

FDA HEADQUARTERS

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018	
				President's Budget	President's Budget +/- FY 2017 CR
FDA Headquarters	299,524	301,574	293,259	322,486	29,227
<i>Budget Authority</i>	<i>191,549</i>	<i>191,374</i>	<i>191,201</i>	<i>125,432</i>	<i>-65,769</i>
<i>User Fees</i>	<i>107,975</i>	<i>110,200</i>	<i>102,058</i>	<i>197,054</i>	<i>94,996</i>
<i>Prescription Drug (PDUFA)</i>	52,139	54,405	46,202	82,622	36,420
<i>Medical Device (MDUFA)</i>	6,259	8,293	5,732	29,260	23,528
<i>Generic Drug (GDUFA)</i>	24,690	26,680	25,050	47,270	22,220
<i>Biosimilars (BsUFA)</i>	1,354	190	1,388	4,602	3,214
<i>Animal Drug (ADUFA)</i>	913	813	947	5,475	4,528
<i>Animal Generic Drug (AGDUFA)</i>	388	209	453	1,452	999
<i>Family Smoking Prevention and Tobacco Control Act</i>	20,789	19,119	20,749	24,815	4,066
<i>Mammography Quality Standards Act (MQSA)</i>	248	491	253	253	---
<i>Food and Feed Recall</i>	75	---	75	75	---
<i>Food Reinspection</i>	480	---	480	480	---
<i>Voluntary Qualified Importer Program</i>	277	---	277	277	---
<i>Third Party Auditor Program</i>	73	---	73	73	---
<i>Outsourcing Facility</i>	290	---	379	400	21
FTE	1,209	1,209	1,273	1,332	59

*FY 2016 and FY 2017 do not reflect the transfer of \$1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA’s expanded authorities. For FY 2018, FDA proposes to discontinue the transfer.

Authorizing Legislation: The Federal Food Drug and Cosmetic Act (21 U.S.C. 321-399); Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss); The Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Foods Additives Amendments of 1958; Color Additives Amendments of 1960; Animal Drug Amendments (21 U.S.C. 360b); Controlled Substances Act (21 U.S.C. 801-830); The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); Safe Drinking Water Act (21 U.S.C. 349); Saccharin Study and Labeling Act; Federal Anti-Tampering Act (18 U.S.C. 1365); Medical Device Amendments of 1976; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Generic Animal Drug and Patent Term Restoration Act; Prescription Drug Marketing Act of 1987; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Prescription Drug Amendments of 1992; Safe Medical Device Amendments of 1992; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; Food Quality Protection Act of 1996; Federal Tea Tasters Repeal Act (42 U.S.C. 41); Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349); Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Best Pharmaceuticals for Children Act of 2002 (21 USC 355a Sec. 505A); Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12); Pediatric Research Equity Act of 2003 (21 USC 351 Sec. 505B); Project Bioshield Act of 2004 (21 U.S.C.360bbb-3); Minor Use and Minor Species Animal Health Act of 2004; Food Allergy Labeling and Consumer Protection Act of 2004 Medical Device User Fee Stabilization Act of 2005; Sanitary Food Transportation Act of 2005 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1); Pandemic and All-Hazards Preparedness Act, Food and Drug Administration Amendments Act of 2007; Protecting Patients and Affordable Care Act of 2010; The Family Smoking Prevention and Tobacco Control Act of 2009 (P.L. 111-31); The Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333); FDA Food Safety Modernization Act, Public Law 111-353 (January 4, 2011); The Food and Drug Administration Safety and Innovation Act (P.L. 112-144); Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Drug Quality and Security Act (2013), and the 21st Century Cures Act (P.L. 114-255).

Allocation Methods: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA Headquarters (HQ) provides strategic direction and a wide array of services, including cross-agency special medical, scientific, and regulatory programs, legal advice and counsel, and litigation services across FDA's programs. The following narrative describes FDA HQ activities within the FDA Strategic Goal framework.

Enhance Oversight

FDA HQ provides strategic leadership and coordination to enhance FDA's oversight of production, manufacturing, the global supply chain, and post market product use. FDA HQ provides policy direction and expertise to establish standards and guidance to protect patient and consumer safety. FDA HQ develops and standardizes policies and best practices across FDA consistent with statutes and regulations.

FDA's Oversight includes:

- inspecting manufacturing and production facilities
- providing surveillance of adverse events
- preventing unsafe products from harming consumers.

Within the area of Oversight, FDA provides Smart Regulation, Safety and Quality, Regulatory Science and Globalization. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.⁹⁴

Food Safety Modernization Act (FSMA) Rules Published

The FDA Food Safety Modernization Act was signed into law in 2011, creating a blueprint for sweeping changes to the nation's food protection system.

The seven foundational FSMA food safety rules support and strengthen the nation's food safety system by establishing requirements for farmers, food companies and importers to prevent foodborne illness.

2016 FSMA Rules

In 2016 FDA issued the sixth and seventh final rules known as the Sanitary Transportation and Intentional Adulteration rules. The Sanitary Transportation final rule (published in April 2016) creates a modern risk-based framework for food safety by preventing practices during transportation that create food safety risks, such as:

- failure to properly refrigerate food
- inadequate cleaning of vehicles between loads
- failure to properly protect food.

This rule also establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food.

The Mitigation Strategies to Protect Food Against Intentional Adulteration rule, (published in May 2016) directs domestic and foreign food facilities (required to register under the Federal

⁹⁴ Please visit <http://www.fda.gov/> for additional program information and detailed news items.

Food, Drug, and Cosmetic Act) to address hazards that may be intentionally introduced by terrorist acts. These food facilities must develop strategies to minimize or prevent vulnerabilities identified at actionable steps in a food operation.

As part of FSMA implementation, FDA published final guidance in November 2016 to establish a voluntary, fee-based program to expedite review and import of foods into the United States from importers with a proven food safety track record. This program, the Voluntary Qualified Importer Program (VQIP), will benefit both importers and consumers. VQIP allows FDA to focus its resources on the potentially dangerous food imports that are most likely to harm the public.

Emergency Preparedness and Response

FDA HQ coordinates Agency emergency response to adverse events with FDA-regulated products, foodborne illnesses, product tampering issues, man-made and natural disasters, and emergencies affecting FDA staff, systems, and facilities. The Office of Crisis Management (OCM) will continue to enhance agency preparedness and response capabilities through intra- and inter-agency exercises, plan development and execution, standard operating procedures, and enhanced incident management systems in order to improve the overall operation and effectiveness of FDA's emergency response.

FDA HQ provides nationwide, 24-hour, seven-day-a-week emergency response system, including Late Duty Officers coverage after-hours, weekends, and holidays through the Office of Emergency Operations (OEO). OCM also provide surveillance and signal monitoring, including FDA's Emergency Operations Network Incident Management System, and Consumer Complaint reporting and monitoring functions

In FY 2016, FDA HQ coordinated the emergency response to 64 significant incidents including:

- 18 serious adverse or injury event incidents
- 30 natural disasters
- 11 man-made disasters
- 5 National Special Security Events.

FDA HQ evaluated 4,149 consumer complaints including 61 reports of suspected product tampering in FY 2016 to ensure FDA's timely identification of and response to emergency safety concerns related to FDA-regulated products. FDA HQ worked diligently to develop, maintain, and coordinate an effective emergency response capability for public health emergencies by developing guidance detailing FDA's operational approach for responding to emergencies.

In FY 2016 FDA HQ coordinated eleven Agency responses to World Health Organization (WHO) International Food Safety Authorities Network (INFOSAN) inquiries involving food products (strawberries, pistachios, oysters, milled flour, scallops, etc.). FDA HQ also addressed eleven draft notices of Public Health Emergency of International Concern (PHEIC) in FY 2016, including multiple Zika notices, chikungunya, novel influenza variants, salmonella associated with an FDA regulated commodity, etc.

In FY 2016, FDA HQ conducted, evaluated and reported Table Top and Full Scale Exercises that included a medically downed patient in a High Containment Laboratory with Federal, State and Local resource participation. The resulting after action report emphasized the need for additional training in basic patient assessment and patient transport to a "clean area" for further triage. In

addition, FDA HQ created and presented 7 training opportunities for over 70 laboratory researchers.

In addition, FDA HQ supported HHS/ASPR/OEM with the following Incident Annex updates; Food, Agriculture Incident Annex, including Plant, Animal and Food Agriculture Input, the Federal Evacuation Annex, and the Chemical Incident Annex development, review and publication.

FDA HQ also provided training for key emergency response staff on how to better respond to complex incidents and make informed decisions during an event. FDA HQ supports ready access to classified information transmitted through secure government networks to ensure complete risk assessments during actual events.

The FDA Coordinated Outbreak Response and Evaluation (CORE) team rapidly detects and responds to major foodborne illness outbreaks in coordination with local, state, and federal agencies and laboratories. For example, in the fall of 2016, FDA, CDC, and state and local officials investigated a multi-state outbreak of hepatitis A. FDA's investigation linked the outbreak to frozen strawberries imported from Egypt. FDA then facilitated the recall of the International Company for Agricultural Production and Processing (ICAPP) frozen strawberry products.

Geographic Information System Mapping

In FY 2016, FDA HQ expanded the use of the Geographic Information System (GIS) to build risk-based models to assess the impact of global events to the U.S. supply chain. FDA HQ completed maps for more than 85 project requests involving FDA regulated firms.

Global Health Security and Counterterrorism

FDA HQ provides leadership, coordination, and oversight for FDA's work to support national and global health security, prevent counterterrorism, and address emerging threats. The portfolios include serving as point of entry on policy and planning matters; serving as a focal point for the HHS [Public Health Emergency Medical Countermeasures Enterprise](#) (PHEMCE) and the Department of Defense (DoD) medical countermeasure (MCM) programs to support the warfighter; and coordinating the [Medical Countermeasures Initiative](#) (MCMi) to facilitate the development of safe and effective MCMs against chemical, biological, radiological, and nuclear (CBRN) agents and emerging threats, such as pandemic influenza, Ebola virus, and Zika virus.

As part of the MCMi, FDA HQ funds research to improve FDA's ability to perform science-based review of MCMs designed to lessen the effects of CBRN and emerging infectious disease threats.

Notable accomplishments in FY 2016 and FY 2017:

- developing a lung model based on 'organs-on-a-chip' technology to use to develop drugs for acute radiation syndrome
- [mapping immune responses](#) to biothreats and MCMs in humans and developing animal models to support MCM development
- studying disease progression and effects of Zika Virus in non-human primate animal models as part of an FDA-established interagency collaboration.

FDA scientists continued activities to support the development of MCMs for Ebola, including:

- development of improved small animal models

- identification of potential markers of Ebola virus disease progression
- development and validation of analytical procedures for evaluating Ebola to use outside of specialized, high-containment laboratories.
- FDA regulatory science initiatives to respond to the Zika virus outbreak included:
 - understanding the effectiveness of technologies that reduce pathogens in blood
 - evaluating the impact of red blood cell storage on Zika virus infection
 - expanding the database of Zika virus-infected samples essential to the development of diagnostic devices
 - developing mouse model to study the long-term effects of Zika virus infection and to support MCM development.

FDA HQ develops and coordinates the implementation policies and procedures to facilitate the availability of MCMs, including safeguarding MCMs from adulteration or disruption of supplies during public health emergencies and enabling access to MCMs through an appropriate mechanism such as [Emergency Use Authorization \(EUA\)](#).

Accomplishments in 2016 that support MCMs include:

- establishment of an [international confidentiality commitment](#) with the Saudi Food and Drug Authority to facilitate communications on medical products used for Middle East respiratory syndrome coronavirus (MERS-CoV)
- issuance of guidance that explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical products
- establishment a Memorandum of Understanding with CDC for developing and issuing Emergency Use Instructions ([EUI](#)) for MCMs
- issuance of [emergency dispensing orders](#) for doxycycline and ciprofloxacin for anthrax preparedness
- finalization of revised draft guidance [Product Development Under the Animal Rule](#).

FDA HQ facilitated international coordination of response activities to emerging public health threats including the Ebola outbreak in West Africa and the [Zika virus](#) outbreak in the Americas.

FDA HQ facilitated the expedited development and availability of MCMs – including vaccines, drugs, protective equipment, and diagnostic tests – and authorized the use of 11 Ebola diagnostic tests and 14 Zika virus diagnostic tests under EUA authority.

FDA HQ also developed policies for the development, use, and export of investigational MCMs as necessary and helped to design clinical trials to evaluate investigational MCMs for Ebola and Zika virus. FDA HQ also:

- supported monitoring for products with unsubstantiated or fraudulent claims for the diagnosis, treatment, or prevention of Ebola and Zika
- led domestic and supported international policy development activities related to Ebola and Zika virus response.
- provided technical support to the World Health Organization and international regulatory counterparts (including West African and Brazilian counterparts).⁹⁵

⁹⁵ FDA signed a joint statement of continued cooperation between FDA and the Brazilian Health Regulatory Agency (ANVISA) to offer mutual support and to collaborate to address the public health emergency presented by the Zika virus disease outbreak in the Americas.

- provided public information and education on response activities via events, press releases and interviews, the FDA website and social media (see Communications with Stakeholders for more information).

Regulatory Policy and Guidance

Below are examples of regulations, guidances, and final rules issued by FDA HQ in 2016. This list does not represent any degree of importance or priority ranking among these items.⁹⁶

FRDTS#	Type	Formal Title	Date of Publication
2016-228	Guidance	Draft Food and Drug Administration Tribal Consultation Policy; Availability; Request for Comments	2/29/2016
2015-917	Guidance	Emergency Use Authorization of Medical Products and Related Authorities; Draft Guidance for Industry and Public Health Stakeholders; Availability	4/4/2016
2016-726	Final Rule	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment	11/29/2016

FDA HQ coordinated with the National Institutes of Health (NIH) on the September 21, 2016 final rule for clinical trial registration and submission of trial results information to ClinicalTrials.gov (42 CFR Part 11). FDA HQ is coordinating with the Centers and ORA to develop its compliance and enforcement program for violations of Title VIII of the Food and Drug Administration Amendments Act (FDAAA).

FDA HQ is leading joint efforts with the Office for Human Research Protections to review public comments and finalize two guidance documents intended to assist institutional review boards (IRBs).

In 2016, FDA HQ reviewed and analyzed over 2100 public comments and provided comments to HHS on various drafts of the final rule. FDA HQ continues to review the final rule to determine its impact on FDA regulations and guidance, and determine areas for potential harmonization, given the FDA’s and HHS’s different legislative and regulatory mandates.

FDA HQ continues to collaborate with the Clinical Trials Transformation Initiative (CTTI) effort on several projects. Examples⁹⁷ include efforts to improve:

- Antibacterial Drug Development
- Clinical Trial Recruitment
- Data Monitoring Committees.

International Inspections

FDA’s Office of International Programs (OIP) works with regulatory counterparts and stakeholders abroad to improve global product development and manufacturing standards and ultimately ensure that products coming to the US market are safe, effective and of high quality. OIP oversees four FDA country or regional offices (China, Europe, India, and Latin America) in seven locations abroad. Engagements involving other countries and regions are covered from OIP’s headquarters. These offices expand FDA’s decision-making and actions by:

⁹⁶ For more information on guidance, please visit <http://www.fda.gov/RegulatoryInformation/Guidances>.

⁹⁷ For more information, visit CTTI’s website: <https://www.ctti-clinicaltrials.org>.

- expanding FDA inspectional capacity targeting firms of highest risk;
- building relationships and partnering with foreign regulators and other stakeholders; and
- sharing information and expertise to strengthen foreign regulatory systems for the benefit of the U.S. consumer.

In FY 2016, 38 percent of inspections conducted in China were performed by investigators based in the China Office or on short term assignments to China from ORA. In India and Latin America, on site FDA investigators also continued to provide significant contributions towards inspectional accomplishments (14 percent and six percent, respectively).

On site relationships with foreign regulatory counterparts enable FDA to leverage their respective authorities and efforts. The following items are examples of these relationships.

The Latin America Office regularly shares information with Mexico about products that do not conform to FDA standards and may pose a risk to human health if they enter the United States. In response, Mexico has implemented a process to follow up and prevent the commercialization of risky products. With this activity, the foreign regulatory authority provides in-country follow-up on FDA information.

Another example is provided in China, where Chinese regulators conducted a year-long investigation after FDA's China Office notified them of a firm that FDA alleged was manufacturing and distributing counterfeit drugs to multiple countries via internet sales. In October 2016, the Chinese government reported that several suspects were arrested, many processing sites were shut down and fake labels found on site were seized. The estimated income generated from these illegal activities was \$1.8 billion.

In another example, after the China Office notified China's Food and Drug Administration (CFDA) of potential contamination in a drug shipment examined by FDA at the U.S. port of entry, CFDA worked with the local Chinese regulatory authority to inspect the production facility within 24 hours. CFDA reported that all products in the firm were destroyed and production was suspended until a cleaning validation had occurred.

Finally, the Europe Office collaborated with FDA's Division of Enforcement and Import Operations and others to engage multiple UK authorities in a complex set of strategic activities that halted large shipments of violative medicines from Europe to the U.S.

International Partnerships

In FY 2016, FDA implemented five new Confidentiality Commitments with:

- The Saudi Food and Drug Authority, to permit information sharing related to the Middle East Respiratory Syndrome Coronavirus
- the United Kingdom's Human Fertilization & Embryology Authority, to facilitate information-sharing regarding biological products
- the Danish Medicines Agency, to update existing confidentiality commitments with the Danish Health and Medicines Authority
- the Export Inspection Council of India, to allow FDA to share non-public information regarding foods manufactured in India
- the College of Pharmacists of British Columbia to facilitate collaboration and information sharing related to the investigation of online pharmacies.

FDA signed three Cooperative Arrangements in 2016 to facilitate regulatory activities:

- a food safety systems recognition arrangement with Health Canada and the Canadian Food Inspection Agency
- a renewed arrangement with Ireland’s Department of Agriculture, Food and the Marine for certification of casein exports to the United States
- a Memorandum of Understanding with the Pan American Health Organization to develop a secure platform for the exchange of regulatory information.

In other partnership activities, OIP Europe and China Offices, working with CFSAN and OFVM, established a trilateral mechanism in 2016 with the Directorate General of Health and Food Safety of the European Commission, and China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) to enhance cooperation and exchange regarding food safety.

In addition, as part of the implementation of the Canada United States Regulatory Cooperation Council (RCC), a presidential initiative to promote economic growth and job creation through increased regulatory transparency and cooperation, FDA’s collaboration with Health Canada on three simultaneous approvals of veterinary drugs lead to quicker availability of those drugs in the Canadian and US markets.

Further, under the U.S.-Mexico Produce Safety Partnership (PSP), the Latin America Office (LAO) worked with Mexican regulatory authorities to secure bacterial isolates to add to the whole genome sequence library maintained by FDA, enhancing the food-borne pathogen illness database for more effective outbreak strain identification.

International Exchange of Information and Sharing of Expertise

FDA Foreign Offices work closely with FDA product Centers and the Office of Regulatory Affairs to exchange regulatory knowledge and expertise. For example, Foreign Offices trained foreign regulatory authorities on topics such as:

- inspectional techniques
- good manufacturing practices
- good clinical practices
- techniques for detecting problems in data integrity
- new rules under the Food Safety Modernization Act (FSMA).

After a series of China Office workshops on data integrity, the China Food and Drug Administration (CFDA) requested FDA’s collaboration on a set of Chinese data integrity guidance documents to ensure that it is aligned with FDA’s 2016 guidance. The Europe Office facilitates work of over a dozen technical working groups –“clusters”– with the European Medicines Agency, Canada, Australia and Japan, to share strategies and technical information to enhance development of medical products, including assessing post market safety signals, pediatric drug development and vaccines.

In 2016, two new clusters were launched based on a decision by FDA, the European Medicines Agency (EMA), and the European Commission (EC), focusing on patient engagement and drug development for rare diseases, areas of high priority for FDA and public health.

China Safety Initiative

FDA continues to expand its efforts to regulate the quality, safety and, as applicable, efficacy of FDA-regulated products entering the United States from China through the China Safety Initiative (CSI), with a primary focus being expansion of the number of FDA investigators, which was accomplished through agreement with the Chinese government.

Through an increase in full-time investigators and those on temporary detail (TDY) to the China Office, the number of drug inspections completed from the China Office has seen a more than three-fold increase from FY 2013 to FY 2016. Furthermore, inspections of food facilities conducted by the China Office increased ten-fold between 2008 and 2015.

In addition, the China Office works closely with FDA product Centers and ORA by providing monitoring and reporting on conditions, trends and events that could affect the safety, quality, and effectiveness of FDA-regulated products exported to the United States from China.

Improve and Safeguard Access

FDA HQ serves as the agency focal point for special programs and initiatives that are cross-cutting and clinical, scientific, and regulatory in nature. FDA HQ promotes high standards of scientific integrity to ensure ethical and responsible research practices such as human subject protection. FDA supports accelerated research and development for medical products to improve greater access to safe and effective medical products for children, and rare disease populations.

FDA HQ plays a vital role in the coordination of:

- review of pediatric science to advance the development of pediatric therapeutics
- product development and an effective and efficient product review process
- data standardization and integrity
- consideration of health disparities and outcomes in regulatory decision making.

The following selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.⁹⁸

Rare Disease Designations, Rare Pediatric Disease Determinations, and Grants

In FY 2016, FDA HQ:

- reviewed a record 569 first-time requests for orphan drug designation and designated 340 promising drugs and biological products for rare diseases
- reviewed 18 first-time requests for Humanitarian Use Device designations and designated 14 promising devices for rare diseases and conditions
- reviewed 45 Rare Pediatric Disease Designation and Consultation Requests and designated or granted 20 drugs and biologics for rare pediatric diseases.⁹⁹
- funded 21 new grant awards and 85 ongoing grants funding clinical studies of promising therapies for rare diseases
- funded 8 pediatric device consortia to provide multidisciplinary advice and funding to assist pediatric device innovators Development of Neonatal Program.

⁹⁸ Please visit <http://www.fda.gov/> for additional program information and detailed news items.

⁹⁹ For more information regarding product designations please see the Office of Orphan Products Development narrative.

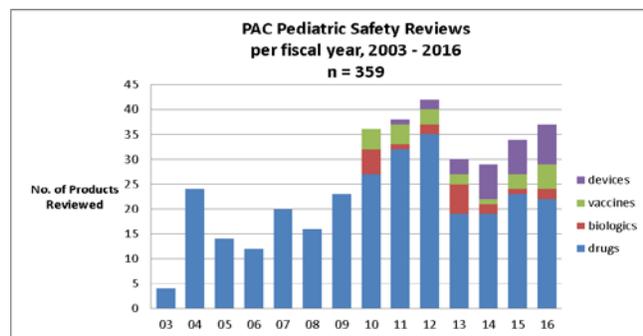
FDA HQ, working with CDER, has worked to stimulate product development for neonates, a vulnerable population which has not benefited from existing legislative incentives. These efforts include:

- enhancing communication on specific scientific issues between FDA scientists and external neonatal groups
- developing a research program with academic researchers on endpoints for neonates with pulmonary arterial hypertension
- establishing a neonatology team, led by a board-certified neonatologist,
- establishing a consultation service
- supporting the development of a public-private partnership to foster neonatal product development (International Neonatal Consortium).

Premarket and Postmarket Support

In FY 2016, FDA HQ responded to approximately 700 requests for combination product premarket review assistance from the FDA staff and regulated industry (including products that are on the shortage list). FDA HQ issued 4 formal combination product requests for designation decisions with 100 percent of these decisions meeting the 60-day statutory decision time requirement. FDA HQ provided timely informal jurisdictional assistance for approximately 157 separate Pre-RFD (informal inquiries). FDA HQ provided clarification and support for 350 premarket applications, 1,130 intercenter consults and 71 separate combination product post market activities.

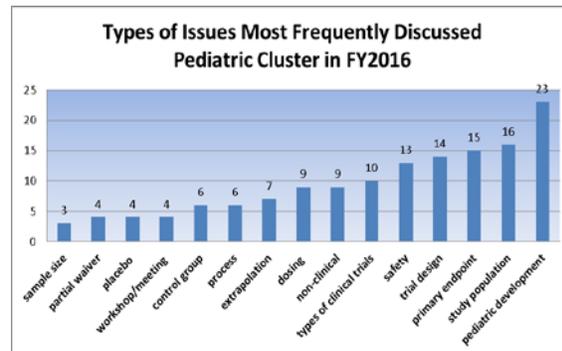
FDA HQ promoted high standards of scientific integrity by providing expert ethical opinions to agency Centers and Offices for more than 100 pediatric ethics issues, more than 600 pediatric development programs, and nearly 50 adult ethics issues. These ethical consultations included issues related to the development of FDA policies for emergencies and crises as seen in the recent Ebola epidemic, the Zika outbreak and research involving the exception from informed consent requirements for emergency research.



FDA HQ enhanced the efficiency of its pediatric safety review process which examines and provides the post market pediatric adverse events and safety reporting issues to the Pediatric Advisory Committee (PAC). Over 300 products have been reviewed by the PAC. In FY 2016, 37 pediatric-focused product safety reviews (drugs, biologics, vaccine and device reviews) were reviewed by FDA's PAC. All CDER products with mandated pediatric safety reviews undergo the same FDA review process. Through the risk-based assessment, low safety risk products will have their mandated pediatric-focused safety reviews posted on FDA's website. Over the last five years the PAC's workload has increased as a result of the legislatively mandated safety assessments on Humanitarian Device Exemptions that have asked for an exclusion from the limitation on profit-making and this will become an increasing part of the workload required to be performed by this committee.

Pediatric Coordination

FDA HQ, working in conjunction with Center subject matter experts through the Pediatric Cluster, met to resolve pediatric scientific differences between European Medicines Agency (EMA) and FDA on 175 issues in FY 2016. Of the 175 issues discussed with the EMA, harmonization was achieved for 77 percent. Examples of the most frequent issues discussed included study design, endpoints, and safety concerns (see graphic).



Promote Informed Decisions

FDA HQ leads the effort to enhance FDA’s communications to better serve the public. FDA HQ manages the communications to key stakeholders including the media, Congress, health professionals, patient advocates, and the general public. FDA HQ ensures important information about the benefits and risks of products is readily available in plain language using different communication methods, such as social media and the FDA website. FDA HQ also educates the public and encourages healthy choices by providing more general information about nutrition and tobacco prevention.

Within the area of Promote Informed Decisions, FDA provides Smart Regulation, Safety and Quality, and Regulatory Science. The following, selected accomplishments demonstrate FDA HQ’s delivery of its regulatory and public health responsibilities within the context of current priorities.¹⁰⁰

Helping Reduce Opioid Abuse

In October 2014, based in part on analyses conducted by the Office of Public Health Strategy and Analysis (OPHSA), the Drug Enforcement Administration moved hydrocodone combination drugs from Schedule 3 to the more restrictive Schedule 2, thus effectively eliminating refills. In FY 2016, OPHSA evaluated the impact of this regulatory change and found it produced a 17 percent reduction in hydrocodone combination drug prescriptions and an overall 5 percent reduction in total opioid prescribing, perhaps the largest national impact of any single intervention since the advent of the opioid crisis. This analysis was published January 2016 in the Journal of the American Medical Association (JAMA) Internal Medicine.

Naloxone, a drug that immediately reverses the deadly effects of an opioid overdose, is an important tool in reducing the harm caused by the epidemic of opioid abuse. OPHSA published an article in the American Journal of Public Health in 2016 demonstrating a 1,170 percent increase in naloxone prescribing between 2013 and 2015. In October 2016, OPHSA conceptualized and led a first-of-its-kind naloxone app competition under the America Competes Act. This competition sought to spur the development of a crowd-sourced mobile phone app that would connect people experiencing opioid overdoses with those carrying naloxone, including lay carriers. A \$40,000 prize was awarded to the winning entry. Funding to help bring these products to market will be available through the National Institute on Drug Abuse.

¹⁰⁰ Please visit <http://www.fda.gov/> for additional program information and detailed news items.

Leading FDA's Engagements with the Government Accountability Office (GAO) and the Office of the Inspector General (OIG)

In this role, OPHSA staff coordinates the Agency response to all these engagements. For each of the several dozen engagements that are ongoing at any moment in time, this requires the identification of appropriate subject matter experts, coordination of FDA responses at a series of meetings and in writing, submission of data in response to requests, and assembly and editing of Agency responses to draft reports. In addition, all responses must be consistent with Agency legal and policy initiatives. The staff also coordinates the annual updates to recommendations contained in the final reports and the Agency's responses to GAO's High Risk List. In recent years, OPHSA staff has assured that a greater number of these recommendations have been closed, and that a greater proportion of those have been closed as implemented.

Support for FDA's Priority Rulemakings

FDA HQ provided crucial support, including developing and drafting the rules and the regulatory impact analyses, to ensure the publication of a number of key proposed and final rules in 2016. These rules included the Final Rule on Produce Safety and the Foreign Supplier Verification Program (FSVP) final rule.

Economic Analysis and Support for Primary FSMA Regulations Published

In 2015, along with the publication of the final rules themselves, FDA HQ Economics published the Economic Analyses for five Food Safety Modernization Act (FSMA) related rules, including Preventive Controls for Human Foods, Preventive Controls for Animal Food and Feed, Foreign Supplier Verification, Produce Safety, and Third-party Accreditation. The support provided via economic analysis spanned more than five years and informed policy decisions throughout the rulemaking process. The outcomes of data analyses and economic modeling provided vital inputs foundational to the publication of the final rules. The result was a complete overhaul of the nation's approach to ensuring food safety that will potentially eliminate millions of foodborne illnesses each year.

21st Century Cures Initiative: Innovation for Healthier Americans

As part of the 21st Century Cures Initiative and the Innovation for Healthier Americans effort, Congress is considering potential legislation that could impact medical product approval standards and regulatory pathways in an effort to expedite getting innovative products onto the market. FDA's work with respect to the initiatives has involved consolidating input from Centers and Offices across the Agency. 21st Century Cures and Innovation for Healthier Americans are priorities for FDA's authorizing committees, and the Agency has worked diligently to provide timely feedback to Congressional offices.

Communication with Stakeholders – Improvements to fda.gov

More than 40 percent of all fda.gov visitors access the site from a mobile device. Since FY 2016, FDA HQ optimized more than 62,000 of the most popular fda.gov pages to better enhance fda.gov visitor experience.

The Patient Network (PN) webpages on fda.gov had more than one million visitors over the past 18 months. The PN web pages also feature the newly developed Expanded Access Form FDA 3926, which provides a streamlined method for submitting an Investigational New Drug Application (IND) for use in cases of individual patient expanded access. Expanded access, sometimes called "compassionate use," is the use outside of a clinical trial of an investigational medical product (i.e., one that has not been approved by FDA).

In February 2016, FDA HQ rapidly established a web page to centralize information about the agency's Zika response activities and includes information on the safety of the blood supply, Emergency Use Authorizations for diagnostic tests, and development of investigational products. The page is updated frequently to help stakeholders easily find the newest information on the FDA's Zika response efforts. The information is also available in [Spanish](#) and [Portuguese](#). As of December 12, 2016, the [Zika Virus Response Updates from FDA web page](#) has received more than 34,000 page views, and the [Emergency Use Authorization](#) page has received 17,500 page views during the Zika response. FDA also sent 18 e-mail updates to approximately 40,000 subscribers; these messages have been opened more than 122,000 times, and recipients have clicked links –mostly to Zika-related information during this timeframe–nearly 11,000 times. FDA Zika-related social media posts have generated at least 4,000 views for FDA web content, in addition to views generated for content from our sister agencies, including CDC.

Communication products to consumers, health care professionals and others

FDA HQ regularly develops communication products about FDA-regulated products, key issues, and other news for consumers, medical professionals, patients, journalists and others.

Since FY 2016, FDA HQ published:

- +225 MedWatch Safety Alerts, which is the FDA's second most popular e-list with more than 350,000 subscribers;
- 191 News Releases and other press announcements in English and/or Spanish with a reach of more than 101,000 subscribers;
- 132 FDA Voice Blogs, which saw a 13 percent increase in readership;
- 77 Consumer Updates in English and Spanish with more than 200,000 subscribers; and
- more than 100 newsletters that reach approximately 700,000 patients and health care professionals.

During National Consumer Protection Week in 2016, FDA HQ launched a multimedia and multilingual initiative to educate at-risk populations against health fraud. YouTube videos, written consumer material and graphics were developed in six languages, and targeted news media and social media outreach was conducted. FDA HQ reached an estimated potential audience of close to 88 million in English and more than 76 million in Spanish.

Meetings with Stakeholders

Since October 2015, FDA HQ conducted approximately 170 meetings with stakeholders and trained and recruited more than 200 patient representatives to advise the FDA. In addition, FDA HQ managed the crosscutting MedWatch Council, which shares best practices across centers related to product safety and safety reporting.

FDA HQ held six Commissioner's Listening Sessions from August through December 2016 with national stakeholder organizations bringing together diverse health professional and patient advocacy organizations across various disciplines. In each of the meetings, the Commissioner provided an overview of FDA's top priorities and emphasized a focus on public health and safety. The Commissioner also engaged with stakeholders on good regulation, innovation, and research. FDA HQ acknowledged the organizations for their prior agency input and expressed an interest in hearing their ideas for best practices to ensure stakeholders' voices are heard within the agency.

FDA HQ also created a new “cluster” on patient engagement with the European Medicines Agency (EMA). The cluster allows FDA and EMA to meet on a regular basis to exchange information on how the organizations engage with and involve patients in regulatory decisions and on ways to enhance future engagement with patients.

Annually, FDA HQ responds to approximately 1,500 inquiries on human subject protection, informed consent, and best practices for the conduct of clinical trials. Archives of these questions and answers are available on fda.gov.

Opioids – State Tours

FDA HQ was instrumental in coordinating and organizing a multi-state (Tennessee, West Virginia and Kentucky) listening tour for the FDA Commissioner to improve understanding of the challenges faced by those who are most affected by the growing opioid epidemic. By listening to stakeholders at the community level, FDA HQ demonstrated its support and commitment to those on the frontlines of the opioid epidemic. The purpose of these visits was to listen, learn, and connect with local health care providers, county medical societies and/or local public health clinics/hospitals.

Stakeholder Outreach Activities

In addition to issuing 225 MedWatch Safety Alerts, two new MedWatch videos were released for consumers and health care professionals. Seven articles on the topic of boxed warning highlights were published in the American Journal of Health-System Pharmacy and the Hospital Pharmacy Journal during FY2016. One article was also published in the official news magazine of the Oncology Nursing Society (ONS), ONS Connect. FDA also collaborated with Medscape on five high-priority topics.

Strengthen Organizational Excellence

FDA HQ ensures the timely and effective implementation of operations and the high quality delivery of services across FDA. FDA HQ plans and manages all resources including:

- budget and financial management
- human resources
- information technology and cybersecurity
- facilities, security and safety
- ethics and equal employment opportunity
- acquisitions activities.

Within the area of Organizational Excellence, FDA provides Stewardship. The following selected accomplishments demonstrate FDA HQ’s delivery of its regulatory and public health responsibilities within the context of current priorities.¹⁰¹

FDA HQ is committed to developing its workforce, recruiting, retaining, and strategically managing diversity. FDA HQ invests in infrastructure, evolving management systems and practices to ensure accountability for accomplishing meaningful results to enhance productivity and workforce capabilities. For example, in FY 2016, FDA retained 81 percent of the 10 Commissioner’s Fellowship Program graduates.

¹⁰¹ Please visit <http://www.fda.gov/> for additional program information and detailed news items.

OpenFDA

OpenFDA is an FDA initiative to provide software developers and researchers Application Programming Interfaces (APIs) to a number of high-value structured datasets, including adverse events, product labeling, and recall enforcement reports.

Since the launch, on June 2, 2014, OpenFDA has received more than 45 million data calls. Half of the calls came from outside the US. There are more than 6,000 registered users, 21,000 connected systems worldwide, and dozens of new software applications that the community has built. During the summer of 2016, FDA held a public meeting to have a robust and interactive discussion with openFDA users to obtain feedback on the openFDA platform.

OpenFDA provides access to:

- adverse events such as FDA’s publically available drug adverse event and medication error reports – over 7.1 million records
- medical device adverse event reports – over 6.1 million records
- unique device identifiers – over 1.3 million records
- device registration and listing – over 230,000 records
- recalls and enforcement report data, containing information from public notices about recalls of FDA-regulated products – over 100,000 recalls records
- Structured Product Labeling for FDA-regulated human drugs – prescription or over the counter – and biologics with over 105,000 records.

FDA Laboratory Modernization

Modernizing FDA’s aged, inflexible and unreliable laboratories is critical to FDA’s ability to effectively carry out its mission and respond to food safety and medical product emergencies. A large majority of FDA’s owned labs were transferred to FDA from other federal agencies, and these buildings as well as the associated site infrastructure were constructed between 30 to 60 years ago.

Similarly, many of FDA’s leased lab facilities were constructed over 20 years ago. All of these labs are aged and the building systems, finishes, and layouts are past their useful life, creating unsafe and unhealthy work environments, which in turn compromises FDA’s ability to meet scientific needs. The facilities and budget organizations within FDA’s Office of Operations (OO) have developed and started implementing a strategy to modernize FDA’s laboratories. The strategy consists of:

- assessing facility conditions
- collaborating with the program utilizing the laboratories to fully understand mission impact
- prioritizing laboratories as needing replacement, relocation within the same geographic area, or repairs and improvements
- requesting resources needed to carry out high priority projects.

These efforts have resulted in FDA receiving a total of \$129 million in Non-recurring Expense Fund (NEF) resources to complete a major laboratory project that is a critical first step at implementing the Master Plan at FDA’s owned Jefferson Labs Complex (JLC), replace FDA’s Winchester Engineering and Analytical Center (WEAC) lab, and relocate the Kansas City and SE Regional labs to new, modern and flexible leased lab space. In addition, FDA was successful

in utilizing FDA appropriated funding in FY 2016 to begin the relocation of the leased San Francisco lab.

FDA HQ continues to work to:

- identify ongoing laboratory replacement, relocation, repair, and improvement projects;
- prioritize these projects
- develop resource requests to implement the highest priority projects.

FUNDING HISTORY¹⁰²

<u>FISCAL YEAR</u>	Program Level	Budget Authority	User Fees
FY 2014 Actual	\$244,990,000	\$172,021,000	\$72,969,000
FY 2015 Actual	\$261,099,000	\$173,292,000	\$87,807,000
FY 2016 Actuals	\$301,574,000	\$191,374,000	\$110,200,000
FY 2017 Annualized CR	\$293,259,000	\$191,201,000	\$102,058,000
FY 2018 President's Budget	\$322,486,000	\$125,432,000	\$197,054,000

BUDGET REQUEST

The FY 2018 Budget Request is \$322,486, 000 of which \$125,432, 000 is budget authority and \$197,054,000 is user fees. This level provides a net increase of \$29,227,000. Budget authority decreases by \$65,679, 000 compared to the FY 2017 Annualized CR level and user fees increase by \$94,996, 000.

FDA HQ will continue to provide policy direction and oversight, advance scientific development, and provide oversight of the global supply chain. FDA HQ will continue working to increase transparency and accountability in the supply chain, developing better enforcement and regulatory tools, encouraging greater responsibility by industry, and enhancing collaboration with international regulatory counterparts and other third parties. FDA HQ along with the Centers and Offices, will evaluate and improve the effectiveness of preventive control standards, and advance the development of predictive safety models. FDA HQ will coordinate across FDA to develop improved methods for rapidly detecting, investigating, and stopping foodborne contaminants, as well as develop comprehensive regulatory approaches for integrating pre- and post-approval and compliance functions. In addition, FDA HQ will continue to provide program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA HQ is committed to delivering cutting-edge technology, innovation, and support to all stakeholders.

¹⁰² FY 2016 and FY 2017 do not reflect the transfer of \$1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities. For FY 2018, FDA proposes to discontinue the transfer.

BUDGET AUTHORITY**Reductions (-\$7.2 million)**

As part of the FY 2018 budget, FDA HQ will reduce investments in risk analysis and regulatory science activities in order to support higher priorities for food and medical product safety. In FY 2016 and 2017, FDA HQ received \$5 million to bolster the important ongoing development and utilization of a targeted, risk-based, and efficient inspection model for foreign high risk facilities; however, these funds are no longer required in FY 2018. In addition, FDA will reduce funding for regulatory science programs, for the Reagan-Udall Foundation, FDA Fellowship Programs, and other special initiatives lead by FDA HQ.

Medical Product Budget Authority Recalibration (-\$57.1 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 and Regulatory Efficiencies (+\$95.0 million)**

The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees. The budget also includes a package of administrative actions designed to achieve greater regulatory efficiency and speed the availability of innovative, safe, and effective medical products in the market.

PERFORMANCE

The FDA Headquarters’ performance measures focus on emergency response, women’s health, science, global cooperation, premarket application review of orphan, pediatric and combination products, outreach, and organization efficiency, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
<p><u>292201</u>: Improve FDA’s ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (Output)</p>	<p>Maintained 99.45% efficiency on response to calls to the FDA After Hours Call Center.</p> <p>Successfully coordinated 42 incidents involving FDA regulated products during the year.</p> <p>Participated in eleven exercises during the year.</p> <p>(All Targets Met or Exceeded)</p>	<p>Develop 50 mapping products in support of FDA’s emergency preparedness, response, and recovery activities.</p> <p>Successfully coordinate 20 incidents involving FDA regulated products during the year.</p> <p>Participate in nine exercises during the year.</p>	<p>Develop 50 mapping products in support of FDA’s emergency preparedness, response, and recovery activities.</p> <p>Successfully coordinate 20 incidents involving FDA regulated products during the year.</p> <p>Participate in four exercises during the year.</p>	<p>NA</p>
<p><u>293206</u>: Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. (Outcome)</p>	<p>FY 2016: FDA completed annual milestones on 7 more intramural research projects under the Nanotechnology CORES program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. (Target Met)</p>	<p>38 CORES projects with completed annual milestones</p>	<p>45 CORES projects with completed annual milestones</p>	<p>+7 projects</p>
<p><u>291101</u>: Percentage of Fellows retained at FDA after completing the Fellowship program. (Outcome)</p>	<p>FY 2016: 81% Target: 40% (Target Exceeded)</p>	<p>50%</p>	<p>50%</p>	<p>Maintain</p>
<p><u>293205</u>: Percentage of requests for combination product designations processed within the 60 day statutory requirement. (Output)</p>	<p>FY 2016: 100% Target: 95% (Target Exceeded)</p>	<p>95%</p>	<p>95%</p>	<p>Maintain</p>

NARRATIVE BY ACTIVITY

FDA HEADQUARTERS

<p><u>293203</u>: Number of pediatric scientific, ethical, product, and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, Japan, and Canada, with Australia as observers. <i>(Output)</i></p>	<p>FY 2016: 54 Target: 40 (Target Exceeded)</p>	<p>50</p>	<p>50</p>	<p>Maintain</p>
<p><u>293204</u>: Number of medical products studied in children with labeling changes and safety reviews completed and presented to FDA's Pediatric Advisory Committee. <i>(Output)</i></p>	<p>FY 2016: 37 Target: 30 (Target Exceeded)</p>	<p>30</p>	<p>30</p>	<p>Maintain</p>
<p><u>292301</u>: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. <i>(Output)</i></p>	<p>FY 2016: 4 Target: 4 (Target Met)</p>	<p>4</p>	<p>3</p>	<p>-1</p>
<p><u>291306</u>: The number of targeted engagements, which are strategic interactions between FDA and stakeholders that produce a tangible result in support of FDA's global mission. <i>(Outcome)</i></p>	<p>FY 2016: 25 Target: 25 (Target Met)</p>	<p>25</p>	<p>25</p>	<p>Maintain</p>
<p><u>291406</u>: Percentage of invoices issued on time within predefined dates in the month. <i>(Output)</i></p>	<p>FY 2016: 100% Target: 98% (Target Exceeded)</p>	<p>98%</p>	<p>98%</p>	<p>Maintain</p>

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