FOODS

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Foods	**913,784**	**903,340**	**998,914**	**1,195,067**	**196,153**
Budget Authority	***903,403***	***903,340***	***987,328***	***1,012,603***	***25,275***
User Fees	***10,381***	---	***11,586***	***182,464***	***170,878***
Center	280,480	279,971	304,544	355,956	51,412
Budget Authority	279,994	279,971	303,994	303,994	---
User Fees	486	---	550	51,962	51,412
Food and Feed Recall	*243*	---	*243*	*243*	---
Voluntary Qualified Importer Program	*243*	---	*243*	*243*	---
Third Party Auditor Program	---	---	*64*	*64*	---
Food Facility Registration and Inspection	---	---	---	*23,717*	23,717
Food Import	---	---	---	*9,974*	9,974
Cosmetics	---	---	---	*12,995*	12,995
Food Contact Substance Notification	---	---	---	*4,726*	4,726
Field	633,304	623,369	694,370	839,111	144,741
Budget Authority	623,409	623,369	683,334	708,609	25,275
User Fees	9,895	---	11,036	130,502	119,466
Food and Feed Recall	*1,000*	---	*1,000*	*1,000*	---
Food Reinspection	*4,575*	---	*4,575*	*4,575*	---
Voluntary Qualified Importer Program	*4,320*	---	*4,320*	*4,320*	---
Third Party Auditor Program	---	---	*1,141*	*1,141*	---
Food Facility Registration and Inspection	---	---	---	*27,891*	27,891
Food Import	---	---	---	*86,122*	86,122
International Courier	---	---	---	*779*	779
Cosmetics	---	---	---	*4,674*	4,674
FTE	**3,720**	**3,667**	**3,925**	**4,109**	**184**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Federal Import Milk Act (21 U.S.C. 142-149); Public Health Service Act (42 U.S.C. 201, et seq.); Food Additives Amendment of 1958; Color Additives Amendments of 1960; 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; Infant Formula Act of 1980; Drug Enforcement, Education, and Control Act of 1986; Nutrition Labeling and Education Act of 1990; Dietary Supplement Health and Education Act of 1994; 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; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Food Allergen Labeling and Consumer Protection Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendments Act of 2007; Food and Drug Administration Food Safety Modernization Act of 2011 (Public Law 111-353); Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C. 379aa-1)

Allocation Methods: Direct Federal/intramural; Contract; Competitive grant

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The purpose of the Foods Program is to protect and promote the health of humans and animals by ensuring the safety and proper labeling of the American food supply, animal feed, and cosmetics, as well as the safety and effectiveness of animal drugs and devices. The Foods Program began with the passage of the 1906 Pure Food and Drugs Act.

FDA's Foods Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The FVM Program is comprised of the Foods and the Animal Drugs and Feeds Programs, including field activities in the Office of Regulatory Affairs (ORA). The operations of the Foods and Animal Drugs and Feeds Programs are administered by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) respectively,[4] both in collaboration with ORA. CFSAN ensures the safety of the human food supply, dietary supplements, and cosmetics as well as the proper labeling of foods and cosmetics. The Foods Program also ensures that the nation's food supply is wholesome and honestly labeled, and that nutrition labeling is informative and accurate, and promotes a nutritionally healthy food supply. The Center for Veterinary Medicine protects human and animal health by approving safe and effective drugs, feed, and devices for animals. The Office of Foods and Veterinary Medicine (OFVM) provides leadership and strategic direction to Foods and Veterinary Medicine programs, including direct oversight of all activities of CFSAN and CVM. Additionally, OFVM manages the crosscutting outbreak response and evaluation team, leads all external communications and stakeholder engagements, and coordinates FVM wide resource planning.

The FVM Strategic Plan[5] provides a guiding strategic vision for FDA's food, feed, and veterinary medicine activities, including the implementation of the Food Safety Modernization Act (FSMA). The Plan contains one cross-cutting goal: protecting consumers and promoting public health, starting with four programmatic goals:

- Goal One: Food Safety- Protect America's Consumers and Animals from Foreseeable Hazards
- Goal Two: Nutrition- Foster an Environment to Promote Healthy and Safe Food Choices
- Goal Three: Animal Health- Protect Human and Animal Health by Enhancing the Safety and Effectiveness of Animal Health Products
- Goal Four: Organizational Excellence- Continuously Improve the Leadership, Management, Staffing, and Organizational Capacity of the FVM Program to Protect Public Health

Outbreaks of foodborne illness and contamination events have a substantial impact on public health:

- an estimated 48 million foodborne illnesses occur every year
- an estimated 128,000 hospitalizations and 3,000 deaths result[6]

[4] The Center for Veterinary Medicine does not implement the Foods Program, and the Center for Food Safety and Applied Nutrition does not implement the Animal Drugs and Feeds Program.
[5] *FDA Foods and Veterinary Medicine Program Strategic Plan, 2012 – 2016*. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf.
[6] CDC. 2011.Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

- foodborne illnesses cost an average $1,626 per case.
- More than $75 billion per year in total medical costs, lost productivity, and illness-related mortality result.[7]

Additionally, poor nutrition contributes to chronic diseases, which are the leading cause of death and disability in the United States. Chronic diseases and conditions—such as heart disease, stroke, cancer, diabetes, obesity, and arthritis—are among the most common, costly, and preventable of all health problems, and 86 percent of all health care spending in 2010 was for people with one or more chronic medical conditions.[8]

FDA faces unique food safety challenges in the twenty first century. The Food Safety Modernization Act (FSMA) enables FDA to better protect the public health by strengthening the food and feed safety system and empowering FDA to modernize its food safety work by:

- shifting the food safety paradigm from the previous system of addressing issues after they occur to a new one focused on prevention
- strengthening FDA's technical expertise and capacity to support the industry in implementing the new prevention standards
- furthering federal, state, local and territorial partnerships and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide
- broadening interaction with foreign partners and increasing oversight of importers by placing more responsibility for the safety of imported foods on them

FSMA also provides FDA with new enforcement authorities designed to achieve high rates of compliance with prevention- and risk-based food and feed safety standards and to better respond to and contain problems when they occur.

The FVM Strategic Plan provides a framework for the implementation of FSMA and other legislative authorities and places high priority on the prevention of foodborne and feed-borne illness of unknown origins, as well as illness that can be specifically attributed to known sources. The Foods Program addresses food safety risks at multiple points of the food supply chain through a combination of regulations, guidance, technical assistance, training, outreach, consumer information, and model codes for food service establishments such as restaurants.

The FVM Strategic Plan also emphasizes the nutrition-related priorities of the Foods Program. Poor diet is a key risk factor which contributes to the high rates of chronic disease, including obesity, in the United States. The Foods Program ensures that nutrition labeling is informative and accurate, and promotes a nutritionally healthy food supply to reduce the hundreds of thousands of deaths each year attributable to poor diet.

In addition to the high-priority initiatives identified in the FVM Strategic Plan, the Foods Program conducts many other important activities related to food safety, nutrition, and cosmetics. These include:

- review of infant formula notifications received from manufacturers prior to marketing of a new formula

[7] Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," Journal of Food Protection, Volume 75, Number 1, January 2012, pp. 123-131(9).
[8] Centers for Disease Control and Prevention. "Chronic Disease Prevention and Health Promotion: Chronic Disease Overview." http://www.cdc.gov/chronicdisease/overview/, Accessed October 23, 2015.

- premarket regulation of ingredients and packaging, such as the review of food additive and color additive petitions
- postmarket monitoring for chemical contaminants
- authorization of nutrient content and health claims
- regulation of dietary supplements
- cosmetics safety and labeling
- other ongoing regulatory, enforcement, research, communications, education, and outreach activities.

The following selected accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities within the context of current priorities and demonstrate progress towards the goals identified in the FDA and FVM Strategic Plans.

Enhance Oversight

The FDA Strategic Plan goal of Enhanced Oversight is the primary goal in which most Foods Program activities are best categorized. As a regulatory and scientific organization responsible for the safety of the nation's foods and cosmetics, much of the Foods Program's mission involves oversight work relating to scientific analysis and support, policy, guidance development, and regulatory research.

Selected Rules Published in 2015

Below are proposed and final rules published by the Foods Program/CFSAN during calendar year 2015. These rules help address various issues.[9]

Date	#	Purpose
Nov 2015	FDA-2011-N-0146	Final Rule – FSMA Final Rule on Accredited Third-Party Certification Establishes user fees to support FDA's Accreditation of Third-Party Auditors Program.
Sep 2015	FDA-2011-N-0920	Final Rule – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food) Modernizes human food CGMPs and requires certain facilities to establish and implement hazard analysis and risk-based preventive controls.
Jul 2015	FDA-2012-N-1210	Supplemental Proposed Rule - Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions Revises proposed nutrition facts label rule to include a daily value for added sugars.
Apr 2015	FDA-2002-N-0323	Proposed Rule – Amendments to Registration of Food Facilities Improves the food facility registration system and implements FSMA registration provisions.

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

Selected Guidances Issued in 2015

Below are draft and final guidances issued by CFSAN during calendar year 2015. These guidances help address various issues.[10]

Date	#	Title	Description
Sep 2015	FDA-2011-F-0172	Labeling & Nutrition (Menu)	Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II
Jun 2015	FDA-2014-D-0052	Allergens	Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications
Jun 2015	FDA-2011-N-0144	Food Defense (Importers)	Draft Guidance for Industry: FDA's Voluntary Qualified Importer Program
May 2015	FDA-2015-D-0138	Food Defense (Recalls)	Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls
Mar 2015	FDA-2011-F-0172	Labeling & Nutrition (Menu)	Guidance for Industry: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide

FSMA Rules

In January 2011, the President signed into law the FDA Food Safety Modernization Act (FSMA). FSMA enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FDA is able to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. This law is the most significant modernization of the U.S. food safety system in 70 years and mandates the development and implementation of seven foundational rules, to establish a new preventive controls framework for domestically produced and imported food, among other things.

Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards. Following the issuance of four of the rules proposed in 2013 – Preventive Controls for Human Food, Preventive Controls for Animal Food, Produce Safety, and Foreign Supplier Verification Programs – FDA received extensive input from industry, consumers, and Members of Congress that prompted FDA to revise these rules. In December 2013 and early 2014, FDA announced that it would issue revised rule provisions for public comment, which resulted in the publication of revised rules in 2015.

Described below are the foundational final FSMA rules published by the Foods Program. The table shows the final rules ordered by their respective publication dates.[11]

Date	#	Purpose
Sep 2015	FDA-2011-N-0920	Final Rule #1 – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food)

[10] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.
[11] For more information on the FSMA rules please visit http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.

Date	#	Purpose
Sep 2015	FDA-2011-N-0922	Final Rule #2 - Establish Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls for Animal Food)
Nov 2015	FDA-2011-N-0921	Final Rule #3 - Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption(Produce Safety rule)
Nov 2015	FDA-2011-N-0143	Final Rule #4 - Foreign Supplier Verification Programs for Importers of Food for Human and Animals (FSVP rule)
Nov2015	FDA-2011-N-0146	Final Rule #5 - Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Accredited Third-Party Certification rule)

The first final FSMA rule 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 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. This rule is discussed further in the Animal Drugs and Feeds Program narrative.

The third final rule addresses standards for produce safety by establishing enforceable science- and risk-based processes for the growing, harvesting, packing, and holding of fruits and vegetables on farms. The 2014 supplemental proposal for this rule revised the criteria for determining the safety of agricultural water for certain uses to add flexibility and introduce a tiered approach to water testing. FDA deferred its decision on an appropriate time interval between the application of raw manure and the harvesting of a crop until additional research is conducted, and FDA removed the nine-month interval originally proposed. Also, FDA proposed eliminating the 45-day minimum application interval for composted manure that meets proposed microbial standards and application requirements.

The fourth final rule 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 rule for Foreign Supplier Verification Programs (FSVP), importers need to verify that their suppliers meet 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.

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 recognizes 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. This program will begin collecting user fees in 2016.

The remaining two FSMA rules are scheduled to be issued in spring 2016. They will address sanitary transportation and intentional adulteration of the food supply.

Released FSMA Operational Strategy
FDA released a FSMA Operational Strategy Document on May 2, 2014.[12] The document highlights how FSMA changes the way FDA approaches food safety and also sets forth the operational strategy for implementing those changes. The operational strategy focuses on how FDA can implement FSMA by prioritizing prevention, voluntary compliance, risk-based oversight, and expanded collaboration across the food safety community.

Next, FDA will design methods to promote voluntary industry compliance with the new rules and also establish preventive and public-health-focused inspection and sampling programs to oversee compliance. FDA is also developing enforcement strategies to address situations when producers, processors, distributors, and importers fail to comply voluntarily.

Published Draft Voluntary Qualified Importer Program (VQIP) Guidance
As part of FSMA implementation, FDA published draft guidance in June 2015 regarding the establishment of a voluntary, fee-based program for the expedited review and importation of foods into the United States from importers with a proven food safety track record. This program is referred to as the Voluntary Qualified Importer Program (VQIP). VQIP will benefit both importers and consumers by enabling FDA to focus its resources on food imports that are more likely to present a risk to public health.

FSMA provides FDA with new authorities to ensure that foods imported into the United States meet the same safety standards as those set for domestically produced foods. In addition to establishing mandatory standards for importers of food, FDA is establishing the VQIP for importers who achieve and maintain a high level of control over the safety and security of their supply chains.

The draft guidance on the eligibility, benefits, and criteria of the VQIP will be available for public comments for a 75-day period. After comments are considered and the guidance is finalized, the program is expected to be open for applications in January 2018 to allow enough time for a facility to be certified under FDA's Accredited Third Party Certification program.

Improved Outbreak Response
The Foods Program and the Coordinated Outbreak Response and Evaluation (CORE) team rapidly detects and responds to major foodborne illness outbreaks. This team coordinates activities across FDA field offices and compliance offices, state investigative and laboratory resources, and local city and county resources. The CORE team also works in cooperation with other federal agencies such as CDC to ensure timely and effective resolution of foodborne illness outbreaks. Examples of these activities include the Cyclospora outbreaks over the years 2012 – 2015 from salads and cilantro; the Hepatitis A outbreak from frozen berries imported from Turkey; and the ice cream Listeria monocytogenes outbreak that involved four states and caused ten illnesses and three deaths.

In preparation for outbreak response, FDA field offices support and provide technical assistance to laboratories awarded International Organization for Standardization (ISO) Cooperative Agreement Program (CAP) grants and laboratories seeking or maintaining their accreditation. This program continues to include additional national food/feed testing laboratories, with 23 laboratories joining the program, of which several are making significant progress towards ISO

[12] FSMA Operational Strategy: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm

accreditation in a short timeframe. Data generated by the awarded laboratories will be available to inform FDA in its enforcement actions, surveillance, and response to foodborne outbreaks. These ISO accredited laboratories will aid FDA with additional resources and exceptional data to maintain the safety of the food chain.

Improved Pathogen Detection and Traceability

FDA established the first national pilot network of whole genome sequencers (WGS), coined the GenomeTrakr. The Network is now in its fourth year and has accumulated more than 35,000 whole bacterial genome sequences from the FDA Network and collaborating sites in a publicly accessible database at The National Institutes of Health. FDA also developed outbreak traceback methodology based on whole bacterial genomes that can distinguish the source of certain outbreaks down to the farm level.

The implementation of WGS has significantly reduced the time necessary to conduct outbreak investigations while greatly enhancing FDA's ability to pinpoint the source of contamination events. Sample collection and sequence cataloging from food production sites can help monitor compliance with FDA's rules on safe food-handling practices, enhancing preventive controls for food safety.

WGS was used extensively in 2015 for foodborne outbreak investigations and compliance actions. For example, a *Salmonella poona* outbreak in summer 2015 sickened more than 600 people. WGS unambiguously linked human illness cases to *Salmonella poona* found on imported cucumbers, identifying the source of the contamination and subsequently limiting the scope of the recall to products from a few specific firms. Additionally, WGS also played a significant role in the investigation of outbreaks related to *Listeria monocytogenes* in ice cream. The use of WGS allowed FDA and its partners to tie clinical isolates collected over the course of the past several years to specific ice cream production facilities, linking previously unassociated cases and pinpointing the source of the outbreak. The combination of real-time clinical and food/environmental surveillance using WGS has dramatically reduced the average cluster size for *Listeria* outbreaks from 9 to 3 over the past two years and has increased the number of illnesses that could be linked to specific food sources. WGS is now applied regularly and as part of standard operations in foodborne outbreak traceability for Salmonella and Listeria monocytogenes in the FDA Foods Program.[13] Moreover, the GenomeTrakr database is now generating, on average, about one whole genome per hour, to increase the numbers of Salmonella and Listeria monocytogenes in the database. The network currently consists of 18 state laboratories, 12 FDA laboratories, and other federal partners from CDC and USDA-FSIS.

FDA's enhanced ability to pinpoint outbreaks is particularly important considering the global nature of the food supply. In the past year, in collaboration with the World Health Organization, an international GenomeTrakr laboratory was established and made operational in Buenos Aires, Argentina. Food and environmental isolates from South America are now being sequenced and

[13] *Listeria monocytogenes* are a bacterium that can cause Listeriosis, a serious infection usually caused by eating contaminated food. The disease primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems. However, rarely, persons without these risk factors can also be affected. The risk may be reduced by recommendations for safe food preparation, consumption, and storage.

submitted to the open-source database. WGS has additional groundbreaking applications for the Foods Program including:

- being utilized to make outbreak investigations faster and more efficient
- being incorporated into quality control protocols for FDA testing and surveillance, leading to enhanced confidence in regulatory actions
- monitoring compliance standards for preventive controls to identify emerging antimicrobial resistance threats in the food supply

Launched 2014 FDA Food Safety Challenge

FDA announced the 2014 Food Safety Challenge in September 2014 to target solutions for foodborne illness with particular focus on Salmonella bacteria. Salmonella represents the leading cause of deaths and of hospitalizations related to foodborne illness while contaminated produce is responsible for nearly half of foodborne illnesses and almost a quarter of foodborne-related deaths.

The Challenge utilizes authority granted under The America COMPETES Reauthorization Act of 2010 to offer a $500,000 prize in FDA's first open innovation competition. The challenge was a call to scientists, academics, entrepreneurs, and innovators from all disciplines to submit concepts applying novel or advanced methodologies to foster revolutionary improvements in foodborne pathogen detection and specifically, to accelerate detection of Salmonella in produce.

In July 2015, five finalists, who were each awarded $20,000, were invited to present their concepts in person to a panel of judges that included food safety experts from FDA, USDA, and CDC. Two finalists were later announced:

- Purdue University received the grand prize of $300,000 for "physical method for concentrating salmonella to detectable levels using automated microfiltration."
- Pronucleotein Inc. received the runner-up prize of $100,000.

As FDA's foods program implements FSMA and incorporates preventive control measures, identifying quicker detection of harmful bacteria, through methods such as those presented in FDA's Food Safety Challenge, can help to prevent foodborne illnesses from occurring.

Developed Seafood Product Labeling Online Learning Module

In order to ensure the proper labeling of seafood products offered for sale in the U.S., FDA developed an online learning module for seafood producers, retailers, state regulators, and others involved in the processing, distribution, sale, or regulation of seafood.

The module provides an overview of federal identity labeling requirements for seafood and also lists the specific laws, regulations, guidance documents, and other materials that are pertinent to the proper labeling of seafood. Stakeholders will be able to better understand FDA's role in ensuring the proper labeling of seafood and get tips for identifying mislabeled seafood, whether it is in the wholesale distribution chain or at the point of retail. The module helps stakeholders properly identify seafood throughout the supply chain while also ensuring that appropriate food

safety controls are implemented and consumers are getting the type of seafood they expect for what they are paying.

This effort included FDA's Fish Seafood Compliance and Labeling Enforcement (SCALE) project, which was recognized by HHS as one of seven Department-wide recipients of the 2015 innovation awards. The project included modernizing FDA's previous method of identifying seafood by proteins, which are unstable under most forms of processing or cooking, and break down over time in previously-required standards.

Instead of protein profiles, FDA now utilizes DNA barcoding which provides a DNA sequence that analysts can compare to standard reference sequences accessible online in a curated FDA library to properly identify different seafood products. These efforts also impact food safety, as FDA field staff are able to more properly identify species of imported puffer fish that can potentially be toxic and is currently restricted to a single species from Japan.

Encouraged the Safe Production of Dietary Supplements

In FY 2015, FDA initiated several focused regulatory actions aimed at addressing ingredient safety for marketed dietary supplements. Additionally, FDA field investigators completed 517 domestic and 52 foreign inspections of firms to enforce dietary supplement regulations, including current Good Manufacturing Practices (cGMPs) and labeling requirements. These inspections and initiatives have resulted in:

- 78 warning letters
- 7 untitled letters
- 5 regulatory meetings
- 5 injunctions.

FDA field investigators continue to enhance their knowledge through regular training sessions on the cGMP requirements, with 118 FDA personnel (and 6 state officials) completing the training at four sessions in FY 2015. Furthermore, cGMP staff members are working with FDA's Center of Excellence at the University of Mississippi's National Center for Natural Products Research (NCNPR) to develop an advanced session focusing on analytical methodology.

Mandatory premarket safety notifications describing new dietary ingredients (NDIs) in dietary supplements are vital to FDA's knowledge of marketed dietary ingredients. FY 2015 saw 35 NDI notifications and most of these (65 percent) resulted in an objection response from FDA due to inadequate safety, incomplete information, or other issues.

To address this high objection rate, FDA intends to issue a revised draft guidance to industry, describing expectations for when an NDI notification is necessary and what it should include. FDA has also initiated regulatory actions aimed at ingredients that did not go through proper FDA review prior to being marketed to ensure the importance of the NDI notification requirement is clear to stakeholders.

In FY 2015, FDA received more than 3,000 voluntary and mandatory adverse event reports associated with dietary supplements. These reports are reviewed to identify any products or ingredients that may have safety implications for the consumer. This information was used for targeted inspections and regulatory actions against unsafe products, e.g., pure powdered caffeine products.

In early FY 2016, FDA announced the creation of the Office of Dietary Supplements[14] (ODSP) within CFSAN. Elevating the program's position from its previous designation as a division to a new, independent office will raise the profile of the dietary supplements program within the agency. The creation of this office will further enhance the effectiveness of dietary supplement regulation by allowing ODSP to better compete for government resources and capabilities to regulate this rapidly expanding industry.

Enhanced Food Emergency Response Network Capacity

In preparation for food-related emergencies and high-profile events, FDA provides direct oversight to the Food Emergency Response Network (FERN) and utilizes FDA's field laboratories as well as Center and FERN laboratories. FERN grants provide state-of-the-art equipment, analytical platforms, methodology, training, and proficiency testing that can be used for surge capacity, outbreak sampling, and large surveillance assignments. FERN support also includes the FERN training program that provides courses for both federal and state laboratory analysts. FDA also maintains the FERN Storeroom that provides reagents and supplies to federal and state laboratories to support analytical activities.

This program increases the FERN capacity and analytical capability for chemical, microbiological, and radiological testing that enhances the response to food emergency events– including food safety and food defense. In FY 2015, FDA awarded 15 microbiological, 14 chemistry, and 5 radiochemistry cooperative agreement grants.

Exercised Science-Based Compliance Actions

When firms violate FDA requirements, FDA monitors firms and encourages prompt voluntary corrective action to obtain full compliance. When firms refuse or are unable to comply with FDA regulations, or FDA identifies a safety risk, FDA pursues regulatory action to prevent unsafe or improperly labeled products from reaching U.S. consumers.

FDA monitors the recalls of food, cosmetic, and dietary supplement products and ensures that violative products are effectively removed from commerce.

In FY 2015, FDA classified 304 Class I (most serious), 254 Class II, and 42 Class III human food recall events. FDA also puts import controls into place when non-compliant food products are discovered or food manufacturers are determined to be manufacturing or shipping non-compliant products. In FY 2015, FDA issued 899 of these import alert notices.

FDA created a new Import Alert # 24-23 in response to the recurring outbreaks of Cyclosporiasis associated with multiple illnesses in the United States due to cilantro contaminated with *Cyclospora cayetanensis*. This new Import Alert imposed import controls for cilantro from the state of Puebla, Mexico from April 1 – August 30, which are the months in which the *Cyclospor*a would be expected to be prevalent. Additionally, CFSAN worked in conjunction with the FDA field to assist in 644 cases where the district needed CFSAN's technical expertise to come to the right decision regarding import admissibility.

In addition, FDA protects the public from impure, adulterated, and misbranded food and acts as an industry-wide deterrent for regulated entities as well as criminal enterprises through its

[14] For more information on the creation of the Office of Dietary Supplements, please visit: http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm478303.htm

authority to initiate criminal cases. For example, in FY 2015, FDA issued three injunctions and one seizure related to adulterated or misbranded food.

Issued Draft Guidance on Mandatory Food Recalls
FSMA provided FDA with the authority to order a responsible party to recall a food if there is a reasonable probability that the food is adulterated or misbranded under certain provisions of the Federal Food, Drug, and Cosmetic Act, and that the use of or exposure to that food will cause serious adverse health consequences or death. Prior to the enactment of FSMA in January 2011, FDA had to rely on manufacturers to voluntarily recall food products. FDA has used this authority twice. In both cases, FDA issued letters to the responsible party warning that if the firm did not voluntarily cease distribution and conduct a recall, FDA may require the firm to cease distribution and give notice to other parties. These letters were effective in compelling industry to recall contaminated products and helped prevent more widespread illness outbreaks.

Regarding this authority on mandatory food recalls, FDA published a draft guidance for industry in May 2015. The draft guidance, which is available for public comment, is in the form of questions and answers that focus on common questions that might arise about how FDA will use this mandatory recall authority. FDA will consider all comments before publishing final guidance.

Removal of Most Artificial Trans Fats from Processed Foods
Based on a thorough review of scientific evidence, in June 2015, FDA finalized its determination that partially hydrogenated oils (PHOs), the primary dietary source of artificial *trans* fat in processed foods, are not "generally recognized as safe" (GRAS) for use in food. PHOs are the primary source of industrially produced *trans* fat and are found in many popular processed foods such as baked goods and frozen foods.

A 2002 study by the National Academy of Science's Institute of Medicine found a direct correlation between intake of trans fat and increased levels of low density lipoprotein (LDL) cholesterol, commonly referred to as "bad" cholesterol, and therefore, increased risk of heart disease. Eliminating *trans* fat from food is expected to reduce coronary heart disease and to prevent thousands of fatal heart attacks each year.

FDA has set a compliance period of three years to allow food manufacturers to either reformulate products without PHOs or petition FDA to permit specific uses of PHOs. FDA has also encouraged consumers seeking to reduce *trans* fat intake to check a food's ingredient list to determine whether or not it contains PHOs.

Published Infant Formula Rule
In June 2014, the Foods Program published a final rule that sets standards for infant formula manufacturers to help ensure that the formulas produced continue to be safe and support healthy growth. Issuance of the final rule provides for greater protection of infants and amends FDA's quality control procedures, requirements about how and when manufacturers must notify FDA about new formulas and changes to formulas, and requirements concerning what records and reports must be established and maintained.

The rule establishes current Good Manufacturing Practices specifically designed for infant formula, including required testing for contamination from harmful bacteria such as *Cronobacter* and *Salmonella*, in addition to the quality factors of normal physical growth and biological quality of the protein. The final rule also helps ensure that infant formula contains all federally

required nutrients to support healthy growth, including protein, fat, and certain vitamins and minerals.

In June of 2015, FDA issued an additional final rule to add selenium to the list of required nutrients for infant formula and to establish both minimum and maximum levels of selenium required in infant formula. Selenium is the 30th nutrient now required by law to be in infant formula. Among its benefits, selenium helps the body defend against oxidative stress and aids in the regulation of thyroid hormones.

In May 2014, the People's Republic of China implemented a decree requiring registration of any formula powders for infants and young children originating from sources outside of China and intended to be exported into China. The same decree also banned the import of the same products by any unregistered enterprise.

FDA worked with other multiple governmental entities to ensure that Chinese concerns were addressed and that U.S. manufacturers could continue to export products to China. The U.S. delegation worked with Chinese representatives to conduct on-site audits of U.S. manufacturing facilities of the subject commodities. At the conclusion of the audits, the Chinese granted approval to certain U.S. infant formula manufacturers resulting in a one billion dollar trade agreement with the United States. FDA efforts will continue under this initiative to ensure U.S. trade capabilities are minimally impacted.

Launched Food Defense Plan Builder

In FY 2015, FDA evaluated comments in response to the proposed rule on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" as part of its implementation of FSMA. The requirements within the rule, once finalized in May 2016, will require that food facilities develop and implement a food defense plan. In anticipation of the final rule, FDA will be updating the Food Defense Plan Builder, a user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities.

This user-friendly tool harnesses existing FDA tools, guidance, and resources for food defense into one single application. The tool guides users through a series of sections:

- Company Information
- Broad Mitigation Strategies
- Vulnerability Assessments
- Focused Mitigation Strategies
- Emergency Contacts
- Action Plan
- Supporting Documents.

The information collected from each of these sections, automatically compiles a food defense plan for their facility. Since its launch in May 2013, the Food Defense Plan Builder received excellent reviews from industry and has been downloaded more than 18,000 times by users from all over the world.

Improve and Safeguard Access

The Foods Program has several programmatic aspects that fall within the FDA goal of improving and safeguarding access that largely consist of premarket review activities. The Foods Program has statutory responsibility for review and approval of all petitions for direct food additives in addition to review and approval of all new food contact substances, food contact materials, packaging, antimicrobials, and other indirect food additives. Also included in this category is review of Generally Recognized As Safe (GRAS) ingredients and products of biotechnology relating to food.

Published Timely Food and Color Additive and Food Contact Substance Reviews
FDA has the primary legal responsibility for determining the safe use of food additives and color additives. To market a new food additive, color additive or food contact substance – or before using an additive already approved for one use in another manner not yet approved – a manufacturer or other sponsor must first petition FDA for its approval, a process that is unique to FDA's regulatory mission. In FY 2015, FDA ensured safe access to the food supply by reviewing 11 Food and Color Additive Petitions, 65 GRAS notifications, and 108 premarket notifications for Food Contact Substances.

Updated Risk Assessment Capabilities
FDA completed a review of how it evaluates the harmful effects of chemicals in foods, cosmetics, dietary supplements, animal food and feed, and veterinary drugs. FDA Centers, led by CFSAN, will continue the process of updating FDA's Toxicological Principles for the Safety Assessment of Food Ingredients – also called the "Redbook" – so that it reflects the most recent science. FDA's overarching goal in this effort is to develop a framework that incorporates the assessment of ingredients present in various products such as:

- food additives
- food contact substances
- ingredients that are generally regarded as safe (GRAS)
- new plant varieties
- dietary supplements and new dietary ingredients
- cosmetic ingredients
- unavoidable chemical contaminants other than microbial pathogens.

Additionally, the Centers will jointly develop a process to ensure consistency of methodologies used for safety and risk assessments within and across offices at CFSAN, and between CFSAN and CVM.

Promote Informed Decisions

The Foods Program is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled. The Nutrition Labeling and Education Act (NLEA) requires most packaged foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements.

The Foods Program also serves as FDA's primary organization for directing, developing, and coordinating web communications, outreach, and consumer education. FDA has statutory responsibility for food safety, and has jurisdiction over all domestic and imported food except meat, poultry, and processed egg products that fall under the authority of the U.S. Department of

Agriculture. Outreach is essential to ensure that consumers and food safety partners have the information needed to make informed decisions.

Updated Nutrition Facts Label
In FY 2014, the Foods Program published two proposed rules, one on updating the Nutrition and Supplement Facts labels, and one on updating FDA's serving size requirements for conventional foods. The proposal to update the Nutrition and Supplement Facts label reflects new public health and scientific information, including links between diet and chronic diseases such as obesity and heart disease. The proposal for updating FDA's serving size requirements incorporates new developments including the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and recent consumer research on the use and understanding of the Nutrition Facts label. These proposals also feature a fresh design to highlight key parts of the label such as calories and serving sizes.

Proposed Rule for Gluten-Free Labeling of Fermented or Hydrolyzed Foods
In November 2015, FDA published a proposed rule to establish additional requirements for fermented, hydrolyzed, and distilled foods or ingredients that are labeled as "gluten-free." Hydrolyzed, fermented, or distilled foods voluntarily bearing the "gluten-free" claim must meet the requirements of the gluten-free food labeling final rule. , These requirements are necessary to ensure that manufacturers have a clear understanding of what is meant by "gluten free" and individuals with celiac disease receive truthful and accurate information about foods that are labeled with this term. Such foods include cheese, yogurt, vinegar, pickles, green olives, some beers and wines and foods containing hydrolyzed soy that is often used to enhance flavor or improve texture.

Menu Labeling Draft Guidance
In September 2015, FDA issued a draft guidance document to help companies comply with the menu labeling final rule. The Menu Labeling Regulation requires certain restaurants and similar retail food establishments selling restaurant-type foods to disclose calorie information on their menus and menu boards for standard menu items and to disclose calorie information for foods on display and self-service foods that are standard menu items. Additionally, covered establishments must have the required additional written nutrition information available upon consumer request on the premises of the covered establishment.

Labeling Food Containing Ingredients Derived from Genetically Engineered Sources
In November 2015, FDA released two guidance documents detailing the agency's current thinking on labeling of food derived from Atlantic salmon that has or has not been genetically engineered and a final guidance for labeling of food that has or has not been derived from GE plants to help those manufacturers who wish to voluntarily make the distinction on the labeling of their food products. Both guidance documents explain FDA's best thinking on how manufacturers who wish to provide such information can do so in a way that is truthful and not misleading.

Launched iRISK® 2.0
FDA released version 2.0 of FDA-iRISK®, a web-based tool whose automated features enable scientists and other food-safety professionals to conduct quantitative risk assessments more rapidly and to report results as key public-health metrics, among many other innovative features. The results inform risk managers' decisions about food-safety policy. The program allows users to compare and rank risks from foodborne hazards and to predict and compare the impact various interventions will have on public health. Examples of enhanced features of version 2.0 are advanced modeling and reporting methods, increased speed, and easier data-sharing. FDA-iRISK® 2.0 and related new documents are available on Foodrisk.org.[15]

FDA, in collaboration with Federal Partners, Developed Improved Method for Attributing Foodborne Illness
FDA, working with The Centers for Disease Control and Prevention (CDC) and the USDA's Food Safety Inspection Service (FSIS) developed an improved method for analyzing outbreak data to determine which foods are ultimately responsible for illnesses related to four major foodborne bacteria. The three agencies, operating as a partnership known as the Interagency Food Safety Analytics Collaboration (IFSAC), released a report titled "Foodborne Illness Source Attribution Estimates for Salmonella, Escherichia coli O157), Listeria monocytogenes (Lm), and Campylobacter using Outbreak Surveillance Data." The CDC estimates the four pathogens discussed in the report cause 1.9 million cases of foodborne illness in the United States each year.

The agencies anticipate that IFSAC's work will enhance their efforts to prevent foodborne illness. The new estimates will help shape agency priorities and support the development of new regulations and performance standards and measures. The recently developed method employs new food categories that align with those used to regulate food products and emphasizes more recent outbreak data. To arrive at these categories, IFSAC experts analyzed data from nearly 1,000 outbreaks in an effort to determine which categories of foods were most responsible for making people sick with Salmonella, E. coli O157, Listeria, and Campylobacter. The pathogens were chosen because of the frequency or severity of the illnesses they cause, and because targeted interventions can have a significant impact in reducing them.

FDA Announced Competitive Grant Program with NIFA to Fund Food Safety Training, Education and Technical Assistance
FDA joined with the U.S. Department of Agriculture's National Institute of Food and Agriculture (NIFA) in a collaborative partnership to administer and manage the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program.

The grant program recognizes the importance of food safety training for small farm owners and food processors and will provide funding to these critical groups. The funds will assist these groups in receiving training, education, and technical assistance consistent with standards being established under FSMA. Priority for the grants will be given to entities training owners and

15 FDA i-Risk® 2.0 and related documents are available online at http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/

operators of small and medium-size farms, farmers just starting out in the business, socially disadvantaged farmers, small food processors, small fruit and vegetable wholesalers, and farms that lack access to food safety training and other educational opportunities.

Among the entities eligible for funding are federal, state, or local agencies, state cooperative extension services, non-profit community based or non-governmental organizations, institutions of higher education, Tribes and tribal stakeholders, or a collaboration of two or more eligible entities.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	$796,638,000	$796,638,000	$0
FY 2014 Actual	$882,814,000	$882,814,000	$0
FY 2015 Actual	$903,340,000	$903,340,000	$0
FY 2016 Enacted	$998,914,000	$987,328,000	$11,586,000
FY 2017 President's Budget	$1,195,067,000	$1,012,603,000	$182,464,000

BUDGET REQUEST

The FY 2017 Budget Request is $1,195,067,000, of which $1,012,603,000 is budget authority and $182,464,000 is user fees. The budget authority increases by $25,275,000 compared to the FY 2016 Enacted level and user fees increase by $170,878,000. This request will provide $355,956,000 to the Center for Food Safety and Applied Nutrition (CFSAN) and $839,111,000 to the Office of Regulatory Affairs (ORA).

The FY 2017 Budget will allow the Foods Program to continue its statutory mission of promoting and protecting public health by ensuring that the nation's food supply is safe, sanitary, and properly labeled, and that cosmetic products are safe and properly labeled. This mission becomes more challenging every year as globalization, advances in science and technology, and shifts in consumer expectations drive change throughout the human and animal food systems. In response to these increasing demands, the Foods Program conducts a variety of activities aimed at providing American consumers with food and cosmetics products that are safe and properly labeled.

The Foods Program will maintain current levels of operational activities to inspect regulated products and manufacturers, conduct sample analyses of regulated products, and review imported products offered for entry into the United States. FDA will continue to work with its state, local, tribal, territorial, and foreign counterparts to make the best use of all available public resources and improve program efficiency and effectiveness.

The Foods Program will continue its efforts to implement a risk-based approach towards food safety. FDA-iRISK® will be enhanced by increasing its capability and usability. FDA's compliance and enforcement activities will support the risk-based implementation of FSMA rules by utilizing new education, technical assistance, inspection, and enforcement strategies to gain compliance with new food safety standards. In order to better assess how the performance of the new FSMA prevention strategy and commodity-based and vertically integrated regulatory

programs may be enhanced, FDA will continue to evaluate its current regulatory and compliance activities, focusing on opportunities to improve risk-based resource targeting and efficiency.

The Foods Program will continue to enhance nutrition education by working with industry and other stakeholders Activities to improve nutritional quality of packaged and restaurant foods will continue in FY 2017 by implementing updated regulations for the Nutrition Facts Label, serving-size regulations for conventional foods, and regulations for calorie labeling for menus and vending machines. The new Nutrition Facts labels will enable consumers to base their food choices on up-to-date serving size and other information, with a focus on better understanding the calorie content per serving size of food.

BUDGET AUTHORITY

Food Safety: $1.0 billion (+$25.3 million)

Since FSMA was enacted, FDA has carried out extensive work to implement the law by publishing key FSMA rules that would provide needed food safety protections for the American public, while at the same time making the rules as flexible as possible and workable across the great diversity of the nation's food system. These rules were informed by current industry practices and extensive outreach and dialogue across the country and overseas with farmers, manufacturers, commercial food handlers, consumers, and government partners. FDA issued five key final FSMA rules in the fall of 2015, and plans to issue additional rules in the spring of 2016.

FDA received a significant funding increase for FSMA implementation in FY 2016 in anticipation of implementing the final rules. This funding is enabling FDA to maintain momentum toward successful implementation of FSMA but still leaves a significant gap in funding in two key areas: state funding for produce safety and ensuring the safety of imported food. Additional funding is needed in these areas, if FDA and the food system are to fully realize the public health and public confidence benefits promised by FSMA. FDA has begun crucial planning and taken initial steps to ensure successful implementation in the following areas: inspection modernization and associated FDA and state staff training; guidance development, education and technical assistance for industry; and establishing an import safety system that addresses problems before food from other countries reaches the U.S. border. With the requested increase for FSMA implementation in FY 2017, FDA plans the following activities:

National Integrated Food Safety System: Produce Safety +$11.3 million
Field: +$11.3 million

Building a national integrated food safety system is a central element of FSMA's mandate to FDA and crucial to successful implementation of FSMA. The FY 2017 request will build on the FY 2016 investments in this area. The request will be used primarily to support state capacity to implement the FSMA produce safety rule through funding of state cooperative agreements and grants.

FDA's implementation strategy for the FSMA produce safety rule depends on States being full partners with FDA and the primary frontline interface with growers to foster efficient compliance with the rule. In FY 2017, FDA and state efforts to implement the produce safety rule will focus on providing educational and technical assistance to industry, especially small and very small farming operations. This requires building the capacity and expertise that state

agencies involved in agriculture and food safety will need to deliver timely and effective education and technical assistance so that farmers can comply with the new produce safety rule. This funding will also build state capacity and continue planning for future inspections to ensure compliance.

Based on the FDA-state strategy of educating before we regulate, FY 2017 resources will also be used to conduct non-regulatory pre-assessments to help growers gauge their current compliance and improve as needed to comply with the new rule.

Neither FDA nor the states have existing programs for conducting on-farm inspections and the other on-farm support activities needed to successfully implement the produce safety provisions of FSMA. Given the states' willingness to partner with FDA and their comparative advantage due to their local presence, knowledge, and relationships with the farm community, FDA believes the states can provide this oversight and direct technical assistance more effectively and efficiently than FDA. The states have made it clear, however, that they cannot perform these functions without federal resources to supplement their current constrained capacity and resources.

Import Safety: +$14.0 million
Field: +$14.0 million

The requested funds will enable FDA to continue progress toward implementing the multifaceted new import safety system mandated by Congress. FDA will focus in FY 2017 on implementing the Foreign Supplier Verification Program (FSVP) rule, under which importers must verify that food they import into the United States has been produced in a manner consistent with FSMA's new standards for produce safety and preventive controls in food facilities. This preventive approach to import safety will improve food safety and consumer confidence in imported food but presents an enormous challenge for both FDA and food importers, given that approximately 90,000 consignees received food import shipments last year. The volume of imported food has increased enormously over the past 20 years, going from fewer than 200,000 line-entries in the early 1990s to over 13 million in FY 2015.

Building on the FY 2016 investment, FSVP will require further investment to:

- hire and train staff to perform FSVP inspections
- provide extensive training and technical assistance for importers
- provide outreach to foreign firms and foreign government partners on the new FSVP requirements.

To improve import safety, FDA will also expand its overseas presence, as mandated by FSMA. This expansion includes increasing and better targeting FDA inspections of foreign food facilities, as well as working with and assisting foreign governments to ensure the safety of food before it is imported by the United States.

Without effective FSVP implementation and greater FDA overseas presence, FDA will not be able to provide the assurances of import safety envisioned by FSMA. This outcome would present a threat to food safety and inhibit the U.S.'s ability to foster two-way trade in food commodities based on consumer and industry confidence in food safety.

USER FEES

Proposed User Fees: +$170.9 million

Proposed Food Import Fee: +$96.1 million
Center: +$10 million / Field: +$86.1 million

The Foods Program request for the proposed Food Import Fee is $96,096,000. Revenue from the proposed Food Import Fee would enable FDA to modernize its import oversight program in ways that would facilitate the entry of safe food.

The volume of imported food has increased enormously over the past 20 years, going from fewer than 200,000 line-entries in the early 1990s to over 13 million in FY 2015. A cascade of contaminated food incidents in recent years, such as bacterial contamination of fresh fruits and vegetables and illegal antibiotics in seafood, has resulted in public distrust of imported food and a belief that the Federal government is not taking adequate steps to ensure imported food safety.

Congress has repeatedly raised the issue of inadequate border screening of food, noting that in FY 2015 approximately two percent of imported food and feed entries were physically examined. The fundamental tenet of the FSMA import provisions is to design an import control strategy that does not solely depend on FDA reviews at the ports of entry but where such reviews are the final step in a comprehensive system of safeguards for improving the safety of the U.S. food supply, with importers responsible for far greater safety assurance responsibilities.

These resources will benefit foreign food producers, U.S. food importers, and the general public. For importers in particular, the fee will result in an improved import program resulting in greater efficiency and predictability for their businesses. The improvements to the import process will not only facilitate the entry of safe products but also improve public health by enabling FDA to focus its attention on higher risk products. The ultimate result will be improved confidence in the safety of food from abroad, thus encouraging future trade opportunities in food.

Importer Support
To improve the safety of imported food, FDA will establish new systems to prevent the import of unsafe foods earlier in the process rather than detaining a product at the border. Additional funds will support the establishment of a "Help Desk" that would assure importers of an available, responsive communications system to help address their concerns and answer their questions about the status of their shipments.

Port-of-Entry Streamlining
Food importers are increasingly complaining that FDA's current import screening process is hindering their ability to trade competitively. These funds will help develop and maintain improved risk analytics and IT systems that will allow FDA to target the highest risk imports, thus resulting in fewer detentions and less delay for lower-risk entries. This will include better integration with U.S. Customs and Border Protection (CBP) IT systems, as importers have urged, and continuous improvement of FDA's import screening system (PREDICT).

These systems will decrease reliance on paper notices and improve FDA's ability to exchange information electronically with industry during the import review process. These funds will also be used to expand the use of analytical tools deployed on-site for faster screening and better targeting of high-risk samples going to traditional laboratories for lengthy analysis. These tools will include technology such as hand-held scanners and small, portable on-site testing capability.

Resources will be invested in the implementation of a Quality Management System across all ports designed to improve uniformity and efficiency of the import decision process. The facilitation of continuous process improvements across all ports of entry will allow FDA to develop measures for quality service and manage import operations to those measures, resulting in greater uniformity and predictability across all FDA ports. A formal assessment will establish baseline measurements against which FDA and importers can evaluate improvements in import business operations as the user fee program is implemented.

Increased Border Staffing
Additionally, these funds will increase FDA border coverage and extend hours of operations at high-priority locations. The result will be fewer instances when FDA investigators are not available to process an entry and will make FDA's response timelier.

Proposed Food Facility Registration and Inspection Fee: +$51.6 million
Center: +$23.7 million / Field: +$27.9 million

Revenue from the proposed Food Facility and Registration Fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models and information technology to improve targeting and risk-based efficiency of inspection. This investment will complement the investment in inspection modernization and training that can be achieved with the budget authority request and ensue that modernization is fully achieved on a timely basis.

The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide. With this investment, FDA will be better able to make sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply.

The resources allocated to planning and response will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge. This funding will support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents and thereby improve future prevention efforts.

Proposed Cosmetics Safety User Fee: +$17.7 million
Center: +$13.0 million / Field: +$4.7 million

FDA will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. FDA will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist it in its safety evaluations and product modifications. The user fees will also enable FDA to meaningfully participate in international harmonization efforts for cosmetic standards. With this investment, FDA will refine inspection and sampling of imported products and apply risk-based approaches to post-market monitoring of domestic and imported products, inspection, and other enforcement activities. As a result, FDA will be better positioned to fulfill its public health

mission and will promote greater safety and understanding of cosmetic products consumers regularly use.

Proposed Food Contact Substances Notification User Fee: +$4.7 million
Center: +$4.7 million

With resources funded by user fees, FDA will expand and develop the Food Contact Notification Program (FCN) to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable FDA to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Proposed International Courier User Fee: +$0.8 million
Field: +$0.8 million

Millions of shipments of food commodities enter the United States through express courier facilities, and the number continues to grow. These shipments are often destined for individual consumers or for illegal distribution. The user fee resources for this activity will allow increased import surveillance of FDA-regulated products at express courier hubs.

Current FDA staffing does not match the expected growth in import volume. Federal Express and other couriers have indicated that they expect a growth of over 60 percent in shipments during the next year, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of these import operations through a new user fee.

With this new user fee, FDA will:

- conduct entry reviews
- sample collections and physical exams to determine product admissibility into the United States
- initiate compliance actions to prevent release of unsafe products into U.S. commerce
- establish import controls to prevent future unsafe products from entering U.S. commerce.

PERFORMANCE

The Foods Program's performance measures focus on premarket application review, incidence of foodborne pathogens, regulatory science activities, and postmarket inspection and import screening activities in order to ensure the safety and proper labeling of the American food supply and cosmetics, 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
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2015: 100% Target: 80% (Target Exceeded)	80%	80%	maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)*	FY 2015: 667 enrolled Target: 638 enrolled (Target Exceeded)	682	697	+15
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2014: 13.45 cases/100,000 CY 2014 Target: 11.4 cases/100,000 (Target Not Met)	10.6 cases/ 100,000	10.2 cases/ 100,000	-0.4
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2014: 0.92 cases/100,000 CY 2014 Target: 1.00 cases/100,000 (Target Exceeded)	0.89 cases/ 100,000	0.83 cases/ 100,000	-0.06
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2014: 15.45 cases/100,000 CY 2014 Target: 13.9 cases/100,000 (Target Not Met)	13.2 cases/ 100,000	12.8 cases/ 100,000	-0.4

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
212410: Reducing foodborne illness in the population. By December 31, 2017, working with federal, state, local, tribal, and industry partners, improve preventive controls in food production facilities and reduce the incidence rate (reported cases per 100,000 population per year) of *Listeria monocytogenes (Lm)* infections by 8%. (Outcome)	CY 2014: .24 cases/100,000 (Historical Actual)	NA	.22 cases/ 100,000	NA
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2015: 3 working days Target: 4 working days (Target Exceeded)	3 working days	3 working days	maintain
214201: Number of prior notice import security reviews. *(Output)*	FY 2015: 80,990 Target: 80,000 (Target Exceeded)	80,000	80,000	maintain
214202: Number of import food field exams. *(Output)*	FY 2015: 174,432 Target: 160,000 (Target Exceeded)	160,000	160,000	maintain
214203: Number of Filer Evaluations. (Output*)*	FY 2015: 1,212 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2015: 8,527 Target: 7,000 (Target Exceeded)	7,000	7,000	maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2015: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	maintain
214209: As required by the FSMA Legislation, cover 100% of the High Risk domestic inventory (approximately 19,500 firms) every three years. *(Output)*	FY 2015: 80% Target: 66% (Target Exceeded)	100%	33%	+33%

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2015: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	maintain

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

Food Additive and Color Additive Petition Review
The Foods Program conducts an extensive review as part of its Food Additive and Color Additive Petition review process, which includes a Chemistry, Toxicology and Environmental evaluation. The current measure requires FDA to complete review and action on the safety evaluation of direct and indirect food and color additive petitions within 360 days of receipt. FDA exceeded the FY 2015 target of 80% by reviewing and completing 100% of the petitions received within 360 days of receipt, a result consistent with the FY 2014 performance of 100% completed within the same timeframe.

Voluntary National Retail Food Regulatory Program Standards
Strong and effective regulatory programs at the state, local and tribal level are needed to prevent food borne illness and reduce the occurrence of food borne illness risk factors in retail and foodservice operations. The voluntary use of the Retail Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing food borne illness. The FY 2015 target for enrollment of State, local and tribal agencies in the Retail Program Standards was far exceeded. Awareness of the value of the using the Retail Program Standards to drive program improvement continues to grow, particularly among local health departments. In addition, more retail food regulatory programs are recognizing that FDA cooperative agreement funds are available to jurisdictions that enroll in the Retail Program Standards and commit to achieving key milestones. The FY 2016 and FY 2017 targets reflect increases in the number of enrollees by 15 above the previous year's actual number of enrollees or target.

Foodborne Illness
FDA's Priority Goal to reduce foodborne illness is a long-term outcome goal that reflects FDA's efforts, along with our partners in CDC and NIH, to decrease the rate of *Listeria monocytogenes (L.m.)*. *Listeria monocytogenes (L.m.)* infections are one of the leading causes of death from foodborne illness in the United States, resulting in an estimated 1,600 illnesses and 260 deaths each year. With enactment of the 2011 Food Safety Modernization Act (FSMA), Congress mandated a paradigm shift to prevention – to establishing a modern system of food safety protection based not on reacting to problems, but on preventing them from happening in the first place. Over the next two years, concentrated efforts to 1) improve preventative controls through inspections and technical guidance to industry, 2) improve surveillance and detection using

whole genome sequencing of *L.m.* isolates, and 3) improve response by more accurately linking illnesses and outbreaks to the food that caused the illness, should lead to a reduction in the overall *L.m.* rate.

Pathogen Detection

FDA microbiologists are evaluating and integrating commercially available instrumentation into its microbiological testing workflow that is vastly improving the ability of FDA to more quickly and effectively detect and characterize foodborne pathogens such as Salmonella directly from the food supply. Improvements in sample throughput, along with the high degree of sensitivity and specificity built into new pathogen detection technologies, will dramatically improve FDA's foodborne response and traceback capabilities. When fully deployed, technologies such as next-generation whole-genome sequencing (WGS) and others will reduce the time to conduct these analyses from 14 days originally to just a few days. One updated technology which provides highly accurate and rapid Salmonella serotype results for FDA, known as the flow cytometry/fluorescence platform, has been validated extensively and is now deployed in nearly all FDA field laboratories, as well as in CFSAN and CVM laboratories. In FY 2015, FDA exceeded the target of four working days, reducing the average number of days to serotype priority pathogens in foods to three working days, which is the minimum amount of time required. The proposed target for FY 2016 and FY 2017 is three working days, which will maintain the level achieved in FY 2015.

FSMA High Risk Domestic Inspection Coverage

FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world. ORA plays a critical role in the implementation of FSMA; and the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting 100 percent of the high-risk domestic inventory every three years. This goal serves to cumulatively track the progress over the three year period as the coverage of inventory approaches the FSMA requirement of 100 percent. FY 2015 marked year two of the three-year cycle, and ORA has made significant progress by inspecting 80% of the total cumulative high-risk domestic inventory. The FY 2016 target is set at 100% and closes the three year cycle. FY 2017 marks the beginning of the next three year cycle, and while the target returns to 33% to signify the first third of the inventory, the delta shows that it is still an increase of 33% because of the new three year cycle.

Laboratory Surge Capacity

A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially adulterated foods for the presence of contaminants. Improvements in surge capacity will have public health value even in non-deliberate food contamination by assisting FDA in identifying and removing contaminated food products from the marketplace as soon as possible in order to protect the public health and mitigate disruption in the U.S. food supply chain.

PROGRAM ACTIVITY DATA

Foods Program Activity Data

CFSAN Workload and Outputs	FY 2015 Actual	FY 2016 Estimate	FY 2017 Estimate
Food and Color Additive Petitions			
Petitions Filed [1]	10	7	7
Petitions Reviewed [2]	11	7	7
Premarket Notifications for Food Contact Substances			
Notifications Received	108	130	130
Notifications Reviewed [3]	108	128	128
Infant Formula Notifications			
Notifications Received [4]	37	40	40
Notifications Reviewed [5]	35	40	40
FDA Review Time	90 days	90 days	90 days
New Dietary Ingredient Notifications			
Notifications Received [6]	35	55	60
Notifications Reviewed [7]	35	55	60
FDA Review Time	75 days	75 days	75 days

[1] This number is for the cohort of petitions filed in the FY.

[2] Number reviewed includes petitions approved, withdrawn, or placed in abeyance due to deficiencies during the FY.

[3] Number reviewed includes notifications that became effective or were withdrawn.

[4] A notification may include more than 1 infant formula.

[5] Number of submissions reviewed includes some submissions that were received in the previous FY.

[6] Number of submissions received in current FY includes some received late in the FY that are expected to be completed in the next FY when the due date occurs.

[7] Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY when the due date occurred in the current FY.

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2015 Actuals	FY 2016 Estimate	FY 2017 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,334***	***8,500***	***8,500***
Domestic Food Safety Program Inspections	5,078	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	220		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	325		
Domestic Fish & Fishery Products (HACCP) Inspections	979		
Import (Seafood Program Including HACCP) Inspections	331		
Juice HACCP Inspection Program (HACCP)	195		
Interstate Travel Sanitation (ITS) Inspections	897		
Domestic Field Exams/Tests	2,154	3,945	3,945
Domestic Laboratory Samples Analyzed	13,157	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***1,357***	***1,200***	***1,200***
All Foreign Inspections	1,357	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***8,691***	***9,700***	***9,700***
IMPORTS			
Import Field Exams/Tests	245,804	160,200	160,200
Import Laboratory Samples Analyzed	21,128	35,300	35,300
Import Physical Exam Subtotal	**266,932**	**195,500**	**195,500**
Import Line Decisions	13,080,429	13,718,926	14,388,591
Percent of Import Lines Physically Examined	2.04%	1.43%	1.36%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	80,990	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,277***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***88***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,225	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	973	1,104	1,104
State Contract Juice HACCP	79	103	103
State Contract LACF	111	68	68
State Partnership Inspections	88	273	273
State Contract Foods Funding	$12,706,038	$13,087,219	$13,479,836
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$20,701,071	$21,322,103	$21,961,766
Total State & Annual FERN Funding	**$33,407,109**	**$34,409,322**	**$35,441,602**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,056***	***20,496***	***20,496***

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

Field Cosmetics Program Activity Data (PAD)

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

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