FOODS

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018	
				President's Budget	President's Budget +/- FY 2017 CR
Foods	**1,009,849**	**998,230**	**992,972**	**922,014**	**-70,958**
Budget Authority	***998,263***	***998,230***	***981,386***	***910,428***	***-70,958***
User Fees	***11,586***	---	***11,586***	***11,586***	---
Center	300,619	300,059	300,041	278,193	-21,848
Budget Authority	300,069	300,059	299,491	277,643	-21,848
User Fees	550	---	550	550	---
Food and Feed Recall	*243*	---	243	*243*	---
Voluntary Qualified Importer Program	*243*	---	243	*243*	---
Third Party Auditor Program	*64*	---	64	*64*	---
Field	709,230	698,171	692,931	643,821	-49,110
Budget Authority	698,194	698,171	681,895	632,785	-49,110
User Fees	11,036	---	11,036	11,036	---
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	*1,141*	---
FTE	**3,841**	**3,841**	**3,888**	**3,686**	**-202**

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 human health by ensuring the safety of the American food supply, dietary supplements, and cosmetics, as well as the proper labeling of food and cosmetics. The Foods Program began with the passage of the 1906 Pure Food and Drugs Act.

FDA's Foods Program is part of the Foods and Veterinary Medicine (FVM) Program. The FVM Program includes the Foods and the Animal Drugs and Feeds Programs and field activities in the Office of Regulatory Affairs (ORA). In collaboration with ORA, the Center for Food Safety and

Applied Nutrition (CFSAN) administers the Foods Programs and the Center for Veterinary Medicine (CVM) administers the Animal Drugs and Feeds Programs.[3]

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 ensures that the nation's food supply is wholesome and honestly labeled, and that nutrition labeling is informative and accurate. The Foods Program also promotes a nutritionally healthy food supply.

The Center for Veterinary Medicine protects human and animal health by approving safe and effective drugs for animals, and ensuring the safety of feed and devices for animals.

The Office of Foods and Veterinary Medicine (OFVM) provides leadership and strategic direction to Foods and Veterinary Medicine programs and oversees all CFSAN and CVM activities. OFVM also manages the crosscutting outbreak response and evaluation team, leads all external communications and stakeholder engagement, and coordinates FVM wide resource planning.

The following accomplishments demonstrate the Foods Program's delivery of its regulatory and public health responsibilities and progress towards reaching the FDA and FVM Strategic Plan goals. Most of the Foods Program activities fall under FDA's Strategic Plan goal of Enhanced Oversight. These activities include scientific analysis and support, policy, regulatory research, and guidance development.

Enhance Oversight of Food Safety and Nutrition

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 [4]
- Foodborne illnesses cost an average of $3,630 per case
- More than $36 billion per year in medical costs, lost productivity, and other burdens to society. [5]

The FVM Strategic Plan[6] provides a framework for implementing the Food Safety Modernization Act (FSMA) and other legislative authorities. The Plan prioritizes the prevention of foodborne and feed-borne illness of both known and unknown origins. The Foods Program addresses food safety risks at multiple points of the food supply chain. The program accomplishes this through regulations, guidance, technical assistance, training, outreach, consumer information, and model codes for food service establishments.

The FVM Strategic Plan also emphasizes nutrition-related priorities of the Foods Program. Poor diet is a key risk factor for chronic diseases – 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

[3] 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.
[4] 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.
5 Minor, T., Lasher, A., Klontz, K., Brown, B., Nardinelli, C. and Zorn, D. (2015), The Per Case and Total Annual Costs of Foodborne Illness in the United States. Risk Analysis, 35: 1125–1139. doi:10.1111/risa.12316
[6] https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM507379.pdf

problems. In 2010, 86 percent of all health care spending was for people with one or more chronic medical conditions.[7]

The Foods Program ensures that nutrition labeling is informative and accurate. The Program 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 other important activities related to food safety, nutrition, and cosmetics. These include:

- review of infant formula notifications from manufacturers before marketing a new formula
- premarket regulation of ingredients and packaging, such as 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.

The FDA Food Safety Modernization Act

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law, significantly reforming food safety laws. FSMA is transforming the nation's food safety system from reactive to proactive by allowing FDA to focus on preventing food safety problems before they occur rather than reacting to problems after the fact. FSMA guides the food safety system in implementing effective measures to prevent contamination. FSMA engages all domestic and foreign participants in the food system to do their part to minimize the likelihood of harmful contamination. For example, FSMA requires food importers to ensure that their suppliers meet U.S. safety standards.

FDA faces unique food safety challenges in the 21st century. The FDA Food Safety Modernization Act (FSMA) enables FDA to better protect the public health by:

- shifting the food safety paradigm from reactive to preventive
- strengthening FDA's technical expertise and capacity to support 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 gives FDA new enforcement authorities to achieve high rates of industry compliance with prevention- and risk-based food and feed safety standards and to better respond to and contain food safety problems when they occur.

FDA finalized seven foundational FSMA rules in 2015 and 2016, and is conducting extensive outreach to industry to ensure that stakeholders understand the new requirements. These seven

[7] 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.

foundational FSMA rules provide a framework for the food industry to implement effective measures to prevent contamination.[8]

Selected Rules Published in 2016

Below are FSMA-related rules published by the Foods Program in the last calendar year. These rules help address various issues. This list does not represent any degree of importance or priority ranking among the published rules.

Date	#	Title	Description
Jul 2016	FDA-2002-N-0323	FSMA Final Rule: Amendments to Registration of Food Facilities	Updates FDA's food facility registration requirements to better protect public health by requiring additional registration information to improve accuracy of the food facility registration database.
May 2016	FDA 2013-N-1425	FSMA Final Rule: Mitigation Strategies to Protect Food Against Intentional Adulteration	Prevents intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply.
Apr 2016	FDA-2013-N-0013	FSMA Final Rule: Sanitary Transportation of Human and Animal Food	Prevents practices during transportation that create food safety risks, such as failure to properly refrigerate food and inadequate cleaning of vehicles between loads.

In 2016, FDA issued the final two foundational rules: Sanitary Transportation of Human and Animal Food and Mitigation Strategies to Protect Food Against Intentional Adulteration.

Sanitary Transportation of Human and Animal Food (published in April 2016) advances FDA's efforts to protect foods from farm to table by keeping foods safe from contamination during transportation. This rule creates a modern risk-based framework for food safety by preventing practices during transportation that create food safety risks – such as failure to properly refrigerate and protect food, and inadequate cleaning of vehicles between loads.

The rule builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (SFTA). Because of illness outbreaks resulting from human and animal food contaminated during transportation, and incidents and reports of unsanitary transportation practices, there have long been concerns about the need for regulations to ensure that foods are transported safely. The rule establishes requirements for vehicles and transportation equipment, transportation operations, records, training and waivers.

Mitigation Strategies to Protect Food Against Intentional Adulteration (published in May 2016) directs domestic and foreign food facilities (required to register under the Federal Food, Drug, and Cosmetic Act) to address hazards that may be intentionally introduced by terrorist acts. These food facilities must develop strategies to minimize or prevent vulnerabilities identified at actionable process steps in a food operation.

[8] http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm

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

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.

Amendments to Registration of Food Facilities
Also published under FSMA authority in 2016, the Amendments to Registration of Food Facilities final rule updates FDA's food facility registration requirements to better protect public health. The final rule requires additional registration information to improve the accuracy of the food facility registration database for facilities both in the United States and abroad.

Food facilities that manufacture/process, pack or hold food for consumption in the United States are required to register with the FDA. This final rule adds new provisions to the current regulations that require the following:

- an email address for registration
- renewal of registration every two years
- assurance that inspection will be permitted in accordance with the Federal Food, Drug, and Cosmetic Act.

This final rule will support FDA's efforts to act quickly in response to food-related emergencies and will help the FDA to use its inspectional resources more efficiently.

Improved Outbreak Response
The Foods Program and the Coordinated Outbreak Response and Evaluation (CORE) team rapidly detect and respond to major foodborne illness outbreaks. This team coordinates activities across FDA field and compliance offices, state investigative and laboratory resources, and local city and county resources. The CORE team works cooperatively with other federal agencies such as CDC and USDA to ensure timely and effective resolution of foodborne illness outbreaks. Examples include:

- the E. coli outbreak associated with flour
- the Hepatitis A outbreaks associated with frozen strawberries from Egypt
- the *Listeria monocytogenes* outbreak associated with frozen vegetables.

To prepare for outbreak responses, FDA field offices support and provide technical assistance to laboratories awarded International Organization for Standardization (ISO) Cooperative Agreement Program (CAP) grants and to laboratories seeking or maintaining their accreditation.

This program continues to add national food/feed testing laboratories. By 2016, a total of 23 laboratories have joined the program and several are working towards ISO accreditation.

Improved Pathogen Detection and Traceability

In 2013, FDA established the first national pilot network of whole genome sequencers (WGS) – GenomeTrakr. Whole genome sequencing reveals the complete DNA make-up of an organism. This technology allows researchers to perform basic foodborne pathogen identification during foodborne illness outbreaks.

The Network is now in its fifth year and has collected more than 100,000 whole bacterial genome sequences from the FDA Network and collaborating sites. These genome sequences are stored in a publicly accessible database at The National Institutes of Health. FDA developed outbreak traceback methodology based on whole bacterial genomes that can determine the source of certain outbreaks down to the farm level.

Applying WGS helps the Foods Program to:

- investigate outbreaks faster and more efficiently
- add innovative technology protocols for testing and surveillance, enhancing confidence in regulatory actions
- identify emerging antimicrobial resistance threats in the food supply.

Implementing WGS reduces the time needed to conduct outbreak investigations and improves 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.

In 2016, FDA collected sequences as a regular part of foodborne outbreak investigations and compliance actions. So far, FDA has used WGS to support more than 300 outbreak investigations and compliance actions.

For example, from 2013 to 2016 FDA used GenomeTrakr to link *Listeria monocytogenes* to a common frozen vegetable source. During this three-year period *Listeria monocytogenes* sickened nine individuals, three of whom died. The low level and sporadic nature of the *Listeria* contamination associated with this product – which led to the recall of more than 11 different frozen vegetable ingredients in more than 350 different products – would have been difficult to identify without WGS.

The combination of real-time clinical and food/environmental surveillance using WGS has reduced the average number of illnesses in *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.

The FDA Foods Program applies WGS regularly to trace foodborne outbreaks for *Salmonella* and *Listeria monocytogenes*.[9] By generating about two whole genomes per hour, GenomeTrakr is rapidly increasing the number of *Salmonella* and *Listeria monocytogenes* genomes in the database. The network includes more than 40 state, international, FDA, and federal partner (CDC and USDA-FSIS) laboratories.

[9] *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. Rarely, persons without these risk factors can also be affected. The risk may be reduced by following recommendations for safe food preparation, consumption, and storage.

FDA's enhanced ability to pinpoint outbreaks is particularly important because of the global nature of the food supply. Guidelines and recommendations for global deployment of WGS to World Health Organization member countries are needed. FDA is participating in meetings with the World Health Organization and the Food and Agriculture Organization that could lead to such guidelines and recommendations.

Because of its extraordinary success in 2015, The American Society for Microbiology (ASM) asked FDA scientists to host a second "Conference on Rapid Next-Generation Sequencing and Bioinformatic Pipelines for Enhanced Molecular Epidemiological Investigation of Pathogens in 2016." FDA scientists will also participate in the ASM Microbe 2017 meeting. Information from such meetings holds promise for advancing FDA's ability to respond quickly and effectively to foodborne illness outbreaks and allows FDA to present information about the applications and public health impact of whole genome sequencing to members of the scientific community.

Developed Novel Technologies to Improve Food Safety

Addressing emerging safety concerns as food science technology advances remains a priority for the Foods Program. In FY 2016, FDA scientists used the results of a 3-year study of foodborne illness outbreaks associated with *Salmonella* Newport [10] contaminated vegetables grown on the Delaware/Maryland/Virginia (Delmarva) peninsula to develop guidance to growers. FDA produce microbiologists helped to lead the research direction and focus of the Delmarva Food Safety Taskforce, the committee of scientists and extension specialists from the Delmarva states and FDA.

In another study aimed at understanding foodborne illness, Foods program scientists applied a new genomic tool known as RNASEQ technology for the first time. This technology actually detects the factors involved in providing survival differences among pathogens living in identical environments. Pilot studies with the technology have begun to reveal the adaptive traits that let *Salmonella* Newport to persist within tomatoes and other produce. These adaptive traits provide potential targets for preventive controls against *Salmonella* known to invade produce production. Other Foods Program accomplishments include:

- Analyzed foods that list live microbes as an ingredient (such as probiotics) to conduct genomic characterization and identify bacteria that may be a safety concern
- Implemented rapid detection methods to improve detection of adulterated food products such as oil and honey
- Developed advanced methods for detecting allergens and gluten in foods, improving FDA's capabilities to inform and protect sensitive individuals from severe adverse effects.

Developed Seafood Product Labeling Online Learning Module

To ensure the proper labeling of seafood products sold 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.

[10] *Salmonella* is a bacteria that can cause diarrhea, fever, and abdominal cramps. For more information, see http://www.cdc.gov/salmonella/general/index.html.

The module explains federal identity labeling requirements for seafood and lists the laws, regulations, guidance documents, and other materials relevant to the proper labeling of seafood. The module helps stakeholders better understand FDA's role in ensuring the proper labeling of seafood. The module also provides tips for identifying mislabeled seafood in the wholesale distribution chain or at the point of retail.

Instead of protein profiles, FDA uses DNA barcoding to identify seafood. Barcoding provides a DNA sequence that allows analysts to identify different seafood products. These sequences are accessible online in a curated FDA library. This allows FDA field staff to better identify potentially toxic species of imported puffer fish currently restricted to a single species from Japan.

Encouraged the Safe Production of Dietary Supplements

In FY 2016, FDA initiated several regulatory actions to address ingredient safety for marketed dietary supplements. Additionally, FDA field investigators completed 678 domestic and 99 foreign inspections of firms to enforce dietary supplement regulations, including current Good Manufacturing Practices (cGMPs) and labeling requirements. These inspections and initiatives resulted in:

- 83 warning letters
- 6 untitled letters
- 49 detentions
- 3 injunctions.

FDA worked closely with the Department of Justice, the Federal Trade Commission, and the U.S. Postal Inspection Service to identify potentially unsafe or tainted products. This resulted in civil injunctions and criminal actions against 117 manufacturers and distributors of dietary supplements and tainted products.

Mandatory premarket safety notifications on new dietary ingredients (NDIs) in dietary supplements are vital to FDA's knowledge of marketed dietary ingredients. In FY 2016, FDA received 58 NDI notifications. FDA objected to 67 percent of the notifications because of inadequate safety, incomplete information, or other issues.

To address this high objection rate FDA issued revised draft guidance to industry in August 2016. This revised draft guidance explained when an NDI notification is necessary and what it should include. To clarify expectations of the NDI notification to stakeholders, FDA initiated regulatory actions aimed at ingredients that did not go through proper FDA review before being marketed.

In FY 2016, FDA received more than 4,600 voluntary and mandatory adverse event reports associated with dietary supplements. FDA reviewed these reports to identify products or ingredients with possible safety implications for the consumer. This review allowed FDA to target inspections and regulatory actions against unsafe products, such as pure powdered caffeine products.

In early FY 2016, FDA announced the creation of the Office of Dietary Supplements[11] (ODSP) within CFSAN. Elevating the program's position from a division to a new independent office raises the profile of the dietary supplements program within the agency. The creation of ODSP further enhances 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

To prepare for food-related emergencies and high-profile events, FDA directly oversees the Food Emergency Response Network (FERN) in addition to using FDA's field, Center, and FERN laboratories. FERN grants provide state-of-the-art equipment, analytical platforms, methodology, training, and proficiency testing. These resources support surge capacity, outbreak sampling, and large surveillance assignments. FERN grants also support the FERN training program that provides courses for both federal and state laboratory analysts. FDA 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.

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 do not 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 the removal of violative products from commerce. In FY 2016, FDA classified 330 Class I (most serious), 315 Class II, and 46 Class III human food recall events.

FDA issues import controls when non-compliant food products are discovered or when food companies manufacture or ship non-compliant products. In FY 2016, FDA issued 785 import alert notices.

FDA created Import Alert # 54-17 in response to high levels of mercury, arsenic and lead found in Ayurvedic supplements manufactured in India. This Import Alert imposed import controls for dietary supplements with levels of heavy metals high enough to make the product injurious to health. Particularly vulnerable populations susceptible to heavy metal poisoning include infants, small children, pregnant women, and people with underlying kidney disorders.

Additionally, CFSAN worked with the FDA field offices to assist in 767 cases where the district needed CFSAN's technical expertise to determine import admissibility.

FDA protects the public from impure, adulterated, and misbranded food and acts as an industry-wide deterrent for regulated entities and criminal enterprises through its authority to initiate criminal cases. In FY 2016, FDA issued six injunctions and one suspension related to adulterated or misbranded food.

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

Implemented New Procedures to Address Food Recalls

In 2016, FDA created a senior leadership team to direct FDA's actions to address challenging recall situations. The team, Strategic Coordinated Oversight of Recall Execution (SCORE), supports FDA's field staff and district offices by evaluating the range of FDA's compliance and enforcement authorities. SCORE quickly decides the best action to take to protect consumers.

For example, in September 2016 SCORE suspended a company's facility registration because a food product from the company was contaminated with *Listeria monocytogenes*. At the FDA's request, the company agreed to a recall and briefly stopped operations to improve its cleaning and sanitation procedures. In follow-up inspections FDA identified contaminated food using environmental sampling, and FDA suspended the firm's food facility registration.

Selected Guidances Issued in 2016

Below are non-FSMA guidances issued by the Foods Program in the last calendar year. These guidances help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances.[12]

Date	#	Title	Description
Jan 2017	FDA-2016-D-4414	Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals	Provides information related to compliance with FDA's final rule: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" and discusses labeling of added sugars
Nov 2016	FDA-2016-D-3401	Draft Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition	Explains current thinking on information needed when submitting a citizen petition and the scientific review approach we plan to use for evaluating scientific evidence
Sep 2016	FDA-2016-D-2241	Draft Guidance for Industry: Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling	Helps infant formula manufacturers and distributors comply with certain labeling requirements for infant formula products.
Sep 2016	FDA-2016-D-2335	Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products	Advises manufacturers who wish to use the implied nutrient content claim "healthy" to label their food products as provided by our regulations.

[12] For more information on guidance please visit http://www.fda.gov/Food/GuidanceRegulation/

Date	#	Title	Description
Aug 2016	FDA-2011-F-0171	Draft Guidance for Industry: Calorie Labeling of Articles of Food in Vending Machines	Provides vending machine operators and industry with better understanding of how to comply with the rule on Labeling of Articles of Food in Vending Machines.
June 2016	FDA-2014-D-0055	Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods	Helps Americans achieve the Dietary Guidelines-recommended sodium levels by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in foods.
Apr 2016	FDA-2011-F-0172	Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods - Part II	Helps restaurants and similar retail food establishments understand nutrition labeling requirements.
Mar 2016	FDA-2013-D-0715	Guidance for Industry: Acrylamide in Foods	Provides information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods.
Apr 2016	FDA-2016-D-1099	Draft Guidance for Industry: Inorganic Arsenic in Rice Cereals for Infants: Action Level	Protects public health by limiting 100 parts per billion of inorganic arsenic in infant rice cereals.

Published Infant Formula Rule and Guidances

Infant formulas are intended for a vulnerable population and may serve as a sole or primary source of nutrition during a critical period of growth and development. Caregivers of babies fed infant formula products must be able to trust that the information on the label is truthful, not misleading, and scientifically supported.

In September 2016, FDA issued guidance for industry to help infant formula manufacturers and distributors comply with certain labeling requirements for infant formula products. In this guidance, [13] FDA clarifies the following infant formula labeling requirements.

[13] Guidance for Industry: Labeling of Infant Formula, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517113.htm

Issued Draft Guidance on Structure and Function Claims Made in Infant Formula Labels and Labeling

In September 2016, FDA's Foods Program issued draft guidance for industry to help infant formula manufacturers who make structure and function claims comply with the requirement that all claims in infant formula labels and labeling be truthful and not misleading. "Structure and function" claims are statements made about the effects of a product or its constituent on the normal structure or function of the body. An example of a structure and function claim in infant formula labeling is a statement that the formula "supports digestion."

In the draft guidance,[14] FDA describes its recommendations for the type and quality of scientific evidence that is appropriate to support structure and function claims made about an infant formula by the product's manufacturers or distributors. The draft guidance provides recommendations for all infant formulas, including formulas marketed for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

Created Internet Resource for Sampling Programs for Food Safety

In FY 2015, FDA developed a new public website to share microbiological surveillance information to help predict and prevent bacterial contamination. In FY 2016, FDA sampled and tested cucumbers and hot peppers under this program and published the test results on the website.[15] This resource helps FDA shift to a prevention-based model by providing information needed to identify hazards. This resource also will help determine if contamination occurs due to factors such as season, region, or import status (domestic vs import).

Arsenic in Rice

In FY 2016, FDA continued to work with stakeholders to understand and address the risks associated with arsenic in food. Arsenic is a naturally occurring substance found in water, air, food, and soil in both an organic and the more toxic inorganic form. Arsenic can be found in many foods – including grains, fruits, and vegetables – due to absorption from the soil and water. Recently, FDA conducted more sophisticated sample analyses to quantify the presence of inorganic arsenic in foods. FDA's sampling and risk analyses focused on rice and rice products for the following reasons:

- Rice has higher average levels of inorganic arsenic than other foods measured by FDA
- Rice is an ingredient in a variety of foods and beverages, including foods for infants and young children.

In April 2016, FDA published proposed draft guidance to industry on the limit or "action level" recommended for inorganic arsenic in infant rice cereal. The proposed limit stems from the following FDA actions:

- extensive testing of rice and non-rice products
- scientific studies showing an association between adverse pregnancy outcomes and neurological effects in early life with inorganic arsenic exposure
- evaluation of the feasibility of reducing inorganic arsenic in infant rice cereal.

[14] Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm514640.htm
[15] Source: Microbiological Surveillance Sampling: FY16 Cucumbers and Hot Peppers, http://www.fda.gov/Food/ComplianceEnforcement/Sampling/ucm473115.htm

Launched Food Defense Plan Builder
In FY 2016, FDA published the final rule on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" as part of its implementation of FSMA. The rule requires food facilities to develop and implement food defense plans.

FDA plans to update the Food Defense Plan Builder – a user-friendly software program that helps owners and operators of food facilities develop 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, which include:

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

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

Improve and Safeguard Access

The Foods Program has statutory responsibility for the following premarket review activities that fall within the FDA goal of improving and safeguarding access:

- review and approval of all petitions for direct food additives
- review and approval of all new food contact substances, food contact materials, packaging, antimicrobials, and other indirect food additives
- review of Generally Recognized as Safe (GRAS) ingredients and products of biotechnology related 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. This petition process is unique to FDA's regulatory mission. In FY 2016, FDA ensured safe access to the food supply by reviewing 7 Food and Color Additive Petitions, 73 GRAS notifications, and 111 premarket notifications for Food Contact Substances.

Updated Risk Assessment Capabilities

FDA Centers, led by CFSAN, continue to update 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 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.

The Centers plan to jointly develop a process to ensure use of consistent methodologies for safety and risk assessments throughout 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. NLEA also requires food labels – that bear nutrient content claims and certain health messages – to comply with specific requirements.

The Foods Program 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.

Provide Outreach and Education on FDA Regulated Products

FDA strives to provide consumers with material about healthy choices using the most up-to-date science. CFSAN's social scientists use scientific methods to learn about and understand human behavior to help FDA fulfill its public health mission. In FY 2016, CFSAN conducted consumer studies using a variety of methods such as focus groups, surveys, and eye tracking studies. In one study FDA surveyed 4,169 Americans ages 18 and older to learn more about consumers' attitudes, behaviors, and knowledge of food safety. Survey results inform FDA's efforts to improve consumer food safety behaviors through targeted education outreach. Results are also used in the Healthy People 2020 initiative.[16]

In 2016, FDA released findings from its 2014 Health and Diet Survey. This survey helps FDA make informed regulatory, educational, and other decisions with a better understanding of consumer knowledge, attitudes, and practices about current and emerging nutrition and labeling issues.[17]

[16] Food Safety Survey Shows Consumer Knowledge Up, Still Room to Grow, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm529604.htm
[17] FDA Releases 2014 Health and Diet Survey Findings, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm499141.htm

Issued Final Guidance for Updates to the Nutrition Facts Label, Menu, and Vending Machine Labeling Requirements

In FY 2016, FDA finalized updates to the Nutrition Facts label that require declaration of the percent daily value for added sugars, and change the current footnote on the Nutrition Facts label to help consumers understand the percent daily value concept. FDA also finalized a 2014 proposal to update FDA's serving size requirements. These updates feature a fresh design to highlight key parts of the label such as calories and serving sizes. This information will help consumers to make healthy food choices. Most food manufacturers will be required to use the new label by July 2018.

In April 2016, FDA issued final guidance 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. Covered establishments must have the required additional written nutrition information available onsite upon consumer request. Throughout 2016, FDA hosted public workshops about menu labeling in three different geographic locations to help industry comply with these new requirements.

Issued Requests for Information and Draft Guidance on Fiber and Use of the term "Healthy" in Food Labeling

In November 2016, FDA's Foods Program issued a Request for Information (RFI) and Draft Guidance on Fiber on the Nutrition Facts Label. The request for information, along with the accompanying draft guidance, will help industry understand how FDA reviews the scientific evidence to determine whether other fibers beyond the seven identified in the rule should be added to the regulations. It also provides an opportunity for stakeholders to add to or comment on FDA's review of the science with respect to whether any of 26 additional types of fiber are beneficial to human health and therefore should be included in the fiber definition.

In September 2016, the Foods Program published a Request for Information (RFI) and Guidance for Industry on the Use of the term "Healthy" in the Labeling of Human Food Products. The guidance advises manufacturers who wish to use the implied nutrient content claim "healthy" to label their food products in accordance with FDA's regulations.

More specifically, this guidance is intended to advise food manufacturers of FDA's intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim "healthy" on their labels which:

- Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or
- Contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

Issued Draft Guidance for Industry Voluntary Sodium Reduction Goals

In June 2016, FDA issued voluntary guidance to help Americans meet the Dietary Guidelines' recommended sodium levels. This voluntary guidance encourages food manufacturers, restaurants, and food service operations to reduce sodium in foods and is intended to complement existing efforts by food manufacturers, restaurants, and food service operations to achieve these goals.

Approximately 75 percent of total sodium intake comes from processed and commercially prepared (e.g., restaurant) foods. FDA recognizes the important role of sodium in food for microbial safety, stability, and other functions. This guidance is not intended to undermine these functions. Instead the guidance is intended to provide measurable voluntary short-term (2 year) and long-term (10 year) goals for sodium content in commercially processed, packaged, and prepared foods to reduce excess population sodium intake.

FDA Developed Improved Method for Attributing Foodborne Illness (in Collaboration with Federal Partners)
FDA, working with the Centers for Disease Control and Prevention (CDC) and USDA's Food Safety Inspection Service, developed an improved method for analyzing outbreak data to determine which foods are 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 paper titled "Comparing Characteristics of Sporadic and Outbreak-Associated Foodborne Illnesses, United States, 2004-2011."

The results of this study provide evidence that *Campylobacter*, *Listeria monocytogenes*, and *E. coli* O157 outbreak illnesses are not significantly different from sporadic illnesses with respect to patients' illness severity, gender, and age. The study also provides evidence that *Salmonella* outbreak illnesses are not significantly different from sporadic illnesses with respect to illness severity and gender. Analyses, such as this study, help us better understand the relationship between sporadic foodborne illnesses and those that are identified as a part of an outbreak. Such analyses are essential to advancing scientific progress in this field.

Investigated Adverse Event Reports Related to the Use of Cosmetic Products
In an effort to protect consumers from potentially dangerous cosmetics products, FDA initiated an investigation on reports of hair loss, hair breakage, balding, itching, and rash associated with the use of WEN by Chaz Dean Cleansing Conditioner products. As of November 15, 2016, FDA received 1,386 adverse event reports directly from consumers with some reports occurring after general outreach to consumers and health care professionals. Of note, FDA was made aware, during inspections of manufacturing and distribution facilities, of more than 21,000 complaints reported directly to Chaz Dean, Inc. and Guthy Renker, LLC. This is the largest number of adverse event reports associated within the category of cosmetic hair cleansing products. The FDA also has reached out to physicians and other health care providers asking them to notify their patients of hair loss and other complaints associated with the use of these products and to report adverse events to the agency. FDA encourages consumers to stop using these products if they have a reaction, contact their health care provider, and report the incident to FDA.

Developed Additional Education Materials Related to Risks Associated with Tattoo Inks
State and local authorities oversee the practice of tattooing. However, ink and color additives (such as pigments) used in tattoos are subject to FDA oversight. The CFSAN Adverse Event Reporting System (CAERS) database continues to receive adverse event reports associated with tattoo inks. These reports include infections from tattoo inks contaminated with microorganisms, and allergic reactions to ingredients in the inks.

FDA developed educational materials to alert consumers to potential problems from tattooing and difficulties with tattoo removals. FDA is continuing research projects on the safety and quality of tattoo inks and pigments.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2014 Actual	$882,814,000	$882,814,000	$0
FY 2015 Actual	$903,340,000	$903,340,000	$0
FY 2016 Actuals	$998,230,000	$998,230,000	$0
FY 2017 Annualized CR	$992,972,089	$981,386,089	$11,586,000
FY 2018 President's Budget	$922,014,000	$910,428,000	$11,586,000

BUDGET REQUEST

The FY 2018 Budget Request for the Foods Program is $922,014,000, of which $910,428,000 is budget authority and $11,586,000 is user fees. Budget authority decreases by -$70,958,000 compared to the FY 2017 Annualized CR level and user fees remain flat. The Center for Food Safety and Applied Nutrition (CFSAN) amount in this request is $277,643,000. The Office of Regulatory Affairs amount is $632,785,000.

In FY 2018, the Foods Program will continue its most critical public health and safety activities. For CFSAN, these activities include: responding to outbreaks, working with industry to implement FSMA regulations, reviewing infant formula notifications, helping to ensure the safety of dietary supplements, conducting reviews of food ingredients and packaging, and ensuring that foods are safe and properly labeled. ORA will maintain food manufacturing inspections conducted through state contracts and will be able to keep reductions to the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) to a minimum.

BUDGET AUTHORITY

Reductions (-$70.9 million)

Center: -$21.8 million (Food Safety)
CFSAN will absorb funding reductions by reducing FTE through attrition and reducing operating expenses. FDA will balance reducing the federal footprint with providing specialized staff expertise to inform the Agency's response to the large volume of incoming work from a diverse array of stakeholders. FDA's goal is to minimize the impact of these reductions on FDA's core mission activities.

CFSAN will continue support for partnerships with academic institutions, state and local health organizations, and other groups that play a key role in outreach, research, and training needed to support FDA's food safety mission at reduced levels. CFSAN's support will be at reduced levels overall, which may include the elimination of support for some partnerships, such as the Centers of Excellence.

CFSAN will continue research, cosmetics safety, and international outreach activities at reduced levels.

Field: -$49.1 million (Food Safety)
The FY 2018 Budget continues partnerships, training, IT and lab equipment, and program office operations at reduced levels. Resources for operational activities including field exams, import entry review, investigations, sample analysis, and inspections for surveillance, compliance, and

follow up activities, both domestically and abroad are a priority. ORA will reduce existing workforce levels through attrition. FDA will prioritize maintaining operational activity levels with its existing staff at the proposed levels in the FY 2018 Budget.

Reduced investments in IT and lab equipment, and its related maintenance and operating expenses will require FDA to reprioritize and refocus ORA's resources for analyzing samples for surveillance and compliance purposes and for detection of emerging threats or potential outbreaks from contamination or adulteration. In the event of a food related outbreak, FDA would readjust its prioritization and reallocate resources from other less urgent operational activities in order to respond to emerging issues. Other areas of decreased investments include partnerships and training.

ORA will continue state cooperative agreements at reduced funding levels; those include agreements for:

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

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 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
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 2016: 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 2016: 711 enrolled Target: 682 enrolled (Target Exceeded)	697	712	+15
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2015: 12.97 cases/100,000 CY 2015 Target: 11.0 cases/100,000 (Target Not Met)	10.2 cases/100,000	9.7	**-0.5**
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2015: 0.95 cases/100,000 CY 2015 Target: 0.95 cases/100,000 (Target Met)	0.83 cases/100,000	0.76	**-0.07**
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2015: 15.89 cases/100,000 CY 2015 Target: 13.6 cases/100,000 (Target Not Met)	12.8 cases/100,000	12.4	**-0.4**
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 2015: .24 cases/100,000 (Historical Actual)	0.22 cases/100,000	0.22	**Maintain**

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2016: 3 working days Target: 3 working days (Target Met)	3 working days	3 working days	Maintain
214212: Percentage of planned import food field exams (approximately 160,000 in total). *(Output)*	FY 2016: 172,449 Target: 160,158 (Target Exceeded)	99%	99%	**Maintain**
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2016: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	**Maintain**
214209: As required by the FSMA Legislation, cover all of the High Risk domestic inventory (approximately 19,000 firms) every three years. *(Output)*	FY 2016: 99.8% Target: 100% (Target Not Met)	33%	66%	**Maintain**
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2016: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	**Maintain**

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 2016 target of 80 percent by reviewing and completing 100 percent of the petitions received within 360 days of receipt, a result consistent with the FY 2015 performance of 100 percent 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 2016 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 2017 and FY 2018 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.)*. *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 2016, FDA met the target of reducing the average number of days to serotype priority pathogens in foods to three days. The proposed targets for FY 2017 and FY 2018 are three days, maintaining the critically important downward progress in analytical return times achieved in FY 2016.

FSMA High Risk Domestic Inspection Coverage

FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world. ORA plays a critical role in the implementation of FSMA, and recognizes the importance of complying with high-risk domestic inspections mandated by FSMA legislation. FSMA legislation requires inspecting the entire high-risk domestic inventory every three years. This goal serves to cumulatively track the progress over the three-year period as the coverage of the high-risk domestic inventory approaches the FSMA-driven goal of 100 percent. FY 2016 marked the final year of a three-year cycle.

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

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

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

PROGRAM ACTIVITY DATA TABLES

Foods Program Activity Data

CFSAN Workload and Outputs	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
Food and Color Additive Petitions			
Petitions Filed [1]	7	7	7
Petitions Reviewed [2]	7	7	7
Premarket Notifications for Food Contact Substances			
Notifications Received	99	130	130
Notifications Reviewed [3]	111	128	128
Infant Formula Notifications			
Notifications Received [4]	23	22	22
Notifications Reviewed [5]	19	18	18
FDA Review Time	90 days	90 days	90 days
New Dietary Ingredient Notifications			
Notifications Received [6]	58	66	66
Notifications Reviewed [7]	56	66	66
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 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,933***	***8,000***	***8,000***
Domestic Food Safety Program Inspections	5,783	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.
Imported and Domestic Cheese Program Inspections	182		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	249		
Domestic Fish & Fishery Products (HACCP) Inspections	716		
Import (Seafood Program Including HACCP) Inspections	321		
Juice HACCP Inspection Program (HACCP)	161		
Interstate Travel Sanitation (ITS) Inspections	922		
Domestic Field Exams/Tests	2,398	2,500	2,500
Domestic Laboratory Samples Analyzed	16,927	13,000	13,000
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***1,269***	***1,400***	***1,400***
All Foreign Inspections	1,269	1,400	1,400
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***9,202***	***9,400***	***9,400***
IMPORTS			
Import Field Exams/Tests	252,766	168,200	168,200
Import Laboratory Samples Analyzed	23,736	35,300	35,300
Import Physical Exam Subtotal	**276,502**	**203,500**	**203,500**
Import Line Decisions	13,952,537	14,650,164	15,382,672
Percent of Import Lines Physically Examined	1.98%	1.39%	1.32%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	87,817	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***8,952***	***9,088***	***9,088***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***676***	***100***	***100***
State Contract Food Safety (Non HACCP) Inspections	7,897	8,000	8,000
State Contract Domestic Seafood HACCP Inspections	964	1,000	1,000
State Contract Juice HACCP	91	100	100
State Contract LACF	110	100	100
State Partnership Inspections	676	100	100
State Contract Foods Funding	$13,283,752	$13,682,265	$14,092,732
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$19,038,534	$17,705,837	$16,466,428
Total State & Annual FERN Funding	**$32,322,286**	**$31,388,101**	**$30,559,161**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***18,830***	***18,588***	***18,588***

Field Cosmetics Program Activity Data (PAD)

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

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

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