# FDA HEADQUARTERS

| (Dollars in Thousands) | FY 2015 Final | FY 2015 Actuals | FY 2016 Enacted | FY 2017 President's Budget | FY 2017 +/- FY 2016 |
|---|---|---|---|---|---|
| **FDA Headquarters** | **277,453** | **261,099** | **289,562** | **298,682** | **9,120** |
| ***Budget Authority*** | ***173,362*** | ***173,292*** | ***181,587*** | ***178,287*** | -3,300 |
| ***User Fees*** | ***104,091*** | ***87,807*** | ***107,975*** | ***120,395*** | ***12,420*** |
| *Prescription Drug (PDUFA)* | *48,639* | *45,300* | *52,139* | *52,763* | 624 |
| *Medical Device (MDUFA)* | *6,733* | *6,770* | *6,259* | *7,101* | 842 |
| *Generic Drug (GDUFA)* | *24,205* | *18,150* | *24,690* | *25,133* | 443 |
| *Biosimilars (BsUFA)* | *1,321* | *178* | *1,354* | *1,388* | 34 |
| *Animal Drug (ADUFA)* | *898* | *937* | *913* | *919* | 6 |
| *Animal Generic Drug (AGDUFA)* | *277* | *318* | *388* | *415* | 27 |
| *Family Smoking Prevention and Tobacco Control Act* | *20,668* | *15,878* | *20,789* | *19,132* | -1,657 |
| *Mammography Quality Standards Act (MQSA)* | *243* | *276* | *248* | *253* | 5 |
| *Food and Feed Recall* | *75* | --- | *75* | *75* | --- |
| *Food Reinspection* | *480* | --- | *480* | *480* | --- |
| *Voluntary Qualified Importer Program* | *277* | --- | *277* | *277* | --- |
| *Third Party Auditor Program* | --- | --- | *73* | *73* | --- |
| *Outsourcing Facility* | *275* | --- | *290* | *302* | 12 |
| *Food Facility Registration and Inspection* | --- | --- | --- | *4,662* | 4,662 |
| *Food Import* | --- | --- | --- | *5,766* | 5,766 |
| *International Courier* | --- | --- | --- | *313* | 313 |
| *Cosmetics* | --- | --- | --- | *1,061* | 1,061 |
| *Food Contact Substance Notification* | --- | --- | --- | *282* | 282 |
| **FTE** | **1,134** | **1,104** | **1,167** | **1,200** | **33** |

**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, and the Drug Quality and Security Act (2013)

**Allocation Methods**: Direct Federal/Intramural

## PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

FDA Headquarters (HQ) provides strategic direction and a wide array of services, 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, coordination, and expertise 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 the safety of patients and consumers. FDA HQ provides advice and assistance to develop and standardize policies and best practices across FDA, consistent with statutes and regulations. FDA HQ also advances regulatory science to inform standards development, analysis, and decision-making to improve FDA oversight before and after FDA-regulated products enter the marketplace.

FDA HQ helps reduce risks in FDA-regulated products through surveillance and enforcement activities, such as inspections of manufacturing and production facilities and active surveillance of adverse events. FDA HQ supports eight foreign posts and conducts activities to promote oversight of the global supply chain. In addition to foreign inspections, these activities include advancing diplomacy, strengthening global regulatory systems, collecting and sharing intelligence and information, and utilizing global data networks and analytics.

FDA HQ leads emergency response and crisis management policies and programs, including global public health issues such as the recent Ebola epidemic. FDA HQ enhances transparency and working relationships with internal and external stakeholders to address foodborne outbreaks and safety issues with regulated products. FDA HQ also plays a key role in providing the legal, regulatory, and policy framework that ensures laws, regulations and policies help support preparedness for and response to Chemical, Biological, Radiological, Nuclear (CBRN) and emerging infectious disease threats.

FDA HQ is also responsible for coordinating pediatric product development, its ethical implementation at FDA, and the legislatively-mandated post marketing safety reporting to the Pediatric Advisory Committee on all products studied in children under the Best Pharmaceuticals for Children Act, the Pediatric Research Equity Act, and for certain devices approved in pediatrics. Pediatric studies, often require multiple centers and countries to fulfill enrollment requirements because of the small number of eligible pediatric subjects. FDA HQ also coordinates and administers the Pediatric International harmonization program known as the "Pediatric Cluster," an international oversight committee that provides regulatory coordination of pediatric studies through monthly scientific and regulatory exchanges with the European Medicines Agency's pediatric program, Japan, Canada, and Australia's regulators. In addition FDA HQ administers the Neonatal and Pediatric Ethics consultative services and Pediatric Scientific outreach programs. These services include consultative services for the Centers, administration of a successful IPA program with academic centers, analysis and publication of pediatric studies (14 peer reviewed publications in 2015) and a monthly publication in the American Academy of Pediatrics newsletter directed to new pediatric labeling information for practitioners.

FDA HQ also oversees the regulation of combination products through developing guidance documents and regulations, training and other activities to ensure timely and effective review, and provides consistent and appropriate postmarket regulation of combination products.

FDA HQ administers several rare disease programs to incentivize the development of products for rare diseases. These include the agency's designation programs for orphan drugs, rare pediatric diseases, humanitarian use devices, and grant programs for orphan drugs and pediatric medical device consortia. FDA HQ coordinates and administers the International "Orphan Cluster."

FDA HQ also leads the development of regulations and policy aimed at ensuring the protection of human subjects, reliability of clinical trial data, and regulatory compliance of FDA-regulated clinical trials. FDA HQ participates in conferences and workshops with agency stakeholders and works with domestic and international partners to harmonize these good clinical practice policy efforts.

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.[98]

**Food Safety Modernization Act (FSMA) Rules Published**

FDA proposed seven new foundational food safety rules under FSMA to modernize the food safety system and focus on preventing food safety problems, rather than relying primarily on responding to problems after they occur. In September 2014, FDA issued supplemental notices of proposed rulemaking for four out of seven these rules in response to stakeholder in response to stakeholder input in an effort to make the focused proposals more flexible.

The first rule, now finalized, on preventive controls for human food, requires manufacturers, processors, and packers of food for consumption in the United States to take steps such as creating written plans that identify likely hazards, identifying monitoring procedures, recording monitoring results, and implementing corrective actions if problems occur. The second proposed rule on standards for produce safety would establish enforceable science and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms.

The second final rule on preventive controls focuses on animal food safety, and sets Current Good Manufacturing Practice standards that take into consideration the unique aspects of the animal food industry.

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

The third final rule on standards for produce safety establishes enforceable science- and risk-based standards for the growing, harvesting, packing, and holding of fruits and vegetables on farms.


The fourth final FSMA rules sets the foundation for a new approach to the oversight of the safety of imported food. Imported food comes to the United States from about 150 different countries. Under the proposed rule for Foreign Supplier Verification Programs (FSVP), importers would need to verify that their suppliers are meeting the same level of public health protection as required of domestic producers. Requirements for verification activities are based primarily on the type of food, nature of the hazard identified, and the foreign supplier. This supplement proposed rule requires importers to conduct a more comprehensive evaluation of food and foreign supplier risk and more flexibility for importers in determining appropriate supplier verification measures based on that risk evaluation.

The fifth final rule establishes the program for the accreditation of third-party certification bodies to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements. FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality. The accreditation bodies, which may be foreign government agencies or private companies, would in turn accredit third-party auditors to audit and issue certifications for foreign food facilities.

The remaining two FSMA rules are scheduled to be finalized in spring 2016. They address Sanitary Transportation and Intentional Adulteration of the food supply. Rules

Below are rules published by FDA HQ during calendar year 2015. These rules help address various issues.[99]

| Date | # | Purpose |
|---|---|---|
| Nov 2015 | FDA-2011-N-0921 | Produce Safety – establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce (final rule) |
| Nov 2015 | FDA-2011-N-0143 | Foreign Supplier Verification Programs (FSVP) – require importers to verify that foreign suppliers are producing food consistent with U.S. standards (final rule) |
| Nov 2015 | FDA-2011-N-0146 | User Fees for Accreditation of Third-Party Auditors Program – Establishes user fees to support FDA's Accreditation of Third-Party Auditors Program (final rule) |
| Sept 2015 | FDA-2011-N-0920 | Preventive Controls for Human Food – modernize human food CGMPs and require that certain facilities establish and implement hazard analysis and risk-based preventive controls. (final rule) |

[99] For more information on FDA rules please visit http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm.

| Date | # | Purpose |
|---|---|---|
| July 2015 | FDA-2012-N-1210 | FDA revises proposed nutrition facts label rule to include a daily value for added sugars (supplemental proposed rule) |
| June 2015 | FDA-2013-N-0067 | Infant Formula – the addition of minimum and maximum levels of selenium to infant formula and related labeling requirements (final rule) |
| April 2015 | FDA-2002-N-0323 | Registration of Food Facilities – improve the food facility registration system and implement FSMA registration provisions (proposed rule) |

**Emergency Preparedness and Response**

FDA Coordinated Outbreak Response and Evaluation (CORE) team rapidly detect and respond to major foodborne illness outbreaks and also coordinates with:

- FDA field offices and compliance offices
- State investigative and laboratory resources
- Local city and county resources
- Other federal agencies such as CDC assure timely and effective resolution of foodborne illness outbreaks.

Some examples of these activities in FY 2015 include the:

- multistate *E. coli* O157 linked to Chipotle Mexican Grill
- Blue Bell Ice Cream *Listeria monocytogenes* outbreak that involved four states and caused ten illnesses and three deaths
- *Listeria monocytogenes* outbreak linked to caramel apples that caused 34 hospitalizations in 12 states
- Cyclospora outbreaks from 2012 through 2015
- Hepatitis A outbreak from frozen berries imported from Turkey

In FY 2015, FDA HQ collaborated with the Center for Food Safety and Nutrition, and stakeholders from HHS and USDA to develop a National Agriculture and Food Defense Strategy as mandated under FSMA. This strategy will enhance the preparedness, improve detection capabilities, and ensure efficient response to agriculture and food systems after an agriculture and food emergency.

FDA coordinated the emergency response to 57 incidents including:

- 27 serious adverse or injury event incidents
- 18 natural disasters
- 12 man-made disasters

FDA HQ evaluated 4,245 consumer complaints including over 30 reports of suspected product tampering in FY 2015 to insure 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, including revising FDA's Emergency Operations Plan and Annexes, the FDA Joint Information Center Handbook, and the FDA Incident Management Handbook. These documents improve

understanding and communication across the agency and with the public during emergency responses; furthering public perception of the FDA's ability to respond in crisis situations.

In FY 2015, FDA HQ continued to provide and enhance a robust Geographic Information System (GIS) for the agency with improved mechanisms for mapping of FDA regulated firms in foreign countries and performed complex spatial analysis when events impacting FDA regulated products occurred. FDA HQ completed over 1,200 maps for 77 project requests, during the fiscal year.

**Regulatory Policy and Guidance**

Below are the regulations and guidances issued by FDA HQ in 2015. They help address various issues.[100]

| Date | # | Title | Description |
|---|---|---|---|
| Nov 2015 | FDA-2015-D-3638 | Minutes of Institutional Review Board (IRB) Meetings | Draft guidance: Describes regulatory requirements and recommendations for preparing and maintaining meeting minutes. |
| July 2015 | FDA-2011-D-0398 | Food Safety (Shell Eggs) | Questions and Answers regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation |
| June 2015 | FDA-2014-D-0052 | Allergens | Food Allergen Labeling Exemption Petitions and Notifications |
| June 2015 | FDA-2011-N-0144 | Food Defense (Importers) | Draft Guidance: FDA's Voluntary Qualified Importer Program |
| May 2015 | FDA-2015-D-0138 | Food Defense (Recalls) | Draft Questions and Answers Regarding Mandatory Food Recalls |
| Mar 2015 | FDA-2011-F-0172-0555 | Labeling & Nutrition (Menu) | Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide |
| Mar 2015 | FDA-2011-F-0172 | Labeling & Nutrition (Menu) | Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide |
| Jan 2015 | FDA-2015-D-0198-0002 | Current Good Manufacturing Practice Requirements for Combination Products (Draft) | Further describes and explains the final rule on CGMP requirements for combination products (final rule as codified in 21 CFR part 4) that FDA issued on January 22, 2013 |

FDA HQ is coordinating with the National Institutes of Health (NIH) on the development of the final rule for clinical trial registration and submission of trial results to ClinicalTrials.gov. In addition, FDA continues to evaluate the impact of the proposed regulation on future FDA compliance and enforcement efforts related to violations of Title VIII of the Food and Drug Administration Amendments Act (FDAAA). FDA also provided technical assistance on sections

[100] For more information on guidance, please visit http://www.fda.gov/RegulatoryInformation/Guidances.

of the proposed 21st Century Cures legislation impacting ClinicalTrials.gov reporting requirements.

FDA HQ led efforts to amend FDA's regulations on acceptance of data for medical devices. Under the proposed rule, clinical investigations outside the US would be required to be conducted in accordance with good clinical practice, defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate, and that the rights, safety, and well-being of trial subjects are protected.

The proposed rule also would revise (21 CFR 812) and (21 CFR 807 Subpart E) to address the acceptance of domestic clinical data, which are currently not described in these regulations. Clinical investigations conducted in the United States and submitted in support of investigational device exemption applications and premarket notification submissions would be required to comply with the human subject protection (21 CFR 50), institutional review board (21 CFR 56), and (21 CFR 812) regulations. FDA HQ has developed a draft guidance to accompany the final rule.

FDA HQ prepared the "Rare Pediatric Disease Priority Review Voucher Draft Guidance for Industry" in FY 2015. This guidance provides information on the implementation of section 908 of FDASIA whereby FDA will award priority review vouchers to sponsors of certain rare pediatric disease applications that meet the criteria specified.

FDA HQ led the review and drafting of detailed comments on various Health and Human Services' (HHS's) regulatory proposals including Common Rule Notice of Proposed Rulemaking (NPRM), published September 8, 2015. The goal of the NPRM is to facilitate low risk research and reduce burdens on sponsors, researchers, and IRBs while ensuring ethical oversight of clinical trials and protection of the rights, safety, and welfare of human subjects. FDA evaluated the impact of the NPRM's proposed revisions and other proposed guidance documents on FDA-regulated research and the extent to which the agency's regulations could be harmonized with the Common Rule 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. Examples include efforts to improve:

- informed consent documents
- clinical investigator training and qualifications[101]
- use of centralized Institutional Review Board (IRB) review where appropriate.

FDA HQ sponsored a Pediatric Clinical Investigators Training meeting to help ensure that academic investigators understand their responsibilities when conducting product development trials involving children. FDA HQ is planning a similar two-day training session in 2016.

FDA HQ participated in the development of two cross-cutting guidance documents to incorporate content applicable to combination products. These are the "Guidance for Industry Providing Regulatory Submissions in Electronic Format —Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (2015)"and the

[101] Available at: http://www.ctti-clinicaltrials.org/what-we-do/study-start/gcp-training.

"Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use" Draft Guidance (October 2015).

FDA HQ coordinated with the Association for the Advancement of Medical Instrumentation (AMMI) Combination Products Committee on development and publication of the AAMI TIR48:2015 that provided an industry reference on *the Application of the U.S. FDA's CGMP Final Rule on Combination Products*.

**Medical Countermeasures Initiative Regulatory Science Program**

FDA HQ provides funding for targeted research on projects aligned to the Public Health Emergency Countermeasures Enterprise. This research is focused on improving FDA's ability to perform science-based review of medical countermeasures (MCMs) designed to mitigate the effects of CBRN and emerging infectious disease threats such as pandemic influenza and Ebola virus disease. Notable accomplishments in FY 2014 and FY 2015 include developing a lung model based on 'organs-on-a-chip' technology to use in the development of drugs for acute radiation syndrome and the evaluation of a portable electroencephalogram (EEG) technology that could be used to detect brain injury in victims of traumatic events such as accidents or explosions.

FDA scientists also improved methods to test the quality of influenza and anthrax MCMs and developed a publically available microbial genomic reference sequence database and an antimicrobial resistant organism isolate bank that contains an initial set of panels of antimicrobial resistant bacteria with varying antimicrobial resistance profiles – available to diagnostic manufacturers, pharmaceutical developers and researches at no cost – that can help advance the development of diagnostic tests for biological threats including antimicrobial resistant bacteria. Additionally, FDA scientists have also responded to the Ebola epidemic in West Africa in multiple areas including investigating various methods for measuring Ebola vaccine efficacy and providing high-quality sequence data to better inform the development of vaccines, therapeutics, and diagnostic assays. FDA scientists were members of HHS's National Advisory Committee on Children and Disasters that submitted a report to the Assistant Secretary for Preparedness and Response on Healthcare Preparedness for Children in Disasters, which included a section on incentivizing industry for pediatric MCM development.

**International Inspections**

FDA has investigators based overseas within the foreign offices in China, India, and Latin America. These investigators provide FDA with the capability to respond quickly to emerging issues concerning the safety, efficacy, or quality of FDA-regulated products without the delays associated with international travel such as the time needed to obtain a visa. Investigators stationed in foreign offices also provide FDA with country-specific expertise regarding local industry practices and local culture.

In FY 2015, 28 percent of FDA inspections conducted in India (102 of the total 367 inspections) were performed by investigators based within FDA's India Office and on short term assignments. Similarly, 23 percent of FDA inspections conducted in China (105 of the total 455 inspections) were performed by investigators based in FDA's China Office and on short term assignments. In addition, FDA's Latin America Office, which began performing inspections in FY 2014, conducted 7 percent of inspections in that region (29 of the total 430 inspections) in FY 2015.

The China, India, and Latin America Offices routinely inform foreign counterpart authorities of FDA inspections in their countries and invite the foreign authorities to observe the FDA inspections. Foreign regulatory authorities often accept these invitations, which provide learning experiences for the foreign authorities.

FDA's India Office and the Indian drug regulatory authority will collect data pertaining to either regulatory agency's observations of the other's inspections. This data-gathering exercise will facilitate data analyses for developing a better understanding of current inspectional and regulatory practices of each regulatory agency and developing strategies to better cooperate on matters of mutual regulatory concern.

The Latin America Office has conducted concurrent inspections with foreign regulatory authorities. In such inspections, the Latin America Office and the foreign regulatory authority simultaneously conduct their own inspections of an establishment. During these inspections, there is constant communication and discussion between the regulatory authorities. At times during the concurrent inspections, certain foreign authorities take regulatory action on the spot – even ordering the destruction of potentially contaminated products - when conditions that pose a serious risk to the health of consumers are encountered. The Latin America Office also conducted concurrent environmental assessments with foreign regulatory authorities during FY 2015. "Environmental assessments" are investigations to determine how the "environment" contributed to the introduction and transmission of pathogens or other hazards that caused illness or contamination; FDA conducts environmental assessments to learn the probable cause(s) of an outbreak of foodborne illness or a food contamination event and uses that information to identify preventive controls to prevent reoccurrence of an outbreak or contamination event.

After inspections, the China Office has shared information, as appropriate under current Arrangements, with regulatory counterpart organizations in China. This has resulted in actions by the regulatory counterpart organizations to follow up on violations observed by FDA. For example, after the China Office notified FDA's Chinese counterpart organization of significant violations found during two 2015 inspections at pharmaceutical manufacturers, the Chinese counterpart organization instructed its provincial regulatory authorities to conduct their own investigations. In another case, after the China Office notified FDA's Chinese counterpart organization about regulatory actions, such as Warning Letters and Import Alerts, taken by the FDA against Chinese pharmaceutical companies, the Chinese counterpart organization instructed provincial regulatory authorities to conduct follow-up inspections. The Chinese regulatory authority told FDA's China Office that they considered the information valuable and indicative of risk factors and would like to work with FDA to solve the problems.

In addition to conducting inspections, FDA's overseas offices with and without investigators contribute to FDA's international inspections by providing pre-inspection briefings, coordinating with foreign competent authorities and U.S. Government interagency personnel in-country, and analyzing reports/audits by regulatory counterparts to aid in facility selection.

**International Partnerships**

The ability to share non-public information with foreign regulatory counterparts is key to FDA's international cooperation and leveraging, and enables FDA to obtain foreign regulatory information that assists FDA decision making. In FY 2015, FDA implemented 10 new Confidentiality Commitments to promote information-sharing with foreign counterpart agencies and international organizations.

FDA also signed six arrangements to further cooperative activities with foreign counterparts. In FY 2015, FDA signed two Implementing Arrangements with its Chinese regulatory counterparts that outline commitments regarding inspections of food and drug facilities. Since the signing of the two Implementing Arrangements, FDA has received visas for 10 new staff members, some of whose visas had been previously delayed. Additionally, cooperation and the exchange of regulatory enforcement information have increased. For example, in FY 2015 Chinese regulatory counterparts voluntarily shared their inspection findings regarding adulterated gingko leaf extracts discovered during their nationwide campaign to crack down on adulterated medical products. In addition, in August FY 2015 the Chinese regulatory authority for the first time notified FDA's China Office about their upcoming inspections to be conducted at a pharmaceutical company in Dallas, Texas. The Chinese regulatory counterpart also assisted the China Office when China Office investigators encountered difficulties in entering a manufacturing facility.

In addition, in FY 2015 FDA signed a Memorandum of Understanding (MOU) with Export Inspection Council of India that will further cooperative activities in the area of food safety, an MOU with the Republic of Korea addressing the safety of shellfish shipped to the United States, a Letter of Intent with the French government reinforcing law enforcement cooperation in the public health arena, and an overarching Cooperative Arrangement with New Zealand related to the safety and defense of foods for human consumption and animal feeds..

In FY 2015, FDA participated in a number of Trans-Pacific Partnership (TPP) and Transatlantic Trade and Investment Partnership (TTIP) negotiating rounds to ensure public health, consumer safety and FDA's mandates were reflected in U.S. Government policy positions and incorporated into the negotiating texts for the agreements. FDA also advised and supported the U.S. Trade Representative during Ministerial-level negotiations for specific chapters of the TPP agreement. Through this effort, FDA was able to ensure that nothing in the TPP agreement undermines FDA's authorities.

Building on Confidentiality Commitments, the FDA through its Latin America Office, CFSAN, and ORA implemented the U.S.-Mexico Produce Safety Partnership (PSP). Established through a Statement of Intent in July 2014, the partnership completed its first year of activities in FY 2015. Through working groups on produce safety system information sharing, education and outreach, training of auditors and inspectors, laboratory collaboration, and outbreak response, this partnership provided opportunities for both FDA and the Mexican food safety regulators to learn and enhance the understanding of how each nation currently operates its food safety systems in support of the goal of achieving high rates of compliance with standards for the safety of fresh and minimally processed produce of each nation.

In FY 2015, FDA HQ has coordinated seven agency-wide emergency responses in collaboration with the International Food Safety Authorities Network (INFOSAN), involving dietary supplements, food products (almonds, salmon, caramel apples, ice cream), and a spice (ground cumin).

**International Exchange of Information and Sharing of Expertise**

FDA's foreign offices facilitate the exchange of data, information, and technical expertise with foreign regulatory counterparts to protect consumers and leverage resources. The FDA's foreign offices also work with global health organizations, academia, regulated industry, and other U.S. Government agencies. Such activities are essential to building strong working relationships, and

strengthening foreign regulatory capabilities so that they can align with FDA and help assure the safety of foreign products that are exported to the United States. International outreach also helps inform industry and other stakeholders about FDA requirements so that they can ensure their products exported to the United States meet those requirements.

FDA's India Office partners with Indian regulators to train them on food- and drug-related issues and inspectional techniques, good manufacturing practices, and the detection of data integrity issues. The Office is also in dialogue with Indian regulators to offer training on food safety and labeling. In addition, the India Office meets with the leadership of the food and drug industries, facilitated by stakeholder organizations, to address matters pertaining to current good manufacturing practices.

The Latin American Office's Mexico post has facilitated information exchange, training, pilot activities and other cooperative programs with FDA's two Mexican counterpart agencies. One form of information exchange focuses on products that do not conform to product standards and may pose a risk to human health. In response, one of the Mexican counterpart agencies implemented an internal procedure to follow up on FDA information, as a mode to prevent the commercialization of risky products, seize contaminated products, and close manufacturing facilities and warehouses.

In FY 2015, FDA's Latin America Office delivered 10 training modules, in conjunction with a Mexican trade association, that focus on FDA drug regulations, good manufacturing practices, data integrity and inspections. The Latin America Office also conducted conferences in collaboration with other government agencies and academia on good manufacturing practices, data integrity, medical devices regulation, drugs and medical devices import-export, and counterfeit drugs.

The Europe Office helped facilitate a decision by FDA, the European Medicines Agency (EMA), and the European Commission (EC) to establish a new "cluster" (information sharing group), on patient engagement to share experience and best practices regarding the involvement of patients in the development, evaluation and post-authorization activities related to medicines. This adds to the 10 previously-established FDA-EMA clusters.

The China Office's areas of focus in FY 2015 included regulation and enforcement of food and medical products, good manufacturing practices, and integrity of the data used to support product applications. Examples of specific engagement include implementing collaborative programs with Chinese regulatory counterparts, active engagement and partnerships with universities, and promoting FDA initiatives. The China Office also continued to promote aquaculture safety. Of particular note, to assist Chinese regulators in expanding and restructuring their regulatory systems for medical products and food safety, the China Office held a series of meetings with Chinese regulators to increase their knowledge of FDA's regulatory systems. In the data integrity area, as a result of a series of China Office workshops, firms are upgrading equipment and software and conducting their own investigations to address potential data integrity issues; the Chinese regulatory authority, which previously published new guidelines to address electronic data issues, is working on additional guidelines. Lastly, the China and Europe Offices worked closely with CFSAN and OFVM to establish a collaborative mechanism with Directorate General Health and Safety of the European Commission, and China's General Administration of Quality Supervision, Inspection and Quarantine to enhance further cooperation on scientific and technical cooperation and exchange.

**China Safety Initiative**

In FY 2015, FDA expanded upon its efforts to regulate the quality and safety of products entering the U.S. from China through the China Safety Initiative (CSI). The primary activity of the CSI is to expand the number of FDA investigators in China, which FDA was able to do in FY 2015. Additionally, the CSI is funding a project to verify manufacturing and production sites of FDA-regulated commodities in China to better assess inspection prioritization needs. CSI also funds projects to develop innovative methodologies to monitor and analyze publicly-available private sector and social media data sources that have not been used by FDA traditionally, to provide early signal detection of foodborne illness outbreaks or adverse events in order to better inform Agency decision-making regarding product safety and quality.

**Regulatory Cooperation Council**

In FY 2015, FDA began work on a new phase of the Regulatory Cooperation Council (RCC). The RCC is a Canadian-United States initiative to promote economic growth and job creation through increased regulatory transparency and cooperation In FY 2015, FDA and Canadian counterpart organizations identified areas of mutual regulatory interest and public health benefit for possible convergence in the short, medium, and long terms and developed five work plans in support of this initiative.

**Ebola Response**

FDA HQ led extensive intra- and inter-agency coordination and facilitated international coordination of response activities to the Ebola epidemic in West Africa. FDA HQ facilitated the expedited development and availability of medical countermeasures (MCMs) — including vaccines, drugs, protective equipment, and diagnostic tests — for Ebola, including authorizing the use of ten investigational diagnostic tests for Ebola under our Emergency Use Authorization authority. FDA HQ supported regulatory science programs to help facilitate Ebola MCM development, and developed policies for the development, use, and export of investigational MCMs. FDA HQ provided ongoing review and consultation on the care of Ebola patients receiving treatment in the United States. FDA HQ helped design an innovative and robust common clinical trial design protocol to evaluate the most promising investigational MCMs for Ebola and held an international workshop on clinical trial designs in emerging infectious diseases to leverage the experience gained from the Ebola outbreak and other conditions. FDA HQ issued six warning letters to firms marketing products with unsubstantiated or fraudulent claims of treatment or prevention of Ebola. FDA HQ also led domestic and supported international policy development activities and provided technical support and scientific advice to the World Health Organization (WHO) and international regulatory counterparts (including counterparts in affected West African countries).

## 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 subjects protection, and offers support for accelerated research and development for medical products to improve greater access to safe and effective medical products for children, and rare disease populations.

FDA HQ provides for the coordination of internal and external review of pediatric science, safety, ethical and international issues as mandated by law and agency activities. FDA HQ

schedules the scientific agenda and administers the Pediatric Advisory Committee, the Pediatric Ethics Subcommittee, and the Neonatology Subcommittee. FDA HQ also works with CDER and CBER in developing scientific workshops to Advance the Development of Pediatric Therapeutics (ADEPT), the second of which, on neurocognitive outcomes, occurred in April 2015, with a third workshop on Long Term Pediatric Safety Studies scheduled for April 2016.

FDA HQ advances regulatory science needed to evaluate new products, collaborating with our colleagues in the private, public, and academic settings to facilitate product development and ensuring that our product review process is effective and efficient. FDA HQ is dedicated to improve review efficiency through data standardization and data integrity requirements. FDA HQ will continue to increase consideration of health disparities and health outcomes in regulatory decision-making.

FDA HQ oversees the management and operations of FDA's 50 scientific advisory committees and panels. FDA's advisory committees and panels provide expert, independent advice to the agency on public health issues including product approvals, post-marketing safety, emerging policy matters, tobacco product issues, and food safety.

Within the area of Improve and Safeguard Access, FDA provides Safety and Quality as well as Regulatory Science. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[102]

**Rare Disease Designations, Rare Pediatric Disease Determinations, and Grants**
In FY 2015, FDA HQ

- reviewed a record 440 first-time requests for orphan drug designation and designated 355 promising drugs and biological products for rare diseases
- reviewed 21 first-time requests for Humanitarian Use Device designations and designated 10 promising devices for rare diseases and conditions
- reviewed 31 Rare Pediatric Disease Designation and Consultation Requests and designated or granted 21 drugs and biologics for rare pediatric diseases[103]
- funded 18 new grant awards and 67 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.

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 including developing a research program involving academic researchers' evaluation of endpoints for neonates with pulmonary arterial hypertension
- establishing a neonatology team, led by a board-certified neonatologist, to facilitate and expand the Agency's neonatal product development efforts

[102] Please visit http://www.fda.gov/ for additional program information and detailed news items.
[103] For more information regarding product designations please see the Office of Orphan Products Development narrative.

- supporting the development of a public-private partnership to foster neonatal product development (International Neonatal Consortium) that has its third workshop planned for March 2016.

**Premarket and Postmarket Support**

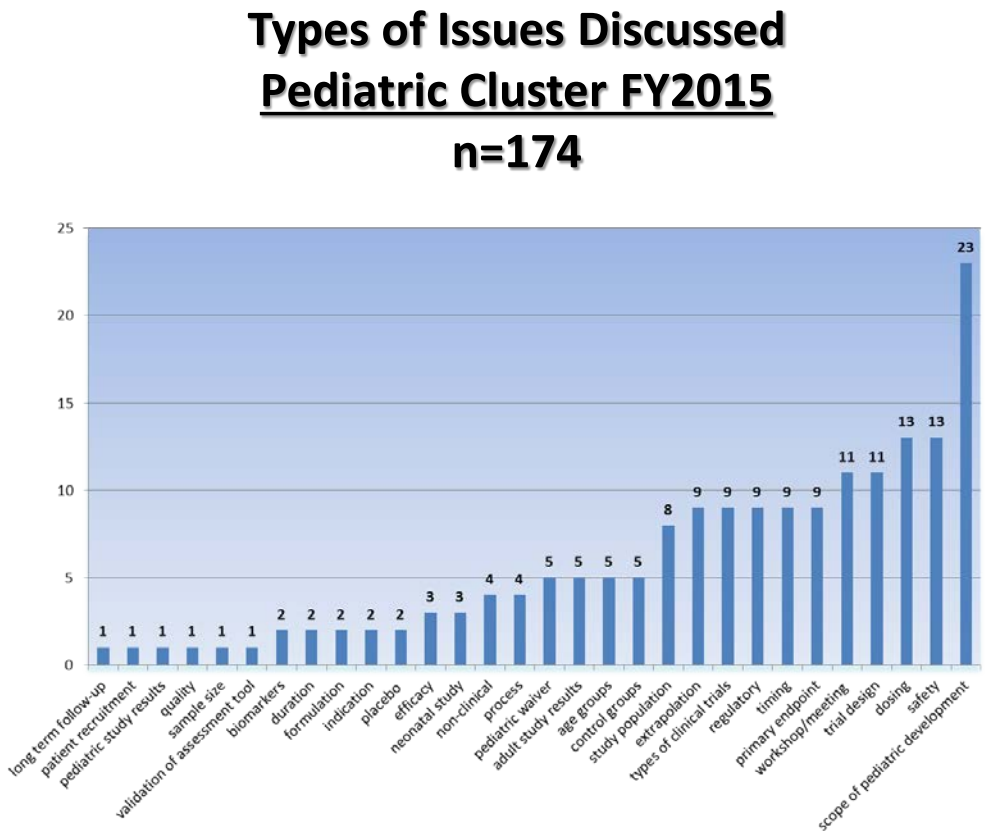
In FY 2015, FDA HQ responded to approximately 650 requests for combination product premarket review assistance from the FDA staff and regulated industry (including products that are on the shortage list). FDA HQ issued 17 formal combination product requests for designation decisions with 100 percent of these decisions meeting the 60-day statutory decision time requirement. FDA HQ provided timely informal jurisdictional assistance for approximately 248 separate informal inquiries. FDA HQ provided clarification and support for 57 separate combination product post market activities.

FDA HQ promoted high standards of scientific integrity to ensure ethical and responsible research practices by providing expert ethical opinions to agency Centers and Offices for more than 100 pediatric ethics issues, more than 600 pediatric development programs, and nearly 50 adult ethics issues. These ethical consultations have included issues related to the development of FDA policies for emergencies and crises as seen in the recent Ebola epidemic affecting West Africa 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 presents the post market pediatric adverse events and safety reporting issues to Pediatric Advisory Committee (PAC). Over 300 products have been reviewed by the PAC. In FY 2015, 34 pediatric-focused product safety reviews (drugs, biologics, vaccine and device reviews) were reviewed by FDA's PAC. Over the last five years the PAC has also provided 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 174 issues in FY 2015. Of the 174 issues discussed with the EMA, harmonization was achieved for 80 percent. Examples of 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.[104]

### Streamlining Access to Investigational Therapies for Patients with Life-Threatening Illnesses

Since the early years of the AIDS epidemic, FDA has authorized "compassionate use" of unapproved investigational drugs. However, the application form was too complex: it called for 26 separate elements of information, seven attachments, and was estimated to take 100 hours to complete. FDA initiated an agency-wide effort to simplify the application form and process, and lead the group to complete its work in just seven months. In February 2015, FDA announced the

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

availability of a new, much simpler draft form that should accelerate patient access to investigational drugs, when appropriate. The new draft form, when finalized, will require only eight elements of information and a single attachment. We estimate that physicians will be able to complete the finalized version of the form in just 45 minutes. Additionally, to further assist the physician seeking access to an experimental therapy, we redesigned FDA's website to make it easier to navigate and to explain the new proposed process in detail. The New York Times editorial board hailed the new form as a "breathtaking reduction in red tape."

**Communication with Stakeholders**

Through 2015, FDA HQ had optimized over 35,000 of the most popular web pages on FDA.gov for mobile devices, to better serve site visitors that accessed the site through mobile devices (over 35 percent of all traffic).

FDA HQ produced and promoted more than 40 Consumer Updates (CUs) and increased subscriptions by 19 percent. FDA HQ published 116 FDA Voice Blogs and increased website page views by 32 percent.

FDA HQ conducted over 200 stakeholder meetings, increased external stakeholder communications by over 13 percent, with over 576,130 subscribers to our multiple communications vehicles such as MedWatch Safety Alerts, various newsletters, and disease-specific subscriptions. FDA HQ has trained and recruited over 200 patient representatives to advise FDA, manages an internal MedWatch Council, which generates new policies on the reporting impact of safety information to the public.

Annually, FDA HQ responds to approximately 1,500 inquiries about human subject protection, informed consent, and best practices for the conduct of clinical trials. Archives of these questions and answers are available on FDA's website.[105]

## Strengthen Organizational Excellence

FDA HQ ensures the timely and effective implementation of operations and the high quality delivery of services across the agency and centers. FDA HQ plans and manages all resources including budget, financial management, human resources, information technology, facilities, security and safety, ethics, equal employment opportunity, and acquisitions activities. FDA HQ is committed to developing its workforce, recruiting, retaining, and strategically managing diversity. In FY 2015, FDA retained 80 percent of the 10 Commissioner's Fellowship Program graduates. FDA HQ invests in infrastructure, evolving our management systems and practices to ensure accountability for accomplishing meaningful results which enhance productivity and workforce capabilities.

Within the area of Organizational Excellence, FDA provides Stewardship. The following, selected accomplishments demonstrate FDA HQ's delivery of its regulatory and public health responsibilities within the context of current priorities.[106]

**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

[105] Replies to Inquiries to FDA on Good Clinical Practice. http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm.
[106] Please visit http://www.fda.gov/ for additional program information and detailed news items.

events, product labeling, and recall enforcement reports. Since the launch, on June 2, 2014, OpenFDA has received over 20 million data calls, half of which were 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.

OpenFDA provides access to: Adverse events such as FDA's publically available drug adverse event and medication error reports (over 4.9 million records 2004 from 2015), and medical device adverse event reports (over 4.5 million records from 1991 to 2015); recalls and enforcement report data, containing information gathered from public notices about certain recalls of FDA-regulated products (over 20,000 recalls records from 2012 to 2015); and Structured Product Labeling for FDA-regulated human drugs (prescription or over the counter) and biologics (over 67,000 records from 2009 to 2015).

## FUNDING HISTORY

| Fiscal Year | Program Level | Budget Authority | User Fees |
|---|---|---|---|
| **FY 2013 Actual** | $220,035,000 | $160,112,000 | $59,923,000 |
| **FY 2014 Actual** | $244,990,000 | $172,021,000 | $72,969,000 |
| **FY 2015 Actual** | $261,099,000 | $173,292,000 | $87,807,000 |
| **FY 2016 Enacted** | $289,562,000 | $181,587,000 | $107,975,000 |
| **FY 2017 President's Budget** | $298,682,000 | $178,287,000 | $120,395,000 |

## BUDGET REQUEST

The FY 2017 Budget Request is $298,682, 000 of which $178,287, 000 is budget authority and $120,395,000 is user fees. The budget authority decreases by $3,300, 000 compared to the FY 2016 Enacted level and user fees increase by $12,420, 000. The FY 2017 Budget request allows FDA to continue overall performance in the Strategic Goal Areas of Enhanced Oversight, Improve and Safeguard Access, Promote Informed Decisions, and Strengthen Organizational Excellence.

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. The request continues to include $10 million to support the China Initiative.

In FY 2016, FDA HQ will utilize the $5 million increase provided in FY 2016 to bolster the important ongoing development and utilization of a targeted, risk-based, and efficient inspection model for foreign high risk facilities. The funding will support efforts to develop key systems,

processes, and data sources in different commodity areas including food safety and medical products. These efforts may include mutual reliance or other methods to leverage inspection and site data from foreign regulators. Additionally, these efforts will support the incorporation of commercially available information on high-risk establishments for onsite verifications. The increased funding will drive significant progress in achieving these multi-year objectives, but without these funds in FY 2017 the pace and scale of implementation will most likely be negatively affected.

FDA HQ will continue to advance international initiatives to ensure FDA's capability to work with foreign regulatory stakeholders in response to international emergencies involving or impacting FDA-regulated products, and to share information with such entities during emergencies to strengthen FDA's global product safety net. FDA will continue to provide improved collaboration and information sharing tools among FDA and its domestic and international partners regarding response efforts to coordinate and disseminate critical information during emergency incident response and subsequent product recalls and/or alerts. FDA will also continue to improve the accuracy of firm manufacturing site data to improve inspection planning.

FDA HQ 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 will also provide surveillance and signal monitoring, including FDA's Emergency Call Center and Consumer Complaint reporting and monitoring functions

FDA HQ will explore and test interdisciplinary approaches of integrating qualitative and quantitative social science data with traditional and social media analysis and pharmaco-epidemiological data to assess communication effectiveness in the use of regulated products. FDA HQ will analyze the intersection of economic and behavioral effects of health and safety information about regulated products.

In addition, FDA HQ will continue to provide program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA HQ is committed to delivering cutting-edge technology, innovation, and support to all stakeholders.

**BUDGET AUTHORITY**

**Medical Product Safety and Availability: $91.1 million (+$1.7 million)**[107]

**Precision Medicine: $0.2 million**

FDA's precision medicine initiative provides a crowd-sourced, cloud-based platform to advance regulatory science around NGS-based analytical tools and datasets. This platform plays an important role in the Precision Medicine Initiative by engaging the community of NGS-based test providers, standards-making bodies, pharmaceutical and biotechnology companies, healthcare providers, academic medical centers, research consortia and patient advocacy groups to determine the best currently available approach to assessing the accuracy and reproducibility of NGS analytical software. The $200,000 in FY 2017 will be used to monitor portal usage, support community member use and engage, support, and steer the community toward

[107] Includes restoration of $1.5 million transferred from FDA to HHS Office of the Inspector General.

innovation in regulatory science. Some specific targeted activities will include: community code-a-thons and community challenges around challenging questions such as how common bioinformatics workflows perform on known reference data sets and how comparison tools and approaches can be improved to better compare results.

**USER FEES**

**Current Law User Fees: +$0.3 million**

FDA HQ will utilize these current law user fees to provide support to FDA Centers and Offices. FDA HQ will provide strategic coordination, direction, and oversight across FDA UF programs.

**Proposed User Fees: +$12.1 million**

The FDA HQ request includes an increase of $12.1 million for proposed user fees, which will allow FDA to fulfill its mission of protecting the public health by ensuring the safety and proper labeling of domestic and imported foods, cosmetics, and allowing for increased surveillance of FDA-regulated products at express courier hubs.

## 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 2016 Target | FY 2017 Target | FY 2017 +/- FY 2016 |
|---|---|---|---|---|
| 292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. *(Output)* | Maintained 98.7% efficiency on response to calls to the FDA After Hours Call Center.<br><br>Successfully coordinated 57 incidents involving FDA regulated products during the year.<br><br>Participated in six exercises during the year.<br><br>Conducted 12 tests per year of FDA's system for contacting agency officials nationwide after-hours in the event of an emergency.<br><br>(All Targets Met or Exceeded) | Maintain 95% efficiency on response to calls to the FDA After Hours Call Center.<br><br>Successfully coordinate 20 incidents involving FDA regulated products during the year.<br><br>Participate in seven exercises during the year. | Develop 50 mapping products in support of FDA's emergency preparedness, response, and recovery activities.<br><br>Successfully coordinate 20 incidents involving FDA regulated products during the year.<br><br>Participate in nine exercises during the year. | +2 |
| 291305: Number of electronic and print communications disseminated to women's health stakeholders. *(Output)* | FY 2015: 35<br>Target: 25<br>(Target Exceeded) | 39 | 39 | maintain |

| Measure | Year and Most Recent Result / Target for Recent Result (Summary of Result) | FY 2016 Target | FY 2017 Target | FY 2017 +/- FY 2016 |
|---|---|---|---|---|
| 293206: Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. *(Outcome)* | FY 2015: FDA completed annual milestones on 6 more intramural research projects under the Nanotechnology CORES program to promote cross-center and external collaborative regulatory science research opportunities, focusing on studies evaluating nano-materials. (Target Met) | 30 CORES projects with completed annual milestones | 36 CORES projects with completed annual milestones | +6 |
| 291101: Percentage of Fellows retained at FDA after completing the Fellowship program. *(Outcome)* | FY 2015: 80% Target: 40% (Target Exceeded) | 50% | 50% | Maintain |
| 293205: Percentage of requests for combination product designations processed within the 60 day statutory requirement. *(Output)* | FY 2015: 100% Target: 95% (Target Exceeded) | 95% | 95% | Maintain |
| 293203: Number of pediatric scientific, ethical, product, and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, Japan, and Canada, with Australia as observers. *(Output)* | FY 2015: 174 Target: 40 (Target Exceeded) | 50 | 50 | Maintain |
| 293204: Number of medical products studied in children with labeling changes and safety reviews completed and presented to FDA's Pediatric Advisory Committee. *(Output)* | FY 2015: 34 Target: 30 (Target Exceeded) | 30 | 30 | Maintain |

| Measure | Year and Most Recent Result / Target for Recent Result (Summary of Result) | FY 2016 Target | FY 2017 Target | FY 2017 +/- FY 2016 |
|---|---|---|---|---|
| 292301: The number of new multi-faceted educational programs for patient advocates and health professionals on major FDA public health issues. *(Output)* | FY 2015: 4<br>Target: 4<br>(Target Met) | 4 | 4 | Maintain |
| 291306: Number of collaborative actions taken based upon meaningful analyses of the global regulatory landscape. *(Output)* | FY 2015: 27<br>Target: 25<br>(Target Exceeded) | 25 | 25 | Maintain |
| 291406: Percentage of invoices issued on time within predefined dates in the month. *(Output)* | FY 2015: 100%<br>Target: 98%<br>(Target Exceeded) | 98% | 98% | Maintain |
| 293207: Percentage of reviews of first-time and amended orphan drug designation applications completed in 90 days or less. *(Output)* | FY 2015: 90%<br>Target: 75%<br>(Target Exceeded) | 75% | 75% | Maintain |
| 293208: Percentage of Humanitarian Use Device designation reviews completed in 45 days or less. *(Output)* | FY 2015: 100%<br>Target: 95%<br>(Target Exceeded) | 95% | 95% | Maintain |

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

**Nanotechnology Development**

For the FDA, a science-based regulatory agency whose mission is to protect and promote public health, nanotechnology poses regulatory challenges that are inherent in emerging technologies. Like many emerging technologies, nanotechnology can potentially benefit medicine and other FDA-regulated product areas, but the risks to human and animal health are not yet completely identified or understood. Establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions will promote innovation and predictability in the development of safe and effective nanotechnology-based products. Collaborative Opportunities for Research Excellence in Science (CORES) projects are designed to produce internal and external reports and testing methods that FDA staff can use to

evaluate FDA regulated products that contain or use nanotechnology. From 2011 to 2015, FDA has completed annual milestones on 24 CORES projects, and plans to complete 30 annual milestones by the end of FY 2016, and 36 by the end of FY 2017. Because some of the projects are multi-year projects, completing the annual milestones for each project is defined as complete for that year.

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