

FDA continues to move aggressively toward targeting worldwide organized criminal groups involved in the distribution of illicit FDA-regulated products. As part of a larger Agency-wide strategy to combat this threat, OCI will assign two additional OCI Special Agents overseas. These two postings will be based out of U.S. Embassies and act as the single point of contact for embassy personnel in all matters relating to the law enforcement jurisdiction of the FDA.

Further, they will serve in a diplomatic role representing the FDA and the U.S. Government with foreign partner agencies. Currently, OCI has Special Agents stationed at Europol, in the Netherlands, and the Interpol Global Complex for Innovation (IGCI) in Singapore. These new positions enhance OCI's capabilities to share and receive criminal intelligence, plan and execute enforcement operations, and the further development of viable international partnerships.

OCI's ongoing Import Operations Program (IOP) is intended to detect violative shipments of FDA-regulated commodities entering our national ports and mail systems. There are 12 full-time and six part-time OCI IOP Special Agents overseen by two Senior Operations Managers. Their priorities include responding to international mail facilities, fast parcel carriers, ports, and mail hubs. This initiative enables OCI Special Agents to collaboratively work with their regulatory colleagues from FDA, CBP, and other Federal law enforcement agencies to stop the flow of violative or counterfeit human and animal drugs, vaccines, medical devices, and other biologic and tobacco products into the United States. During FY 2019, OCI anticipates doubling the size of IOP.

In recognition of the global supply chain, OCI has continued to place a strong emphasis upon international engagement. For example, OCI plays leading coordinating roles in the annual Operations Pangea and Opson. Operation Opson targets counterfeit and substandard food and beverages. Operation Pangea targets illicit medicines. Demonstrating the seriousness of the threat posed by illicit medicines, Operation Pangea X involved 123 of Interpol's 193 member countries. Further, Operation Pangea X was responsible for:

- over 400 arrests
- 470,000 seizures valued at over $51 million
- 3,524 websites being taken down worldwide.

OCI also maintains a leadership position within the Permanent Forum of International Pharmaceutical Crime, thereby placing its Special Agents in direct contact with their law enforcement counterparts from around the world. During FY 2018, OCI strengthened its Cybercrime Investigations Unit (CcIU) by assigning five additional full-time Special Agents to this program. Currently, there are 11 full-time CcIU Special Agents whose activities are managed by a Senior Operations Manager and supported by dedicated analytical staff. Their priorities include the strategic targeting of transnational criminal groups misusing the internet and those that support them by attempting to penetrate the FDA regulated supply chain, or by intentionally misrepresenting the nature of their products. Looking forward to FY 2019, OCI anticipates doubling the size of CcIU.

During FY 2018, OCI facilitated several workshops including

- one in Santo Domingo, Dominican Republic, involving representatives from more than 8 countries, titled "Measures against trade in illicit counterfeit health and safety products;" and
- one in Bangkok, Thailand, involving representatives from more than fifteen countries, Interpol, and regulated industry, targeting counterfeit goods being sold online.

IFSS and Program Standardization

To support an IFSS and protect the nation's food supply through domestic oversight, FDA relies on the strength and capability of federal and SLTT public health regulatory programs. FDA provides resources to SLTT public health regulatory agencies to build infrastructure, provide education to industry, complete regulatory inspections, and implement national regulatory program standards. FDA currently has 48 human manufactured food contracts covering 44 states and Puerto Rico. FDA also has 32 animal food contracts and 5 eggs contracts. Through FDA Contracts, over 11,000 inspections, 1,600 site visits, and 9,700 sample collections are planned in FY19.

FDA collaborates with SLTTs and numerous regulatory and public health associations to develop guidance, training, and standards to ensure uniformity in the regulation and approach taken by our food safety partners. FDA also works with the Partnership for Food Protection (PFP) and 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
- provide a collaborative vision and approach for a sustainable uniform electronic data exchange with IFSS partners.

FDA has worked collaboratively with its SLTT regulatory partners to develop three sets of national regulatory program standards:

- Manufactured Food Regulatory Program Standards (MFRPS)
- Animal Feed Regulatory Program Standards (AFRPS)
- Voluntary National Retail Food Regulatory Program Standards (VNRFRPS).

National standards establish a uniform foundation for the design and management of human and animal food regulatory SLTT programs. One of the key principles of FSMA is to rely on partner agencies to meet inspection mandates. National regulatory standards increase consistency and uniformity among partner agencies, and promote interagency confidence for effective, and efficient action to protect public health. As of October 2018, we have 43 SLTT programs enrolled in the MFRPS, 22 in the AFRPS, and 839 in the VNRFRPS.

FDA has awarded produce safety cooperative agreements to 46 states and 1 territory to increase their capacity and training efforts. By funding states to establish or expand produce safety resources FDA is able to leverage resources and advance the Produce Safety Rule. FDA is committed to working with state partners and other stakeholders to develop educational materials for inspections and outreach. In FY18, FDA collaborated with external stakeholders to develop plans and documents to ensure national consistency for the implementation of produce inspections, compliance, and enforcement. Produce inspections are set to begin nationwide in 2019.

Mitigating Significant Increases in Import Entry

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.

Import Operations

IMPORT LINES BY PROGRAM AREA
FY 2014-FY 2020 (Est.)

Program Area	2014	2015	2016	2017	2018	5 Yr Actual Percent Growth*	2018 Percent of Total Lines	Estimate 2019	Estimate 2020
Foods	12,180,223	13,080,429	13,952,537	15,251,687	16,859,790	8%	38.62%	17,702,780	18,587,918
Cosmetics	2,596,057	2,930,682	2,939,034	2,625,555	2,729,584	3%	6.25%	2,866,063	3,009,366
Human Drugs	641,908	688,208	739,309	789,853	871,212	8%	2.00%	914,773	960,511
Animal Drugs & Feeds	391,388	416,860	434,384	426,484	456,684	4%	1.05%	479,518	503,494
Biologics	82,710	150,673	151,911	157,080	170,575	21%	0.39%	179,104	188,059
Medical Devices & Rad Health	16,668,422	17,252,283	18,757,725	20,584,138	22,291,902	9%	51.06%	23,852,335	25,521,999
Tobacco Products	20,161	16,680	32,972	199,066	281,097	126%	0.64%	295,152	309,909
Total	32,580,869	34,535,815	37,007,872	40,033,863	43,660,844	8%	100.00%	46,289,724	49,081,257

*Percentage growth based off a 5 year average (FY 2014 - FY 2018)

ORA works with the U.S. Customs and Border Protection (CBP) through several partnerships and Memoranda of Understanding to improve and streamline the import process and expedite the release of compliant products. FDA is one of 12 partner government agencies present at CBP's Commercial Targeting and Analysis Center (CTAC). CTAC is designed to promote interagency collaboration to target high-risk shipments and increase compliance with Federal standards and regulations.

FDA and CBP continue to work together to assess recommendations from Commercial Operations Advisory Committee (COAC) for implementation. COAC is a 20-member council that meets quarterly and advises government agencies on the commercial operations of CBP and related functions. Taken into consideration are such issues as:

- global supply chain security and trade 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.

ORA continues to implement the Voluntary Qualified Importer Program (VQIP). The FDA VQIP portal launched this year and is open to accept VQIP applications for importer benefits that begin in FY 2020; with review of applications to begin in January 2019. VQIP is a fee-based program that provides an expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains. As part of the application, importers must submit certifications issued under the FDA Accredited Third Party Certification program. Expedited entry incentivizes importers to adopt a robust system of supply chain management and allows FDA to focus its resources on food entries that pose a higher risk to public health.

FDA has developed and implemented an account management system, the Industry Trade Auxiliary System (ITACS), for bilateral communications with importers and other industry stakeholders. ITACS is voluntary and allows additional information to be requested by FDA on entries and submitted from trade. Additionally, and perhaps just as importantly, ITACS generates an electronic notification to trade rather than requiring the information to be sent out through traditional mail. The system went live in September 2017 and has received accolades from industry.

Premarket Medical Product Activities

To ensure products are produced as outlined in medical product application, ORA inspects manufacturing facilities. Implementation of GDUFA allows FDA to complete inspections of establishments which have not been previously inspected, those 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 and coordinates inspections of generic drug manufacturing facilities with Center application reviews. In addition, ORA and CDER are working to decrease the amount of time required to complete domestic and foreign inspections of establishments conducting bioequivalence analytical and clinical studies. To reduce the time from application to review decision, tighter timeframes have been applied. In addition, ORA and CDER have reached an agreement to allow CDER to conduct some analytical site inspections. This arrangement allows FDA to conduct more inspections in a shorter period, speeding the review of generic drug applications.

CDER and ORA have developed a streamlined process for Pre-Approval Facility Evaluation and inspections, thru our concept of operations (Con-Ops) strategic framework. This framework

discusses how the Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) will work together regarding application review, inspections, and the compliance activities associated with them. These activities directly supports the assessment of marketing applications by assuring that the data in the applications is accurate, complete, and any manufacturing facility named in the application conforms to Current Good Manufacturing Practice (cGMP) requirements. In addition, CDER and ORA have developed a streamlined approach involving aligned, patient-focused, and risk-based drug product quality recommendations inclusive of drug substance, drug product, manufacturing, and facilities.

Strengthen Science and Efficient Risk-Based Decision Making

Risk-Related Prevention Focus

ORA supports a risk-related preventive focus. For example, ORA uses a risk-based model to focus inspection efforts, in conjunction with FDA Centers, to prioritize resources on the highest risk firms both domestically and abroad. In addition, ORA advocates for enhanced collaboration with federal, SLTT, and global public health regulatory partners.

To improve coverage of the domestic inventory FDA provides support and funding to SLTT food safety partners to support an IFSS. Strengthening the domestic network of regulators allows ORA to apply its investigators to the areas of regulation that pose the highest risk to the public, including the increase in unsafe, unapproved, and misbranded FDA regulated products imported from the global marketplace.

Over the years, sampling approaches have evolved to help FDA understand risks, assess the value of strategies to control those risks, and prevent contaminated products from reaching consumers. FDA has created a vision for the sampling process that is not just traditional surveillance and compliance-based. The process also serves as a mechanism to actively identify risks and areas where preventive controls should be placed to protect public health. As FDA increases its understanding of contamination sources in high risk commodities and practices, resources can be effectively allocated to address public health risks through compliance sampling, targeted sampling or other risk mitigation strategies.

The Center for Food Safety and Applied Nutrition (CFSAN) and ORA have developed a model where various information sources, including those from our regulatory partners and external stakeholders, can be used to shape sampling assignments. For example, if a state or external stakeholder has done research on a certain product, FDA may include that data to inform its decision making on assignments.

The Center for Drug Evaluation and Research (CDER) and ORA entered an unprecedented Concept of Operations (ConOps) agreement to integrate facility evaluations and inspections for human drugs. The agreement, "Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations", outlines the responsibilities and the workflow for Pre-Approval, Post-Approval, Surveillance, and For-Cause inspections at domestic and international facilities. ConOps has streamlined FDA's process for inspections and compliance to reduce the time to issue advisory and enforcement actions. For example, as of July 2018, 81% of our enforcement/advisory actions were issued within six months of the close of the inspection.

Additionally, CDER and ORA are continuing to work together to develop a new and efficient inspection and reporting paradigm to better assess and record the state of quality in manufacturing facilities. This project, known as the New Inspection Protocol Project (NIPP),

uses standardized electronic inspection protocols, templates and semi-automated inspection reports. Following four years of developing, pilot testing and refinement, the first two NIPP protocols, one covering sterile drug surveillance inspections and the other sterile pre-approval drug inspections, were fully implemented starting on October 29, 2018. The new protocols will not change the role of the investigator. Instead they will provide a more structured tool for completing inspections and completing the establishment inspection report. Additional protocols are being developed and will be piloted for implementation through 2020. It is expected that as NIPP data is collected, analysis will reveal anomalies, patterns and correlations, which will help drive decision-making and further reduce risks related to drug quality.

ORA and CDER are also working together to implement, the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), which DSCSA outlines requirements to develop and enhance drug supply chain security by 2023 and includes product tracing requirements for manufacturers, repackagers, wholesale distributors and dispensers. The DSCSA directs FDA to establish national standards for licensing wholesale distributors (WDDs) and third-party logistics providers (3PLs) to improve drug supply chain security. The DSCSA also created a new licensing scheme for WDDs and 3PLs that will license in states that don't have a licensing program in accordance with federal standards. The licensure program, still under development, can be categorized into three primary areas: accreditation, licensing, and inspection. These three areas must include: accepting and reviewing applications; developing a program for accrediting third parties to conduct inspections; developing an inspection program; and accepting user fees. Regulations to implement the licensing provisions are currently undergoing final review and are expected to be proposed in the first half of CY2019.

In order to maximize ORA's medical device inspectional resources, and mitigate the harm to consumers, the Center for Devices and Radiological Health (CDRH) and ORA incorporated a risk-based model for the identification of facilities to be inspected each year. For surveillance purposes, ORA focuses their medical device inspectional staff of approximately 120 investigators on products and facilities identified as highest risk through CDRH's risk-model.

Mammograms are critical to early detection of breast cancer. Each year, FDA and inspectors in 44 states evaluate the level of compliance at more than 8500 mammography facilities. Rad Health Representatives (RHR) within ORA work directly with the states to ensure that every mammography clinic is inspected yearly. The RHRs communicate with CDRH and with the states to ensure consistent compliance scrutiny and enforcement.

In addition, FDA participates in the Medical Device Single Audit Program (MDSAP) which allows an Auditing Organization to conduct a single regulatory audit of a medical device manufacturer in five (5) countries: the US, Australia, Brazil, Canada and Japan. Approximately 2900 facilities around the world are participating in the MDSAP program. ORA works closely with CDRH to ensure any signals of significant public health risk are communicated and appropriate "For Cause" inspections are initiated.

In FY19, ORA will conduct inspections of over 800 U.S. blood establishments. By providing this oversight, ORA plays an important role in maintaining the safety of the US blood supply. According to the 2015 National Blood Collection and Utilization Survey, 16 Million units of red cells, platelets and plasma were transfused in the US in 2015.

ORA conducts inspections of domestic and foreign vaccine manufacturers to help ensure the safety and availability of vaccines for U.S. children and adults. In the 2017-2018 flu season, 155.3 million doses of influenza vaccine were distributed in the U.S.

Under the Bioresearch Monitoring program, ORA conducts over 1100 domestic and 315 foreign inspections each fiscal year. These inspections are driven by risk-based selection models developed in each of FDA's six product centers to ensure that the rights, safety, and welfare of human and animal subjects are protected during participation in trials. In addition, inspections are conducted of postmarket adverse event reporting and risk evaluation and mitigation strategies (REMS) to ensure patients continue to be protected after products are available on the market.

Implementation of Program-Based Organizational Model

Over the years, the products regulated by FDA have become more complicated, the markets more global, and the rules governing our actions more complex. Changing our operational model enables ORA to adapt to meet challenges and improve our efforts to protect public health. Program Alignment (PA) was implemented in May 2017 and realigned ORA's five geographic regions into six specialized programs for operations:

- Biological Products
- Bioresearch Monitoring
- Human and Animal Foods
- Medical Devices and Radiological Health
- Pharmaceutical Quality
- Tobacco.

In addition, ORA aligned Import Operations as its own program of specialization, although it still oversees all products regulated by FDA. ORA laboratories have also specialized and been aligned into Human and Animal Foods Labs or Medical Product, Tobacco and Specialty Labs.

The FDA PA initiative moved the agency toward a more collaborative program-based model. PA allows employees to become specialized in their work, where appropriate, and over time will modify certain processes with the goal of improved cross-agency communication, collaboration, and clarity in roles and responsibilities. PA modernizes and strengthens the FDA workforce to improve public health response in a way that keeps pace with the acceleration of scientific innovation, global expansion of markets, and modern legal authorities. For those regulated by FDA, the new organizational model will result in uniformity in both process and policy across the organization and coordinated interactions within FDA between the field and the centers.

Workforce and Leadership Development

Training and development of ORA staff is critical. Increasingly complex inspections, along with new regulations and legislation, require employees completing inspections to have specialized knowledge in each regulatory program area. Under PA, staff training and development have been elevated in the reporting structure to raise its visibility and cross-organizational importance.

To develop the ORA leaders of the future with the skills needed to lead our complex and diverse workforce, the Management and Leadership Development Program (MLDP) continues to offer training and development opportunities for all ORA staff, with an emphasis on those seeking a future management position or career advancement. The program curriculum provides

participants with successively complementary leadership and management skills that lead to the Executive Core Qualifications necessary for senior agency leaders.

ORA continues to complete Job Task analyses which deconstructs job functions to determine the knowledge skills and abilities needed to complete work in each focus area. In FY 2018 Job Task Analyses were completed in Pharma and Tobacco for investigators, and Chemistry for Analysts. In FY 2019, new Job Task Analyses will be completed for Microbiology (both Food and Medical Products) and State Liaisons, with updates to those already existing in Biologics, Clinical BIMO, and Medical Devices. Using previously collected data, ORA is redesigning the pharmaceutical investigator training to reflect the changing industry landscape. This redesign will provide for flexible and specialized workforce with the project carrying through FY2020 and FY2021. Similar development project work is already underway for the bioresearch monitoring, medical devices, and radiological health program areas with new courses being piloted in FY2019 and FY2020.

Reduce the Burden of Addiction Crises that are Threatening American Families

Tobacco Enforcement

On May 10, 2016, the "Deeming Rule" was published in the Federal Register giving FDA the authority to "deemed" tobacco products such as electronic cigarettes, cigars, hookah, and pipe tobacco and their components and parts. The Tobacco Operations Staff completed 71 inspections of tobacco product manufacturers (66 Domestic and 5 Foreign), 33 investigations and investigated 7 free sample events in FY 2018. The FDA sent letters to several companies requiring them to submit important documents to better understand the reportedly high rates of youth use and appeal of their electronic cigarette products. In addition, ORA inspected companies for the purposes of collecting evidence and documentation to determine the establishment's compliance with the relevant provisions of the Food Drug and Cosmetic Act (FD&C Act). CTP requested that ORA conduct an initial comprehensive evaluation to collect inspectional documentation to evaluate complaints regarding the sale of tobacco products to under age youth, illegal sales, and improper samples of products prohibited by the FD&C Act. CTP is currently reviewing these documents and may notify firms of their potential violations based on ORA's evidence. In fiscal year 2019, ORA's Tobacco Operations Staff will be performing at least 200 manufacturing inspections and investigating a minimum of 7 free sample events.

Foster Competition and Innovation

Cultivating a Global Regulatory Network

FDA continues to increase its regulatory presence globally to ensure that the human and animal food and medical products available in the United States meet U.S. regulatory requirements. FDA fosters this global product safety net by enhancing existing partnerships, encouraging new partnerships, and developing cross-agency coalitions with domestic and foreign partners. ORA continues to improve and increase information sharing and joint work planning and compliance collaborations with SLTT, federal, and global regulatory partners.

FDA recognizes that it must embrace new approaches to enhance the safety of imported foods and fulfill its public health mission in a global age. Recognizing the value in leveraging the expertise of foreign food safety systems, FDA continues to pursue systems recognition arrangements as a tool to:

- set regulatory priorities
- establish closer regulatory partnerships
- improve efficiency
- strengthen the nation's food safety supply.

Systems recognition determines if a foreign country's food safety system and food safety authority/authorities provide similar oversight and monitoring for food produced under its jurisdiction. Systems recognition assists the FDA to prioritize the scope and frequency of its oversight activities including foreign facility inspections, import field exams, and import sampling. FDA has established systems recognition with New Zealand, Australia, and Canada and is working to evaluate a system recognition agreement with member states in the European Union.

FDA continues to participate as an active member of Pharmaceutical Inspection Cooperation Scheme (PIC/S), the multinational organization that now contains 52 participating authorities representing the pharmaceutical inspectorate. The mission of PIC/S is to lead the international development, implementation, and maintenance of harmonized Good Manufacturing Practices (GMP) standards and quality systems of inspectorates in the field of medicinal products. ORA has Increased their participation in PIC/S by joining the Joint Visits Programme (JVP) for Good Clinical Practice (GCP) and Good Pharmacoviligelence Practice (GVP). Under the JVP, ORA is conducting joint inspections with PIC/S members to compare inspectional focus and practices, with the goal of regulatory confidence building and information sharing with international partners. In September 2018, FDA hosted the annual PIC/S Training Seminar: Management of Risk Through the Product Life-Cycle, in Chicago, Illinois. The seminar was attended by over 200 inspectors from 46 countries.

The U.S. FDA – Mexico Produce Safety Partnership (PSP), is a bilateral partnership that focuses on the safety of produce traded across our respective borders. The goal of the PSP is to implement preventive practices and verification measures that support high rates of compliance with produce safety standards and best practices to reduce risk of foodborne illness or death associated with produce. The PSP collaboration reinforces preventive practices and allows both countries to respond rapidly in the event of a potential or actual outbreak. Mexico and the U.S. have cooperated on joint inspections, joint traceback investigations and root-cause-analysis environmental assessments, in addition to enhancing laboratory capacity.

Leveraging Laboratory Capabilities

ORA provides oversight of regulatory science standards in laboratories through the use of programs, systems, and cooperative agreements. FDA works with external partners, including states, foreign government regulatory authorities, and industry, to provide input on laboratory standards and on the identification of sampling assignments. This strategy gains cooperation up front, allows stakeholders to take part in developing assignments, and strengthens the surveillance of FDA-regulated food products.

ORA funds the Food Emergency Response Network (FERN) cooperative agreements designed to assist state laboratories build their capability and capacity to respond to large-scale food contamination events. Currently there are 33 FERN network laboratories, including 14 microbiological, 14 chemical, and 5 radiological laboratories. In addition, ORA provides cooperative agreements to 45 state human and animal food testing laboratories to meet and

maintain the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2005.

Figure 16 Figure 2 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

ORA labs are standing up specialized pharmaceutical testing research programs to develop regulatory methods to evaluate new biotech drugs in the cancer and auto-immune therapy sectors. There are two groups that specialize in pharmaceutical testing research programs on each side of the country, one located at Pacific Southwest Laboratory and the other at Northeast Laboratory. ORA is acquiring advanced instrument platforms such as Nuclear Magnetic Resonance Spectroscopy and Mass Spectrometry systems for these laboratories to probe the critical quality attributes of protein-based or nanoparticle-based drugs.

ORA continues to expand its analytical repertoire by developing and using cutting-edge technology to respond to public health needs. Employing a newly integrated technology called Whole Genome Sequencing (WGS), an ORA lab contributed to the first recall in FDA history that was primarily based on WGS results. The regulatory outcome was built on a solid scientific case that represented effective federal-state collaboration, communication, and use of new technology. To promote this technology further, ORA works with state regulatory partners to initiate and use WGS in state laboratories on a national level.

IT systems and Initiatives

ORA is committed to increasing productivity and maintaining program integrity through our information technology systems and initiatives. Capabilities of ORA operational and reporting systems were enhanced to develop functionality specifically: Import Certification and Third Party Accreditation; Voluntary Qualified Importer Program; and Foreign Supplier Verification Program Preventive Controls for Human and Animal Food.

In collaboration with the U.S CBP and 46 partner government agencies, ORA has transitioned to the Automated Commercial Environment/International Trade Data System (ACE/ITDS) which enhances capabilities and productivity to ensure the safety of imported products under FDA's regulatory authorities. ACE/ITDS is a single access point where industry can electronically submit all data required by various government agencies involved in international trade and receive dispositions on the goods they present for import.

ORA established importer Industry account management functionality which allows electronic communications between importers, filers and FDA staff thus saving both postage and staff resources. In addition, the application programming interface (API) developed by ORA for industry to access product code information, allows external users to check for product codes or validate them prior to submission to FDA to ensure entries are not held or rejected due to inaccurate product code information.

ORA developed an FDA Data Dashboard providing greater transparency to the public about FDA's inspectional, enforcement, recall, and compliance activities. The Dashboard has also been expanded to support the FSMA requirement to provide industry with information needed to support the FSVP program.

FUNDING HISTORY[95]

Funding History	Program Level	Budget Authority	User Fees
FY 2016 Actual	$1,092,819,000	$1,022,759,000	$70,060,000
FY 2017 Actual	$1,108,570,000	$1,040,199,000	$68,371,000
FY 2018 Actual	$1,152,189,000	$1,061,760,000	$90,429,000
FY 2019 Annualized CR	$1,173,404,000	$1,061,799,000	$111,605,000
FY 2020 President's Budget	$1,223,992,000	$1,110,861,000	$113,131,000

BUDGET REQUEST

The FY 2020 Budget Request is $1,223,992,000, of which $1,110,861,000 is budget authority and $113,131,000 is user fees. The budget authority increases by $49,062,000 compared to the FY 2019 Annualized Continuing Resolution level and user fees increase by $1,526,000.

The FY 2020 President's Budget allows FDA to continue to ensure that the food, feed, and medical products available to the American public are safe and effective.

[95] Numbers reflect comparability adjustments for FY 2018, FY 2019, and FY 2020 consistent with budget figures.

BUDGET AUTHORITY

Medical Product Safety (+$26.6 million / 32 FTE)

Opioids: +$21.8 million / 12 FTE
Field Human Drugs: +$21.8 million / 12 FTE

ORA is increasing FDA presence at International Mail Facilities (IMF) facilities, while taking into consideration the corresponding divisions under program alignment, incoming IMF parcel volume as well as existing personnel. With one-time funding from the FY 2018 Omnibus, ORA is hiring an additional 125 FTE in support of the nine IMFs and will increase the number of reviews from 15,000 to 100,000 per year. In addition, ORA is requesting additional staff and funds to support lab work related to the increased package screening.

Compounding: +$2.8 million / 10 FTE
Field Human Drugs: +$2.8 million / 10 FTE

Outsourcing facilities are working to ensure that their facilities and compounding practices result in compounded drugs of acceptable quality. With additional resources, FDA would be able to provide additional assistance to outsourcing facilities in their efforts to meet this important public health objective. FDA investigators, experts, and other staff would be able to dedicate more time and attention to facility inspections, reviewing the evidence collected, evaluating the corrective actions, and take appropriate measures to ensure that patients receive drugs compounded under appropriate conditions. Outsourcing facilities would benefit from more frequent and in-depth information-sharing meetings with FDA experts and correspondence with the Agency regarding quality improvements. Purchasers of compounded drugs would also have access to more up-to-date information regarding the outsourcing facilities so that they can make informed sourcing decisions. State and federal regulatory partners would also benefit from the availability of more timely and robust outsourcing facility information.

New Domestic Drug Industry: +$2.0 million / 10 FTE
Field Human Drugs: +$2.0 million / 10 FTE

ORA will support the Center of Excellence on Compounding for Outsourcing Facilities and provide hands-on assistance to these facilities to improve compliance. ORA also will support training and outreach initiatives to strengthen state oversight of compounding, as well as a pilot program of contracted state inspections.

In addition, ORA will establish a specialized group of investigators who will spend a majority of their time on outsourcing facility inspectional activities. As discussed above, outsourcing facilities are in their early growth years and would benefit from more frequent FDA inspections and site visits, which outsourcing facilities in the past have requested. These visits would not only help the sector come into compliance, but also help address regulatory hurdles in states that refuse to license these facilities unless they receive annual inspections by FDA. Furthermore, outsourcing facilities are distinct from conventional manufacturers in numerous ways and require specialized knowledge to inspect. A specially trained group of investigators who spend a majority of their time on outsourcing facility oversight will develop a highly sophisticated expertise; will become intimately familiar with the facilities, systems, and technologies that they routinely inspect; and will provide timely, consistent, substantive feedback when compliance issues are identified. This initiative will also help FDA meet annual inspection targets and conduct additional facility visits when requested by the outsourcing facility.

Food Safety (+$22.4 million / 23 FTE)

Advancing FSMA: +$10.3 million
Field Human Foods: +$10.3 million

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct domestic food and feed facility inspections required by FSMA. ORA will enhance its oversight of industry's compliance with the human food preventive control rules by expanding funding of cooperative agreements with state food regulatory programs.

To ensure effectiveness and efficiency, FDA expects that states will continue or increase their number of inspections as FDA transitions to prevention-oriented inspections and determines industry compliance with the new FSMA standards and rules. NASDA and AFDO also have requested funds for FDA to provide states to complete Preventive Control (PC) inspections.

Field Animal Drugs & Feeds: +$5.6 million

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct [IS11] domestic food and feed facility inspections required by FSMA. FDA expects that states will continue to gradually increase the number of inspections they conduct as FDA transitions to prevention-oriented inspections. NASDA and AAFCO have requested funds for FDA to provide states to complete Preventive Control (PC) inspections by updating and building new state programs. The cooperative agreements will support work for states to implement the recommendations of the NASDA PC Animal Food Framework that include evaluating and building infrastructure, updating inspection and enforcement programs, developing outreach and training programs, and shifting laboratory resources to focus on analysis of hazards.

Strengthening Response Capabilities for Foodborne Outbreaks: +$6.5 million / 23 FTE
Field Human Foods: +$6.5 million / 23 FTE

In recent years FDA has refined its traceback methods to increase speed and efficiency during outbreaks and recalls. Additional resources are required to ensure that, as soon as possible, contaminated food is detected and removed from the marketplace and that consumers are alerted.

FDA is requesting additional FTEs to support new procedures for collecting, reviewing, and posting retail consignees for certain Class I and Class II recalls. To ensure we have complete information, FDA will expend significant resources collecting consignee lists throughout the distribution chain (recalling firm, distributors, etc.) and then reviewing them to identify retailers that may have sold the recalled product. The list of retailers will be consolidated into one master list and posted onto FDA's website. This will protect public health by allowing consumers to recognize whether they have purchased recalled products."

USER FEES

Current Law User Fees: +$1.5 million

The ORA request includes an increase of $1,526,000 for user fees authorized under FDARA, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of medical products and accelerating innovation in the industry.

PERFORMANCE

ORA's performance measures focus on import screening activities, laboratory capacity, and domestic and foreign inspections 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 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	Baseline: 90% (New Measure)	80%	80%	Maintain
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	Baseline: 86% (New Measure)	80%	80%	Maintain
234221: Percentage of Biologics significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	Baseline: 75% (New Measure)	70%	70%	Maintain
254221: Percentage of Medical Device and Radiological Health significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	Baseline: 89% (New Measure)	80%	80%	Maintain
214222: Percentage of Human and Animal Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 78% (New Measure)	65%	65%	Maintain
224222: Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 67% (New Measure)	55%	55%	Maintain
234222: Percentage of Biologics follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 71% (New Measure)	65%	65%	Maintain
254222: Percentage of Medical Device and Radiological Health follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 81% (New Measure)	65%	65%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
253221: Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	Baseline: 90% (New Measure)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2018: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2018: 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
214212: Percentage of planned import food field exams. (Output)	FY 2018: 123% Target: 95% (Target Exceeded)	NA	NA	NA
214209: As required by the FSMA Legislation, cover all of the High Risk domestic inventory every three years. (Output)	FY 2018: 75% Target: 66% (Target Exceeded)	NA	NA	NA
224211: Percentage of planned foreign and domestic high-risk human drug inspections. (Output)	FY 2018: 70% Target: 70% (Target Met)	NA	NA	NA
234212: Percentage of planned domestic blood bank and biologics manufacturing inspections. (Output)	FY 2018: 105% Target: 95% (Target Exceeded)	NA	NA	NA

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020 +/- FY 2019
234213: Percentage of planned human foreign and domestic tissue establishment inspections. (Output)	FY 2018: 105% Target: 85% (Target Exceeded)	NA	NA	NA
244212: Percentage of planned domestic and foreign high-risk animal drug and feed inspections. (Output)	FY 2018: 97% Target: 95% (Target Exceeded)	NA	NA	NA
244203: Cover targeted prohibited material BSE actual inventory. (Output)	FY 2018: 92% Target: 95% (Target Not Met)	NA	NA	NA
253211: Percentage of work plan issued Medical Device Bioresearch Monitoring (BIMO) inspections. (Output)	FY 2018: 106% Target: 91% (Target Exceeded)	NA	NA	NA
254211: Percentage of planned domestic and foreign device inspections. (Output)	FY 2018: 88% Target: 80% (Target Exceeded)	NA	NA	NA

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

New ORA Field Performance Measures

ORA is embarking on an initiative to move from output focused performance goals such as inspection counts to public health outcome based performance goals. This initiative seeks to provide more meaningful performance goals for internal and external stakeholders, and to showcase more direct public health impacts for ORA. The new performance goals introduced for FY 2019 measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention, and allows for a more robust analysis.

Since these targets are based on a planned number of inspections, it is possible to inspect more than what was planned and thus have an actual inspection rate over 100 percent. This is particularly true for import food field exams because even when import investigators meet their work plan target, they are still required to continue exams for incoming high-risk products being flagged for review by a risk-screening tool for imports called PREDICT.

Coverage of Targeted Prohibited Material BSE Actual Inventory Goal Target Not Met

The only goal not met this year was the coverage of targeted prohibited material BSE inventory coverage. This goal fell short by three percentage points. Similar to last year, resource constraints and shifting priorities (e.g.: response to natural disasters) impacted the full completion of this goal. BSE coverage is also a collaborative effort between FDA and State partners and as such, inspection coverage may vary given differing fiscal year timeframes. The ability for FDA to track BSE inventory and BSE work conducted by the States is problematic due to IT constraints and FDA continues to work on infrastructure improvements for future success.

New ORA Field Performance Measures

PROGRAM ACTIVITY DATA TABLES

Field Foods Program Activity Data (PAD)

Field Foods Program Activity Data (PAD)			
Field Foods Program Workload and Outputs	**FY18 Actuals**	**FY2019 Estimate**	**FY2020 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***8,629***	***8,000***	***8,000***
Domestic Food Safety Program Inspections	5,876	**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	162		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	234		
Domestic Fish & Fishery Products (HACCP) Inspections	809		
Import (Seafood Program Including HACCP) Inspections	191		
Juice HACCP Inspection Program (HACCP)	149		
Interstate Travel Sanitation (ITS) Inspections	1,046		
Domestic Field Exams/Tests	3,059	2,500	2,500
Domestic Laboratory Samples Analyzed	15,470	13,000	13,000
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,638***	***1,400***	***1,400***
All Foreign Inspections	1,638	1,400	1,400
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***10,267***	***9,400***	***9,400***
IMPORTS			
Import Field Exams/Tests	185,761	168,200	168,200
Import Laboratory Samples Analyzed	20,895	35,300	35,300
Import Physical Exam Subtotal	**206,656**	**203,500**	**203,500**
Import Line Decisions	16,859,790	17,702,780	18,587,918
Percent of Import Lines Physically Examined	1.23%	1.15%	1.09%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	84,113	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,073***	***9,062***	***9,062***
State Contract Food Safety (Non HACCP) Inspections	7,210	8,000	8,000
State Contract Domestic Seafood HACCP Inspections	788	1,000	1,000
State Contract Juice HACCP	57	100	100
State Contract LACF	117	100	100
State Contract Foods Funding	$13,620,000	$13,756,200	$13,893,762
Number of FERN State Laboratories	33	33	33
Annual FERN State Cooperative Agreements/Operations Funding	$15,865,891	$15,865,891	$15,865,891
Total State & Annual FERN Funding	**$29,485,891**	**$29,622,091**	**$29,759,653**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,340***	***18,462***	***18,462***

[1] The FY 2018 actual unique count of foreign inspections includes 171 OIP inspections (120 for China, 38 for India, & 13 for Latin America).

[2] ORA is currently evaluating the calculations for future estimates.

3 State partnership inspections have been removed from the PAD as they have been phased out. All state inspections are now accounted for under the "state contract" inspection category.

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Activity Data (PAD)			
Field Cosmetics Program Workload and Outputs	**FY 2018 Actuals**	**FY 2019 Estimate**	**FY 2020 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***71***	***100***	***100***
Domestic Inspections	71	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***6***	***0***	***0***
Foreign Inspections	6	0	0
IMPORTS			
Import Field Exams/Tests	6,195	1,600	1,600
Import Laboratory Samples Analyzed	335	400	400
Import Physical Exam Subtotal	**6,530**	**2,000**	**2,000**
Import Line Decisions	2,729,584	2,866,063	3,009,366
Percent of Import Lines Physically Examined	0.24%	0.07%	0.07%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***77***	***100***	***100***
1 ORA is currently evaluating the calculations for future estimates.			

Field Human Drugs Program Activity Data (PAD)

Field Human Drugs Program Workload and Outputs	FY 2018 Actuals	FY 2019 Estimate	FY 2020 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,662***	***1,709***	***1,709***
Pre-Approval Inspections (NDA)	81	100	100
Pre-Approval Inspections (ANDA)	90	90	90
Bioresearch Monitoring Program Inspections	667	600	600
Drug Processing (GMP) Program Inspections	632	650	650
Compressed Medical Gas Manufacturers Inspections	42	50	50
Adverse Drug Events Project Inspections	73	88	88
OTC Monograph Project and Health Fraud Project Inspections	19	70	70
Compounding Inspections[1]	127	142	142
Domestic Laboratory Samples Analyzed	1,041	1,300	1,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***1221***	***1360***	***1360***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	102	98	98
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	159	190	190
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	280	255	255
Foreign Drug Processing (GMP) Program Inspections	743	900	900
Foreign Adverse Drug Events Project Inspections	8	10	10
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,883***	***3,069***	***3,069***
IMPORTS			
Import Field Exams/Tests	8,607	10,000	10,000
Import Laboratory Samples Analyzed	735	620	620
Import Physical Exam Subtotal	**9,342**	**10,620**	**10,620**
Import Line Decisions	871,212	845,143	904,303
Percent of Import Lines Physically Examined	1.07%	1.26%	1.17%
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS	***2,883***	***3,069***	***3,069***

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

[2] The FY 2018 actual unique count of foreign inspections includes 115 OIP inspections (48 for China and 67 for India).

3 ORA is currently evaluating the calculations for future estimates.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Activity Data (PAD)			
Field Biologics Program Workload and Outputs	**FY 2018 Actuals**	**FY 2019 Estimate**	**FY 2020 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,849***	***1,892***	***1,892***
Bioresearch Monitoring Program Inspections	75	100	100
Blood Bank Inspections	807	900	900
Source Plasma Inspections	243	190	190
Pre-License, Pre-Market Inspections	81	55	55
GMP Inspections	45	28	28
GMP (Device) Inspections	13	7	7
Human Tissue Inspections	625	650	650
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***70***	***47***	***47***
Bioresearch Monitoring Program Inspections	15	11	11
Foreign Human Tissue Inspections	1	0	0
Blood Bank Inspections	7	7	7
Pre-License, Pre-market Inspections	6	7	7
GMP Inspections (Biologics & Device)	38	20	20
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,919***	***1,939***	***1,939***
IMPORTS			
Import Field Exams/Tests	73	45	45
Import Line Decisions	170,575	179,104	188,059
Percent of Import Lines Physically Examined	0.04%	0.03%	0.02%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,919***	***1,939***	***1,939***

[1]ORA is currently evaluating the calculations for future estimates.

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs & Feeds Program Activity Data (PAD)									
Field Animal Drugs and Feeds Program Workload and Outputs	**FY 2018 Actuals**			**FY 2019 Estimate**			**FY 2020 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	***1,436***	***160***	***1,276***	***1,664***	***298***	***1,398***	***1,664***	***298***	***1,398***
Pre-Approval /BIMO Inspections	33	33	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	120	120	0	175	175	0	175	175	0
BSE Inspections	746	0	746	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	5	0	5	25	0	25	25	0	25
Illegal Residue Program Inspections	322	0	322	450	0	450	450	0	450
Feed Manufacturing Program Inspections	179	0	179	200	0	200	200	0	200
Domestic Laboratory Samples Analyzed	1,223	13	1,210	1,560	20	1,540	1,560	20	1,540
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS [1]	***74***	***70***	***4***	***74***	***69***	***5***	***74***	***69***	***5***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	20	20	0	40	40	0	40	40	0
Foreign Drug Processing and New ADF Program Inspections	51	51	0	33	33	0	33	33	0
Foreign Feed Inspections	2	0	2	5	0	5	5	0	5
BSE Inspections	1	0	1	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,510***	***230***	***1,280***	***1,738***	***367***	***1,403***	***1,738***	***367***	***1,403***
IMPORTS									
Import Field Exams/Tests	3,557	868	2,689	3,795	495	3,300	3,795	495	3,300
Import Laboratory Samples Analyzed	963	0	963	867	2	865	867	2	865
Import Physical Exam Subtotal	**4,520**	**868**	**3,652**	**4,662**	**497**	**4,165**	**4,662**	**497**	**4,165**
Import Line Decisions	456,684	65,887	390,797	479,518	69,181	410,337	503,494	72,640	430,854
Percent of Import Lines Physically Examined	0.99%	1.32%	0.93%	0.97%	0.72%	1.02%	0.93%	0.68%	0.97%
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***3,050***	***0***	***3,050***	***3,396***	***0***	***3,396***	***3,396***	***0***	***3,396***
State Contract Inspections: BSE	2,713	0	2,713	3,500	0	3,500	3,500	0	3,500
State Contract Inspections: Feed Manufacturers	549	0	549	620	0	620	620	0	620
State Contract Inspections: Illegal Tissue Residue	85	0	85	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$3,369,732	0	$3,369,732	$3,470,824	0	$3,470,824	$3,574,949	0	$3,574,949
State Contract Tissue Residue Funding	$0	0	$0	$0	0	$0	$0	0	$0
Total State Funding	**$3,369,732**	**$0**	**$3,369,732**	**$3,470,824**	**$0**	**$3,470,824**	**$3,574,949**	**$0**	**$3,574,949**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***4,563***	***230***	***4,333***	***5,134***	***367***	***4,799***	***5,134***	***367***	***4,799***

[1] The FY 2018 actual unique count of foreign inspections includes 5 OIP inspections (4 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 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.

4 Tissue residue funding has ended in FY18 and state contract illegal tissue residue inspections are no longer being conducted.

Field Devices and Radiological Health Program Activity Data (PAD)

Field Devices and Radiological Health Program Activity Data (PAD)			
Field Devices and Radiological Health Program Workload and Outputs	**FY 2018 Actuals**	**FY 2019 Estimate**	**FY 2020 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***2,550***	***2,498***	***2,498***
Bioresearch Monitoring Program Inspections	308	300	300
Pre-Market Inspections	48	60	60
Post-Market Audit Inspections	35	60	60
GMP Inspections	1,350	1,400	1,400
Inspections (MQSA) FDA Domestic (non-VHA and VHA)	834	700	700
Domestic Radiological Health Inspections	102	50	50
Domestic Field Exams/Tests	43	100	100
Domestic Laboratory Samples Analyzed	174	170	170
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS [1]	***626***	***613***	***613***
Foreign Bioresearch Monitoring Inspections	14	14	14
Foreign Pre-Market Inspections	25	30	30
Foreign Post-Market Audit Inspections	19	20	20
Foreign GMP Inspections	557	550	550
Foreign MQSA Inspections	11	14	14
Foreign Radiological Health Inspections	59	50	50
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***3,176***	***3,111***	***3,111***
IMPORTS			
Import Field Exams/Tests	25,499	19,800	19,800
Import Laboratory Samples Analyzed	624	670	670
Import Physical Exam Subtotal	**26,123**	**20,470**	**20,470**
Import Line Decisions	22,291,902	23,852,335	25,521,999
Percent of Import Lines Physically Examined	0.12%	0.09%	0.08%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS	***7,663***	***7,880***	***7,880***
Inspections (MQSA) by State Contract	7,614	6,800	6,800
Inspections (MQSA) by State non-Contract	1060	1,060	1,060
GMP Inspections by State Contract	49	20	20
State Contract Devices Funding	$76,674	$270,000	$278,100
State Contract Mammography Funding	$10,591,706	$10,803,540	$11,019,611
Total State Funding	**$10,668,380**	**$11,073,540**	**$11,297,711**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***10,839***	***10,991***	***10,991***

[1] The FY 2018 actual unique count of foreign inspections includes 8 OIP inspections in China.

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

3 Domestic MQSA Non-VHA and VHA Inpsections have been combined into one output line.

[4]ORA is currently evaluating the calculations for future estimates.