# FOODS

The FY 2010 program level budget request for the FDA Foods Program including user fees is $845,617,000. The following table shows a three-year funding history for the Foods Program.

**FDA Program Resources Table**

| | FY 2008 | | FY 2009 Omnibus | FY 2010 President's Budget Request | FY 2010 +/- FY 2009 Omnibus |
|---|---|---|---|---|---|
| | Enacted | Actuals | | | |
| **Program Level** | **$576,659,000** | **$507,797,000** | **$648,722,000** | **$845,617,000** | **$196,895,000** |
| Center | $188,167,000 | $167,189,000 | $210,486,000 | $244,981,000 | $34,495,000 |
| FTE | 812 | 753 | 854 | 947 | 93 |
| Field | $388,492,000 | $340,608,000 | $438,236,000 | $600,636,000 | $162,400,000 |
| FTE | 1,980 | 1,861 | 2,165 | 2,569 | 404 |
| **Program Level FTE** | **2,792** | **2,614** | **3,019** | **3,516** | **497** |
| **Budget Authority** | **$576,659,000** | **$507,797,000** | **$648,722,000** | **$782,915,000** | **$134,193,000** |
| Center | $188,167,000 | $167,189,000 | $210,486,000 | $236,418,000 | $25,932,000 |
| Field | $388,492,000 | $340,608,000 | $438,236,000 | $546,497,000 | $108,261,000 |
| *Pay Increase (non add)* | | | | *$10,514,000* | *$10,514,000* |
| *Protect America's Food Supply (non-add)* | | | | *$123,679,000* | *$123,679,000* |
| **Budget Authority FTE** | **2,792** | **2,614** | **3,019** | **3,288** | **269** |
| Center | 812 | 753 | 854 | 921 | 67 |
| Field | 1,980 | 1,861 | 2,165 | 2,367 | 202 |
| **Proposed User Fees** | **$0** | **$0** | **$0** | **$62,702,000** | **$62,702,000** |
| Reinspection | | | | **$6,124,000** | **$6,124,000** |
| Field | | | | $6,124,000 | $6,124,000 |
| FTE | | | | 48 | 48 |
| Export Certification | | | | **$4,078,000** | **$4,078,000** |
| Center | | | | $1,063,000 | $1,063,000 |
| FTE | | | | 7 | 7 |
| Field | | | | $3,015,000 | $3,015,000 |
| FTE | | | | 19 | 19 |
| Inspection and Facility Registration | | | | **$52,500,000** | **$52,500,000** |
| Center | | | | $7,500,000 | $7,500,000 |
| FTE | | | | 19 | 19 |
| Field | | | | $45,000,000 | $45,000,000 |
| FTE | | | | 135 | 135 |
| **User Fee FTE** | **0** | **0** | **0** | **228** | **228** |

**The FDA Foods Program operates under the following legal authorities:**

The Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
The 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*
Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C.379aa-1)
Food and Drug Administration Amendment Act of 2007*

**Allocation Method:** Direct Federal/intramural; Contract

# Program Description and Accomplishments

The Center for Food Safety and Applied Nutrition (CFSAN) administers the FDA Foods Program with the assistance of the Office of Regulatory Affairs (ORA) field offices nationwide. CFSAN, in conjunction with the FDA field force, is responsible for protecting and promoting the public health by ensuring that the food supply of the nation is safe, sanitary, wholesome, and properly labeled and that cosmetic products are safe and properly labeled. The FDA Foods Program is responsible for all domestic and imported food, with the exception of meat; poultry; and frozen, dried and liquid eggs.

The FDA Foods Program regulates $417 billion worth of domestic food, $49 billion worth of imported foods, and $62 billion worth of cosmetics. This regulation takes place from either the products' point of U.S. entry or processing to their point of sale, with approximately 136,000 registered domestic food establishments, and approximately 189,000 registered foreign facilities, and more than 3,500 cosmetic firms.

The Office of Regulatory Affairs (ORA) provides FDA leadership on enforcement, import, inspection, and regulatory laboratory policies. Through ORA field offices nationwide, ORA supports the Foods Program by conducting risk-based domestic and foreign inspections of food establishments to assess industry compliance with current Good Manufacturing Practices (cGMP) and Hazard Analysis and Critical Control Point (HACCP) requirements for FDA-regulated foods. In addition to overseeing the regulated products on a surveillance or “for cause” basis, ORA responds to emergencies and investigates incidents of product tampering and natural or intentional disasters that may affect FDA-regulated goods. In instances of criminal activity, the ORA Office of Criminal Investigations (OCI) complements the regular field force. The ORA Field Foods Program is funded by appropriated dollars that allow ORA to perform inspections and fund inspections through State contracts.

The Office of Information Management (OIM) provides FDA’s leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the

platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Food Safety and Nutrition Program by maintaining its legacy systems and databases used for managing and tracking its programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Food Safety and Nutrition Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

The FDA Foods Program executes its regulatory responsibilities in four areas: Ensuring Food Protection, Improving Nutrition, Improving Dietary Supplement Safety and Improving Cosmetic Safety.

Ensuring Food Protection – CFSAN Activities

The FDA Food Protection Program, encompassing both food safety and food defense, is a comprehensive and integrated strategic approach that involves multiple parts of the FDA. The overarching program goal is to keep the food supply of the nation safe from both unintentional and deliberate contamination. The program builds in safety measures focusing FDA efforts on preventing problems first, using risk-based interventions to ensure preventive approaches are effective, and instituting a rapid response as soon as contaminated food, feed, or harm is detected. Driven by science and modern information technology, the FDA Food Protection Program aims to identify potential hazards and counter those before they can do harm.

In FY 2009 CFSAN scientists have optically mapped chromosomes of *Salmonella* strains from 2008 outbreaks of *S*. Saintpaul (linked to peppers) and Typhimurium (linked to peanut butter paste). Visualization of the genomes showed that foodborne and clinical isolates from each outbreak were identical, verifying Pulse-field Gel Electrophoresis (PulseNet) analysis that established the source strain for each outbreak. During the course of the year CFSAN scientists have used a high-density DNA microarray containing whole genomes of 38 common outbreak strains of *Salmonella* to analyze foodborne and clinical isolates from 2008 outbreaks. The array enabled quick identification of unique gene and plasmid content in the strains and sites containing single nucleotide polymorphisms (SNPs). CFSAN scientists also have developed a method for the isolation of *Yersinia pestis* using a novel enrichment broth and the Pathatrix immunomagnetic capture system which was successfully evaluated by 19 Food Emergency Response Network (FERN) laboratories. This Pathatrix method is faster and more accurate than existing methods. Before the method is moved out of the research environment where it was developed, CFSAN must make sure different laboratories will get the same results no matter where they are located or what microbiologist is using the method. Since 19 different laboratories were able to use the method successfully, it means that the method works (validated) and is ready for use by the FERN laboratories. This is a proactive effort to making sure CFSAN is ready with a good detection method should an emergency such as an outbreak or a bioterrorism event occur involving this bacterial pathogen, *Yersinia pestis* (the organism that causes plague or black death). The validation process is an important process in methods development and implementation.

Additionally, CFSAN published a final rule that allows the use of irradiation to make fresh iceberg lettuce and fresh spinach safer and last longer without spoiling. Irradiating fresh iceberg lettuce and spinach will help protect consumers from disease-causing bacteria such as *Salmonella* and *Escherichia coli* O157:H7, which continue to be public health problems in the United States. CFSAN issued a final rule to require the declaration of the color additives cochineal extract and carmine on all food and cosmetic products. FDA took this action to protect the small number of consumers who are allergic to these color additives.

CFSAN completed the Tomato Safety Initiative assessment activities covering the Eastern Shore of Virginia and 3 regions of Florida (field related). In addition, FDA published the Employee Health & Personal Hygiene Handbook, referencing the FDA Food Code, designed to prevent food workers from transmitting pathogens including viruses to food.

CFSAN FDA also published a white paper on allergen cleaning validation (J. Food Prot (2008) 71: 445 - 458) The objectives of this review were (i) to study the incidence and cause of allergen cross-contact, (ii) to assess the science upon which the cleaning of food contact surfaces is based, and (iii) to identify best practices for cleaning allergenic foods from food contact surfaces.

Food Protection Program – ORA Activities

In support of the FDA Food Protection Program, ORA focused on implementing a risk-based surveillance and inspection strategy. Through risk-based domestic and foreign inspections of food establishments, ORA assesses industry compliance with GMP and HACCP requirements. In addition, ORA responds to public health emergencies and investigates incidences of intentional and naturally occurring product contamination.

Field personnel also play a lead role in response to foodborne illness outbreaks by conducting tracebacks of implicated foods. Information gathered in traceback investigations is used to identify ways to make produce safer and prevent future outbreaks. During April through July 2008, more than 1,300 people fell ill from what was first believed to be a multi-State *Salmonella St. Paul* tainted raw tomatoes outbreak. The outbreak continued after FDA issued the tomato alert in May and tested large numbers of tomato samples. Thereafter, CDC conducted a second case study and determined the need to expand the alert to other types of produce, including serrano and jalapeno peppers. FDA and FERN labs were utilized to test these additional foods and found contaminated jalapeno peppers originating from Mexico that matched the outbreak strain of Salmonella.

To complement the analytical work of FDA labs, ORA developed and supports FERN, a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. During the *Salmonella St. Paul* outbreak, FERN labs provided increased laboratory capacity and capability to allow FDA to create an additional assignment for the outbreak response that targeted retailers and distributors of the products in question. During the course of the approximately four week assignment, over 140 samples were tested by FERN labs of which 11 samples were found positive for Salmonella. While none of the contaminated samples matched the outbreak strain, States did take actions on the results, including recalls of the product.

The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination. With FY 2008 Food Protection increases, FERN added three additional chemical labs in FY 2008 which will increase the surge capacity in FY09 to 1,650 chemical samples per week. ORA will continue to maintain the FERN lab networks in FY 2010.

In addition to domestic food work, ORA conducted 100,718 import food field exams in FY 2008 to monitor the safety of imported products being offered for entry in the United States. The number of import food field exams conducted exceeded FDA's goal by 18 percent. For example, in August 2008, two individuals and two corporations pled guilty in New York to charges of trafficking in counterfeit Colgate toothpaste. These defendants imported over 518,000 tubes of counterfeit Colgate toothpaste from China that failed to contain fluoride and, in some cases, contained microorganisms, such as bacillus spores, and diethylene glycol (DEG), used as a coolant for hydraulics and brake fluids.

However, ORA cannot rely solely on physical examinations of imports to reduce the potential risk. To complement the import inspection program, ORA has made substantial progress in the development of PREDICT, a new electronic system for better risk-based screening of imports. PREDICT uses automated data mining, pattern analysis, exogenous information, expert rules, and detection of data anomalies in determining which shipments need human review. In January 2008, ORA completed evaluation of a three-month pilot test of the prototype system and determined it successful based on several criteria: user acceptance, violation rates; and integration of systems. Further development continues to incorporate additional criteria and to expand the system to encompass all FDA-regulated products. Better electronic, risk-based screening is essential to FDA's efforts to focus inspectional resources on high-priority shipments.

Improving Nutrition – CFSAN Activities

The principal mission of the FDA Nutrition Program is to promote healthful dietary practices by ensuring that packaged and other foods are truthfully and properly labeled. This allows consumers to use this information to make informed choices to improve their health and help them reduce the risk of chronic disease. FDA conducts research, issues guidance and rules, and develops education and outreach programs on improving the accuracy, truthfulness, and usefulness of the food label and nutrition information. CFSAN launched a major consumer research initiative several years ago in response to the Office of Management and Budget Program Assessment Rating Tool (PART) evaluation of the mission of the FDA. FDA agreed to create a long-term outcome goal (PART goal) to increase the consumer understanding of diet-disease relationships, especially between dietary fats and coronary heart disease. The PART goal proposed baseline performance indicators of consumer understanding of three dietary fats (*trans*, saturated, and omega-3 fats). CFSAN developed the baseline indicators in 2005 from a nationally representative telephone survey. The protocol for implementing the survey is under review.

FDA recently initiated two education and outreach efforts. First, with the Cartoon Network, FDA released a public service campaign for tweens to "Spot the Block" that is aimed at building

awareness of the nutrition label and label reading skills. Second, FDA released a web-based program to inform consumers about using the nutrition labels for "Healthy Weight Management." In addition, CFSAN expanded an existing project with the National Science Teachers Association (NSTA) to include nutrition education for middle and high school teachers to help teach students to make healthful food choices using the Nutrition Facts Panel.

In early 2008, FDA prepared a report on folic acid fortification in response to a Congressional Committee report that suggested that the FDA should increase current levels of folic acid fortification in enriched cereal-grain products. In the report, FDA scientists reviewed the current literature and the present fortification standards, and identified a number of issues that FDA would need to consider in revising the current standards.

FDA held a public hearing to address the use of "may contain" labeling for allergens in food products. In 2009, FDA published guidance on the evidence-based system used to evaluate research studies in support of health claims, including qualified health claims. It represents the agency's current thinking on 1) the process for evaluating the scientific evidence for a health claim, 2) the meaning of significant scientific agreement (SSA) and 3) credible scientific evidence to support a qualified health claim. In addition, the FDA published a Federal Register Notice in December 2007 regarding the re-evaluation of scientific evidence for two authorized health claims and two qualified health claims using the evidence-based system. Since then, FDA re-evaluated and amended the regulation authorizing a health claim on the relationship between calcium and a reduced risk of osteoporosis to include vitamin D so that in addition to a claim for calcium and osteoporosis an additional claim may be made for vitamin D and osteoporosis. The amended regulation also eliminated the requirement that the claim list sex, age, and race as specific risk factors for the development of osteoporosis as well as other requirements referring to mechanisms of the reduction and amounts of calcium. FDA also revaluated and adopted as a final rule without change two other health claims, soluble fiber from certain foods and the risk of coronary heart disease; and dietary noncariogenic carbohydrate sweeteners and dental caries.

Improving Nutrition - ORA Activities

ORA determines the compliance of domestic and imported foods with labeling regulations promulgated under the Federal Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act, and the Fair Packaging and Labeling Act. In addition to ensuring that required information is displayed on product labels, ORA verifies the accuracy of health claims made on labels through product sampling and analysis.

An important component of ORA's Food Labeling Program is the regulation of domestic and imported food related products. In February 2008, FDA permanently enjoined two firms that were manufacturing and distributing foods as drugs. A manufacturer and a distributor of various juice concentrates, soft fruit gel capsules, fruit bars, dried fruits, liquid glucosamine, and salmon oil capsules, and two of their top executives, signed a consent decree permanently enjoining the firms from manufacturing and distributing any products with drug claims in labeling and from distributing foods with unauthorized health claims. The companies had a history of promoting unapproved claims on their product labels, brochures, and web sites, stating that the products cure, treat, mitigate, or prevent various diseases.

Improving Dietary Supplement Safety – CFSAN Activities

The mission of the FDA Dietary Supplement Program is to ensure that these products are safe and properly labeled and that any disease or health-related claims are scientifically supported. FDA regulation of dietary supplements falls under the authority of the Federal Food, Drug, and Cosmetic Act in general and the Dietary Supplement Health and Education Act of 1994 (DSHEA) in particular.

Recent surveys indicate that 60-70 percent of the U.S. population use dietary supplements. Many supplements are imported and potentially manufactured without using current good manufacturing practice (cGMP) requirements. In FY 2007, FDA published a final rule establishing cGMP requirements for dietary supplements. The regulation requires that proper controls be in place so dietary supplements are processed in a consistent manner and meet quality standards, including standards for identity, purity, strength, and composition. Beginning in June 2008, FDA began to conduct cGMP inspections, based on the final rule, of both domestic and foreign dietary supplement manufacturing facilities that have more than 500 employees. Dietary supplement cGMP inspections will begin for medium size companies (20-500 employees) in June 2009 and for small companies (fewer than 20 employees) in June 2010.

FDA scientists recently completed a survey to determine the extent of lead (Pb) contamination in vitamins labeled for use by women and children. The results showed that estimates of Pb exposure were below the provisional total tolerable intake levels for young children, older children, pregnant and lactating women, and adult women. In addition, multi-residue methods have been developed for determining 150 pesticides in dietary supplements such as ginseng.

FDA also continues the operation and further development of its voluntary adverse events reporting database called CAERS (CFSAN Adverse Events Reporting System). CAERS collects adverse event reports and complaints from consumers, manufacturers, and healthcare providers, enabling staff to conduct reviews of reports for potential safety issues. Since becoming operational in June 2003, CAERS has received an average of 4,769 reports of adverse events and/or consumer complaints a year. In 2008, a breakdown of adverse event and/or product complaint reports shows as examples: 190 cosmetic, 201 seafood, 1,190 dietary supplement, 111 infant formula or baby food, and 312 bakery product reports

In FY 2008, CAERS began to receive mandatory adverse event reports from dietary supplement manufacturers based on the newly mandated reporting requirements of the Dietary Supplement and Nonprescription Drug and Consumer Protection Act of 2006. FDA published guidance on reporting serious adverse events associated with dietary supplements and instructions on how to fill out a MedWatch Form 3500A. The FDA Post-market Safety Review Program is monitoring this data for signals of potential adverse reactions to dietary supplements and ingredients.

Improving Dietary Supplements – ORA Activities

ORA plays a vital role in ensuring the safety of dietary supplements by collecting and analyzing products to check label accuracy in order to ensure the safety of supplements before they enter

into the U.S. market. ORA also oversees all recalls of contaminated or fraudulent products to remove potentially dangerous products from the U.S. marketplace.
In February 2008, following an OCI investigation, five business owners and their companies were indicted in the Western District of Missouri on charges related to the fraudulent marketing of dietary supplements. The defendants conspired to promote multiple dietary supplements through internet web sites and made illegal drug claims their products could treat, cure, mitigate and prevent disease. These companies continued to illegally market their products despite FDA warning letters and an FDA inspection.

Improving Cosmetics Safety – CFSAN Activities

The mission of the FDA Cosmetics Program is to protect the public health by ensuring the safety of cosmetics. Cosmetics marketed in the United States, whether manufactured here or imported, must comply with the FD&C Act, the Fair Packaging and Labeling (FP&L) Act, and regulations promulgated by FDA under these laws.

The domestic cosmetic industry has annual U.S. sales in the tens of billions, with thousands of facilities in the U.S. alone. Cosmetic products and ingredients also enter the U.S. from a broad range of countries, most of which have different regulatory systems and standards. From 2000-2007, the number of entries of imported cosmetics products almost tripled. In 2008, cosmetics accounted for a little over 9 percent of all imports under FDA jurisdiction, third-highest among FDA-regulated product areas. The past 5-10 years also have seen an explosion in the numbers and types of cosmetic products sold annually. These changes in the industry present both scientific and regulatory challenges that have been increasingly difficult for FDA to meet with existing resources.

As an example, cosmetics represent one of the fastest growing areas for application of nanotechnology. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties, which may pose different safety issues. As part of FDA efforts to develop guidance for industry on this issue and to protect public health, in FY 2008 FDA held a public meeting to discuss the scientific and regulatory issues concerning the use of nanoscale materials in regulated products, including cosmetics. FDA is also conducting collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and their potential health hazards when used in cosmetics. FDA is currently drafting guidance for industry and other stakeholders on the use of nanoscale materials in cosmetics.

FDA implemented a Voluntary Cosmetic Registration Program (VCRP) as a means of maintaining information about cosmetic products currently in the marketplace. FDA uses information from the VCRP, along with other data, to develop guidance and regulations for industry and to identify additional science needed to assess the safety of cosmetic ingredients. In FY 2007, FDA made significant enhancements to its current web-based system; and the number of cosmetic products accepted for filing in the system increased almost 30 percent over FY 2006 level. In FY 2009, FDA eliminated the backlog of old paper-based registrations and completed a purge of old and obsolete paper-based registrations. The current annual level of product

registration is now more than 15 times higher than with the prior paper-based system. FDA continues to provide industry training on the VCRP.

In 2007, the FDA Cosmetics Program re-established an international effort to cooperate on cosmetics regulation, referred to as ICCR. This effort includes regulatory authorities from FDA, Health Canada, the European Commission, and the Ministry of Health, Education, Labor and Welfare of Japan, as well as a joint regulator-industry caucus on one day of the meeting. The first meeting of the group was held on September 25-28, 2007, in Brussels and the second meeting on July 30-August 4, 2008 in Rockville, MD. Issues addressed were: alternatives to animal testing, cosmetic good manufacturing practices (GMPs), nanotechnology, nomenclature, and sharing of information among the regulators. One of the outcomes has been a consensus decision to make use of International Standards Organization (ISO) standards for GMPs. Discussion on alternatives to animal testing will be prominent in 2009, as the first phase of the European Union ban on animal testing of cosmetic ingredients has already taken effect as of March 2009, with additional actions scheduled in 2010 and 2011. New discussions on International Nomenclature of Cosmetic Ingredients (INCI) nomenclature have also been initiated.

The safety of cosmetics is a public health priority and FDA must therefore have the resources to maintain the capacity to issue necessary regulations and guidance. FDA also must maintain robust systems for collecting adverse event reports and voluntary cosmetic product registrations and the resources for product surveys and laboratory investigations. Information from these sources is essential for the FDA risk-based approach to post-market monitoring, inspection, and other enforcement activities. The net result will be improved public health protection through increased availability of safe cosmetic products and removal of unsafe cosmetic products from the marketplace.

Improving Cosmetics Safety – ORA Activities

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching the marketplace.

On November 16, 2007, FDA seized approximately $2 million of Age Intervention Eyelash, a "cosmetic" product sold and distributed by Jan Marini Skin Research, Inc., of San Jose, California. FDA considered Age Intervention Eyelash, promoting increased eyelash growth, a dangerous cosmetic that included a drug ingredient, bimatoprost (which treats elevated eye pressure) that the company made unapproved drug claims and that the use of the product was potentially harmful. On June 19, 2008, a motion for default judgment was granted, directing the U.S. Marshal’s Service to destroy the goods.

### Five Year Funding Table with FTE Totals

The following table shows a five-year funding history for the Food Program's program level, budget authority, and user fee resources.

| Fiscal Year | Program Level | Budget Authority | User Fees | Program Level FTE |
|---|---|---|---|---|
| FY 2006 Actual | $438,721,000 | $438,721,000 | $0 | 2,774 |
| FY 2007 Actual | $457,104,000 | $457,104,000 | $0 | 2,569 |
| FY 2008 Actual | $507,797,000 | $507,797,000 | $0 | 2,614 |
| FY 2009 Omnibus | $648,722,000 | $648,722,000 | $0 | 3,019 |
| FY 2010 Estimate | $845,617,000 | $782,915,000 | $62,702,000 | 3,516 |

# Budget Request

The FY 2010 President's Budget requests $845,617,000 in program level funding for the Foods Program, including user fees, in the support of 3,516 FTEs. The CFSAN portion of the request is $244,981,000 and 947 FTEs, an increase above the FY 2009 Omnibus of $34,495,000 and an increase of 93 FTEs to maintain current service levels. The Field portion of the request is $600,636,000 supporting 2,569 FTEs, an increase above the FY 2009 Omnibus of $162,400,000 and 404 FTEs.

In FY 2010, CFSAN will continue to take the lead in maintaining and improving an already sound food safety protection capability by accomplishing the goals and objectives established in the FDA Food Protection Plan and the Import Safety Action Plan as well as continuing cooperation and information sharing between the U.S. and China.

FDA envisions establishing a new strategic framework for an integrated national food safety system. In order to efficiently and effectively establish a fully integrated national food and feed safety system, FDA must build and expand existing programs and relationships with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners. FDA is requesting funding in FY 2010 to begin establishing the necessary infrastructure for the Field Food and Field Feeds Programs in the following four areas:

- Develop a National Workplan that includes the inspections of food manufacturing and distribution facilities and the collection and analyses of compliance, surveillance, and environmental samples;
- Ensure that programmatic objectives and implementation are coordinated;
- Continue to develop uniform, national standards for such subjects as manufacturing, inspections, and enforcement;
- Build training courses and a certification program to be delivered to state, local, and tribal regulatory partners;

- Increase programmatic oversight and develop a more robust audit program.

A system of this magnitude may require new authorizations such as multi-year budget authority for Federal, State, local, tribal and territorial regulatory partners and the authority to share non-public information with our regulatory partners when it is necessary to protect public health. However, this request is necessary to begin building the framework for an integrated national food safety system.

Furthermore, ORA is requesting funding in FY 2010 to continue building its workforce for more field food and feed work and support for the field food and feed work. In order to do so, ORA is requesting funding to continue hiring investigators, analysts, and support staff in order to continue to increase field and food work such as:

- Increase of 20,000 food and feed import exams by the end of 2011
- Increase of 2,000 domestic food and feed inspections by the end of 2012
- Increase of 50 foreign food and feed inspections by the end of 2012.

Cost of Living Pay Increase

The CFSAN portion of FDA's requested pay increase is $2,986,000 . Without these funds CFSAN would need to reduce FTE in order to adequately cover payroll, which will lead to a decrease in FDA's ability to protect the public health.

Information Technology

The Office of Information Management (OIM) provides FDA's leadership in transforming and improving the systems and infrastructure needed to support critical agency operations. OIM works to align information technology (IT) investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century. With the centralization of IT projects and resources in 2008, OIM supports the Food Safety and Nutrition Program by maintaining its legacy systems and databases used for managing and tracking its programs, for monitoring and tracking adverse event activities, and for conducting various compliance activities. OIM also work with the Food Safety and Nutrition Program through the FDA Bioinformatics Board to ensure that current and future IT enterprise and center investments continue to fulfill program requirements while meeting broader FDA objectives.

User Fees Authority and Increases

Reinspection and Food Export Certification User Fee

This proposal for $25,848,000 and 129 FTEs in Reinspection User Fees supports reinspection costs incurred when FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. ORA's Food request is for $6,124,000 and 48 FTE . This new user fee will amend the Food, Drug, and

Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations.

The FY 2010 budget also proposes a new user fee to support export certification activities. FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collection user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through FDA's enhanced ability to facilitate exports of their products. The total proposed collections for the FDA in FY 2010 are $4,152,000 with $1,063,000 of the collections being allocated to CFSAN.

Food Inspection and Facility Registration User Fee

The FY 2010 budget proposes a User Fee for Food Inspection and Facility Registration for $75,000,000. This proposal allocates $7,500,000 to CFSAN, and $45,000,000 to the Field Foods Program. Food facilities would be charged user fees for inspections and registration of their establishments. These user fees would fund FDA inspections at the facilities.

## Foods Performance Measures Table

**Long Term Objective:** Increase access to safe and nutritious new food products.

| Measure | FY | Target | Result |
|---|---|---|---|
| 213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. *(Output)* | *2010* | 70% | Oct 31, 2011 |
| | *2009* | 60% | Oct 31, 2010 |
| | *2008* | 60% | Oct 31, 2009 |
| | *2007* | 50% | 100% (Target Exceeded) |
| | *2006* | 70% | 87% (Target Exceeded) |
| | *2005* | 75% | 100% (Target Exceeded) |

**Long Term Objective:** Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.

| Measure | FY | Target | Result |
|---|---|---|---|
| 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)* | *2010* | 347 enrolled | Dec 31, 2010 |
| | *2009* | 332 enrolled | Dec 31, 2009 |
| | *2008* | 317 enrolled | 320 enrolled (Target Not Met) |
| | *2007* | 240 enrolled | 302 enrolled (Target Not Met) |
| | *2006* | N/A | 259 enrolled (Target Not In Place) |
| | *2005* | N/A | 185 enrolled (Target Not In Place) |
| 214102: Percentage of the enrolled jurisdictions which meet 2 or more of the Standards *(Outcome)* | *2010* | 32% | Dec 31, 2010 |
| | *2009* | 32% | Dec 31, 2009 |
| | *2008* | 32% | 32% (Target Met) |
| | *2007* | 26% | 32% (Target Exceeded) |
| | *2006* | N/A | 24% (Target Not In Place) |

**Long Term Objective:** Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.

| Measure | FY | Target | Result |
|---|---|---|---|
| 212401: Increase by 40 percent the | *2007* | 45% | May 31, 2009 |

| Measure | FY | Target | Result |
|---|---|---|---|
| percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. *(Outcome)* | *2005* | N/A | 32% (Target Not In Place) |
| 212402: Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. *(Outcome)* | *2007* | 81% | May 31, 2009 |
| | *2005* | N/A | 74% (Target Not In Place) |
| 212403: Improve by 10 percent the percentage of American consumers who correctly identify that omega-3 fat is a possible factor in reducing the risk of heart disease. *(Outcome)* | *2007* | 34% | May 31, 2009 |
| | *2005* | N/A | 31% (Target Not In Place) |

**Long Term Objective:** Detect safety problems earlier and better target interventions to prevent harm to consumers.

| Measure | FY | Target | Result |
|---|---|---|---|
| 214201: Number of prior notice import security reviews. *(Output)* | *2010* | 80,000 | December, 2010 |
| | *2009* | 80,000 | December, 2009 |
| | *2008* | 80,000 | 80,543 (Target Exceeded) |
| | *2007* | 60,000 | 84,088 (Target Exceeded) |
| | *2006* | N/A | 89,034 (Historical Actual) |
| | *2005* | N/A | 86,187 (Historical Actual) |
| 214202: Number of import food field exams. *(Output)* | *2010* | 140,000 | December, 2010 |
| | *2009* | 120,000 | December, 2009 |
| | *2008* | 85,000 | 100,718 (Target Exceeded) |
| | *2007* | 71,000 | 94,743 (Target Exceeded) |
| | *2006* | N/A | 94,545 (Historical Actual) |
| | *2005* | N/A | 84,997 (Historical Actual) |
| 214203: Number of Filer Evaluations. *(Output)* | *2010* | 1,000 | December, 2010 |
| | *2009* | 1,000 | December, 2009 |
| | *2008* | 1,000 | 1,356 (Target Exceeded) |
| | *2007* | 1,000 | 1,355 (Target Exceeded) |
| | *2006* | N/A | 1,441 (Historical Actual) |

| Measure | FY | Target | Result |
|---|---|---|---|
| | *2005* | N/A | 1,407<br>(Historical Actual) |

| | FY | Target | Result |
|---|---|---|---|
| 214204: Number of examinations of FDA refused entries. *(Output)* | *2010* | 5,000 | December, 2010 |
| | *2009* | 5,000 | December, 2009 |
| | *2008* | 4,000 | 5,926 (Target Exceeded) |
| | *2007* | 3,000 | 5,510 (Target Exceeded) |
| | *2006* | N/A | 5,846 (Historical Actual) |
| | *2005* | N/A | 5,655 (Historical Actual) |
| 214205: Number of high risk food inspections. *(Output)* | *2010* | 6,750 | December, 2010 |
| | *2009* | 6,100 | December, 2009 |
| | *2008* | 5,700 | 6,230 (Target Exceeded) |
| | *2007* | 5,625 | 6,421 (Target Exceeded) |
| | *2006* | N/A | 6,795 (Historical Actual) |
| | *2005* | N/A | 7,568 (Historical Actual) |
| 214303: Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange. *(Outcome)* | *2010* | 5 data exchange additions/conversions | December, 2010 |
| | *2009* | 5 data exchange additions/conversions | December, 2009 |
| | *2008* | 5 data entry labs | 11 labs (Target Exceeded) |
| 214206: Maintain accreditation for ORA labs. *(Outcome)* | *2010* | 13 labs | December, 2010 |
| | *2009* | 13 labs | December, 2009 |
| | *2008* | 13 labs | 13 labs (Target Met) |
| | *2007* | 13 labs | 13 labs (Target Met) |
| | *2006* | N/A | 13 labs (Historical Actual) |
| | *2005* | N/A | 6 labs (Historical Actual) |
| 214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)* | *2010* | 2,500 rad & 2,100 chem | December, 2010 |
| | *2009* | 2,500 rad & 1,650 chem | December, 2009 |
| | *2008* | 2,500 rad & 1,200 chem | 2,500 rad & 1,200 chem (Target Met) |

| Measure | FY | Target | Result |
|---|---|---|---|
| | *2007* | 1,000 rad & 1,200 chem | 1,000 rad & 1,200 chem (Target Met) |
| | *2006* | N/A | 1,200 chem (Target Met) |
| | *2005* | N/A | 0 |

## Other Outcome Indicators Measured in the HHS Strategic Plan

| Measure | FY | Target | Result |
|---|---|---|---|
| Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species. | *2010* | 12.3 cases/100,000 | December, 2011 |
| | *2009* | TBD | December, 2010 |
| | *2008* | TBD* | December, 2009 |
| | *2007* | N/A | 12.8 cases/100,000 (Target Exceeded) |
| | *2006* | N/A | 12.7 cases/100,000 (Historical Actual) |
| | *2005* | N/A | 12.7 cases/100,000 (Historical Actual) |
| Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7. | *2010* | 1.0 cases/100,000 | December, 2011 |
| | *2009* | TBD | December, 2010 |
| | *2008* | TBD* | December, 2009 |
| | *2007* | N/A | 1.2 cases/100,000 (Target Exceeded) |
| | *2006* | N/A | 1.3 cases/100,000 (Historical Actual) |
| | *2005* | N/A | 1.1 cases/100,000 (Historical Actual) |
| Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*. | *2010* | .24 cases/100,000 | December, 2011 |
| | *2009* | TBD | December, 2010 |
| | *2008* | TBD* | December, 2009 |
| | *2007* | N/A | .27 cases/100,000 (Target Exceeded) |
| | *2006* | N/A | .31 cases/100,000 (Historical Actual) |
| | *2005* | N/A | .30 cases/100,000 (Historical Actual) |
| Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species. | *2010* | 6.8 cases/100,000 | December, 2011 |
| | *2009* | TBD | December, 2010 |
| | *2008* | TBD* | December, 2009 |

| Measure | FY | Target | Result |
|---|---|---|---|
| | *2007* | N/A | 14.9 cases/100,000 (Target Exceeded) |
| | *2006* | N/A | 14.7 cases/100,000 (Historical Actual) |
| | *2005* | N/A | 14.5 cases/100,000 (Historical Actual) |

* CDC has not published the final FY 2007 FoodNet data, although it was expected to be published this fall.

**1. Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, including petitions for food contact substances, within 360 days of receipt. (213301)**

**Context:** The likely number of submissions to the food and color additives premarket review program was uncertain for FY 2007 and FY 2008 because of statutory triggers in section 409(h) of the FD&C Act that might have dramatically increased the number of submissions to this program. The factors impacting the uncertainty in submission numbers have lessened and performance has stabilized despite reduced program resources.

**Performance:** Because of the 360 day review time associated with this goal, the FY 2008 actual data would not normally be available until October 2009; however, all petitions filed in FY 2008 have been completed as of the end of March 2009. Although this program has reached or exceeded its performance goal each of the last four years, program resources have been reduced. One reason goals have continued to be met is that the actual number of submissions has fallen off over that time period. An increase in the number or complexity of incoming submissions could reduce performance.

**2. 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* and the percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214101 and 214102)**

**Context:** Strong and effective regulatory programs at the state, local and tribal level are needed to prevent foodborne illness and reduce the occurrence of foodborne illness risk factors in retail and foodservice operations. The voluntary use of the Program Standards by a food inspection program reflects a commitment toward continuous improvement and the application of effective risk-based strategies for reducing foodborne illness. The success that FDA's National Retail Food Team has had in increasing enrollment and use of the Standards reflects continued recognition that the Standards help programs improve food safety in foodservice and retail food establishments. Effective use of the Standards is assured by having enrolled complete program self-assessments to identify program strengths and areas for improvement.

**Performance:** FDA exceeded its FY 2008 target by enrolling 18 additional states, local and tribal retail food inspection programs enrolled in the FDA Voluntary National Retail Food Regulatory Program Standards. This raised the total number of enrolled jurisdictions to 320. 102 of these 320, or 32%, of the enrolled jurisdictions reported meeting at least 2 of the 9 Program Standards, based on their own self assessments. The FY 2009 targets in the Outputs Table are

based on an expectation of enrolling fifteen additional enrolled jurisdictions. These targeted increases are more modest than previous year's enrollments in recognition that, in addition to enrolling new jurisdictions, ORA personnel must devote time and resources to assisting the growing number of enrollees with Program Standards implementation. In fact, the target for FY 2009 is to maintain the current percentage of those enrolled jurisdictions that meet 2 or more of the Standards at 32%. Based on enrollment activity in the first quarter of FY 2009 we are on target for meeting the existing FY 2009 Targets. The FY 2010 Targets shown in the table above are based on an expectation that additional local jurisdictions will enroll in FY 2010 and make progress toward meeting the Standards as the result, in part, of FY 2009 efforts by FDA to make funds available to jurisdictions who agree to provide FDA with written reports on their progress.

**3. Increase consumer understanding of diet-disease relationships, and in particular, the relationships between dietary fats and the risk of coronary heart disease (CHD).** (212401, 212402, 212403)

**Context:** Coronary Heart Disease (CHD) is the leading cause of death among Americans, accounting for more than 1 in 5 deaths annually. CHD is also the leading cause of premature, permanent disability in the labor force. Dietary factors, especially consumption of some fats, play a significant role in CHD risk. One modifiable factor that is important for reducing mortality and morbidity associated with heart disease is consumer understanding of the consequences of dietary choices with respect to CHD. Increased understanding will strengthen motivation to adopt and maintain recommended healthy dietary behavior and to make informed dietary choices. The target is directly in line with several of the Department's priorities and strategic goals. First, improving the American diet through informed choice about fats that increase or reduce the risk of heart disease is one of several important steps toward reducing the enormous morbidity and mortality burden of CHD. This burden is borne disproportionately by minority populations, including African-Americans, Hispanics, and Native Americans. As the leading cause of death and a significant cause of illness and disability, CHD also imposes substantial costs on the U.S. health care system.

**Performance:** The baseline data for FY 2005 has been developed. Although the target year for accomplishment was FY 2007, the Health and Diet Survey is currently in the field and data is expected to be available for analysis by the end of May, 2009.

**4. Number of prior notice import security reviews.** (214201)

**Context:** FDA's Prior Notice Center (PNC) was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002 (BTA). Its mission is to identify imported food and feed products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, from entering into the U.S. FDA will continue to focus much of its resources on Intensive Prior Notice Import Security Reviews of products that pose the highest potential bioterrorism risks to the U.S. consumer. All flagged entries (100%) are reviewed every year. FDA expects that as prior notice compliance activities increase and targeting for high risk products becomes more sophisticated, the total number of intensive prior notice security reviews conducted by the PNC may decrease in future years.

**Performance:** During FY 2008, FDA received 10,065,863 prior notice submissions on which the PNC conducted 80,543 import security reviews (exceeding the performance target of 80,000 reviews) to identify and intercept potentially contaminated food and animal food/feed products before they entered the U.S. One shipment was held for potential biosecurity concerns and another 309 shipments were refused for prior notice violations. These operations actively strengthen the U.S. food supply and provide early warning for potential bioterrorist threats. In addition, the PNC responded to 25,220 phone and e-mail inquiries, and conducted 546 informed compliance calls to the import trade in order to facilitate better compliance with the submission of accurate, timely prior notice information.

**5. Number of import food field exams on products with suspect histories.** (214202)

**Context:** The volume of imported food shipments has been rising steadily in recent years and this trend is likely to continue. FDA reviewed approximately 9.4 million line entries of imported food out of an estimated 17.2 million lines of FDA regulated products in FY 2008. In FY 2009, FDA expects approximately 9.5 million line entries of imported food within a total of more than 18.7 million lines of FDA regulated entries. To manage this ever-increasing volume of imports, FDA uses risk management strategies to achieve the greatest food protection with available resources. While the percentage of imports physically examined may decline as imports continue their explosive growth, the exams that ORA conducts are more targeted and more effective than ever before. ORA continues to think that the best approach to improve the safety and security of food import lines is to devote resources to expand targeting and follow through on potentially high-risk import entries rather than simply increasing the percentage of food import lines given a field exam. In FY 2009, FDA used Food Protection Resources to increase the number of import food field exams by 20,000 exams which brings the FY 2009 Target to 120,000 exams over the FY 2008 accomplishments. In FY 2010, FDA will use the FY 2009 resources to increase the number of import food field exams by 20,000 exams which brings the FY 2010 Target to 140,000 exams.

**Performance:** In FY 2008, FDA exceeded the target of 85,000 by completing 100,718 field examinations of imported food lines. Explanation of why this goal was significantly exceeded: It's difficult to estimate the target for this goal because there are several different risk factors that affect how many exams will be done in a certain year, including unplanned agency initiatives and emergencies. Therefore, FDA estimates a conservative target number each year to assure that there is still a reasonable opportunity to meet the goal. However, FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years.

**6. Number of Filer Evaluations of import filers.** (214203)

**Context:** The Food and Drug Administration (FDA) receives electronic import entry data for assessing the admissibility of regulated imported articles. The accuracy of these data directly relates to the level of confidence that American consumers can expect in the quality, safety and compliance of imported articles subject to FDA's jurisdiction. Entry data affects FDA's determination of the labeling, quality, safety, approval status, and efficacy of FDA-regulated

import articles. FDA uses an electronic entry screening system, Operational and Administrative System for Import Support (OASIS), to screen import entry data transmitted by import filers. Filers who fail an evaluation must implement a Corrective Action Plan and pass a tightened evaluation. This protects public health by ensuring reporting compliance for imported articles that FDA regulates. FDA will continue to develop and apply methods to evaluate filer accuracy that are consistent with evolving security and import regulation practices. The FY 2010 target is being maintained.

**Performance:** In FY 2008, FDA exceeded this goal of 1,000 by performing 1,356 filer evaluations. This goal is an agency-wide goal and performance data includes activities from all five program areas**;** however, the majority of the performance activities and resources are from the Foods program.

**7. Number of examinations of FDA refused entries.** (214204)

**Context:** FDA is responsible for the protection of the U.S. public regarding foods, drugs, devices, electronic products and cosmetics. This protection includes refusing entry of products into the U.S. when they are deemed violative and assuring these violative products are either destroyed or exported and do not enter into domestic commerce. Although primary responsibility for supervising destruction or exportation rests with the Bureau of Customs and Border Protection (CBP), FDA monitors the disposition of refused shipments and maintains an open file until the product is exported or destroyed. In cooperation with CBP, FDA will, at times, supervise destruction or examine products prior to export in order to assure that the refused product is actually exported. This performance goal only counts FDA supervised destruction or exportation of refused entries. In other cases FDA relies on notification from CBP that the refused products have been destroyed or exported. The FY 2009 target was increased to 5,000 examinations to better reflect the recent historical actuals for this goal. For FY 2010, the target will be maintained.

**Performance:** In FY 2008, FDA exceeded this goal of 4,000 by performing 5,926 examinations of FDA refused entries as they were delivered for exportation to assure that the products refused by FDA were exported. This goal is an agency wide goal and performance data will include activities from all five program areas; however, the majority of the performance activities and resources are from the Foods program.

**8. Number of high risk food inspections.** (214205)

**Context:** High risk food establishments are those that produce, prepare, pack or hold foods that are at high potential risk of microbiological or chemical contamination due to the nature of the foods or the processes used to produce them. This category also includes foods produced for at risk populations such as infants. The Field intends to inspect such establishments annually, or more frequently for those who have a history of violations. The FDA inventory of high-risk establishments is dynamic and subject to change. For example, firms go out of business, new high-risk food firms enter the market, or the definition of high risk evolves based on new information on food hazards. High-risk establishment inspection frequencies vary depending on the products produced and the nature of the establishment. Inspection priorities may be based on

a firm's compliance history. The FY 2009 target was increased to 6,100 inspections of high-risk food establishments to better reflect the recent historical actuals for this goal. For FY 2010, the target has been increased to 6,750 to reflect the FY 2009 Appropriations.

**Performance:** In FY 2008, FDA exceeded this goal of 5,700 by performing 6,230 inspections of high-risk domestic food establishments.

**9. Convert data from new eLEXNET participating laboratories via automated exchange or convert data from existing manual data streams to automated data exchange.** (214303)

**Context:** The electronic Laboratory Exchange Network (eLEXNET) is a seamless, integrated, secure network that allows multiple agencies (federal, State and local health laboratories on a voluntary basis) engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. eLEXNET enables health officials to assess risks, analyze trends and provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. As of the end of FY 2008, 151 laboratories representing multiple government agencies and all 50 states are contributing data into the eLEXNET system allowing the program to successfully populate its database with valuable information for use in threat detection, risk assessment, inspection planning, and traceback analysis. eLEXNET plays a crucial role in the Nation's food testing laboratory system and is an integral component of the Nation's overall public health laboratory information system. FDA anticipates that increasing data exchange participation will enhance the utility of the data, improve data quality, and increase the effectiveness of the nation's food security efforts.

**Performance:** In FY 2008, FDA exceeded its performance goal by achieving automatic exchange of data from 11 laboratories. Explanation of why this goal was significantly exceeded: This goal was significantly exceeded due to a one-time opportunity to add 9 laboratories with automated data exchange capabilities through a single data network (portal).

**10. Establish and maintain accreditation for ORA labs.** (214206)

**Context:** FDA is a science-based agency that depends on its regulatory laboratories for timely, accurate, and defensible analytical results in meeting its consumer protection mandate. Our laboratories have enjoyed a long history of excellence in science upon which the agency has built its reputation as a leading regulatory authority in the world health community. Accreditation of laboratory quality management systems provides a mechanism for harmonizing and strengthening processes and procedures, thereby improving the quality of operations and the reliability of FDA's science. Such accreditations allow FDA to maintain its reputation as a source of scientifically sound information and guidance both domestically and in the international arena.

**Performance:** In FY 2008, FDA met this laboratory accreditation goal. FDA maintained accreditation for 13 laboratories: Denver District Lab, Forensic Chemistry Center, Arkansas Regional Lab, Pacific Regional Lab Northwest, San Francisco District Lab, Winchester Engineering and Analytical Center, New York Regional Lab, Southeast Regional Lab, San Juan

District Lab, Detroit District Lab, Pacific Regional Lab Southwest, and Kansas City District Lab. All ORA Field Laboratories are accredited to ISO 17025 by the American Association for Laboratory Accreditation. FCC is accredited by the ASCLD (American Society of Crime Laboratory Directors).

**11. Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week)** (214305)

**Context:** A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for the presence of contaminants. To address the need for this surge capacity, The Food Emergency Response Network (FERN), a joint effort between USDA/FSIS and HHS/FDA, was created. FERN is a nationwide laboratory network that integrates existing federal and State food testing laboratory resources capable of analyzing foods for agents of concern in order to prevent, prepare for, and respond to national emergencies involving unsafe food products. 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. FDA awards FERN Cooperative Agreements for chemistry and radiological FERN labs to the States. After receiving the funding, State FERN laboratories can take up to one year to reach full capacity due to the need for training and testing to ensure confidence in the laboratory results. As a result, labs funded in one fiscal year will not show surge capacity until the following year. With FY 2008 Food Protection increases, ORA added three additional FERN chemical labs in FY 2008 which will increase the surge capacity in FY 2009 to 1,650 chemical samples per week. With the FY 2009 Appropriation, ORA will add three additional FERN chemical labs in FY 2009 which will increase the surge capacity in FY 2010 to 2,100 chemical samples per week.

**Performance:** In FY 2008, FDA met this performance goal surge capacity target of 2,500 rad samples per week based on the awarding of cooperative agreements to 3 state radiological labs in FY 2007 resulting in a surge capacity increase of 500 rad samples per lab (1,500 total) in FY 2008. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week.

The FERN laboratories are increasingly providing critical analytical surge capacity during food emergency events. An FDA assignment directed samples to the FERN labs in the Salmonella outbreak in peppers, with over 150 samples tested. FERN laboratories also participated in the FDA surveillance assignment for the political conventions. All of these efforts contribute to increasing FDA's capacity to analyze food samples relative to biological, chemical or radiological acts of terrorism and enhance the food safety and security efforts of state, local, and tribal regulatory bodies.

# Foods Program Activity Data (PAD)

| PROGRAM WORKLOAD AND OUTPUTS | | FY 2007 Actual | FY 2008 Actual | FY 2009 Estimate | FY 2010 Estimate |
|---|---|---|---|---|---|
| ***FOOD & COLOR ADDITIVE PETITIONS*** | | | | | |
| Petitions Filed | | 7 | 8 | 10[1] | 10[1] |
| Petitions Reviewed [1] | | 7 | 7 | 9[1] | 9[1] |
| | | | | | |
| ***PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES*** | | | | | |
| Notifications Received | | 105 | 85[3] | 100[4] | 100[4] |
| Notifications Reviewed[2] | | 115 | 81[3] | 100[4] | 100[4] |
| | | | | | |
| ***INFANT FORMULA NOTIFICATIONS*** | | | | | |
| Notifications Received[5] | | 35 | 29 | 35 | 35 |
| Notifications Reviewed [6] | | 33 | 27 | 32 | 35 |
| FDA Review Time | | 90 Days | 90 Days | 90 Days | 90 Days |
| | | | | | |
| ***NEW DIETARY INGREDIENT NOTIFICATIONS*** [7] | | | | | |
| Submissions Received [8] | | 91 | 94 | 64 | 64 |
| Submissions Reviewed [9] | | 86 | 62 | 64 | 64 |
| FDA Review Time | | 75 Days | 75 Days | 75 Days | 75 Days |

[1] Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.
[2] Number reviewed includes notifications that became effective or were withdrawn.
[3] Our current estimates assume continued funding of the FCN program in FY 2009 and FY 2010.
[4] Number of submissions received in current FY includes some received late in the FY.
[5] Number of submissions reviewed includes some submissions that were received in the previous FY.
[6] A single notification may address one or more new dietary ingredients. For example, FDA as received at least 15 notifications that pertain to 2 up to 16 new dietary ingredients in a single notification
[7] Number of submissions received in current FY includes some received late in the FY that is expected to be completed in the next FY when the due date occurs.
[8] 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 2008 Actual | FY 2009 Estimate | FY 2010 Estimate |
|---|---|---|---|
| ***FDA WORK*** | | | |
| | | | |
| **DOMESTIC INSPECTIONS** | | | |
| ***UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS*** | ***6,562*** | ***7,263*** | ***7,467*** |
| | | | |
| Domestic Food Safety Program Inspections | 3,611 | 3,850 | 4,100 |
| Imported and Domestic Cheese Program Inspections | 391 | 400 | 400 |
| Domestic Low Acid Canned Foods/ Acidified Foods Inspections | 438 | 450 | 450 |
| Domestic Fish & Fishery Products (HACCP) Inspections | 1,827 | 1,850 | 1,850 |
| Import (Seafood Program Including HACCP) Inspections | 359 | 500 | 500 |
| Juice HACCP Inspection Program (HACCP) | 377 | 300 | 300 |
| Interstate Travel Sanitation (ITS) Inspections | 1,042 | 1,555 | 1,555 |
| | | | |
| Domestic Field Exams/Tests | 2,638 | 2,425 | 2,425 |
| Domestic Laboratory Samples Analyzed | 12,043 | 14,500 | 14,500 |
| | | | |
| **FOREIGN INSPECTIONS** | | | |
| ***UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT*** | ***152*** | ***200*** | ***600*** |
| | | | |
| All Foreign Inspections | 152 | 200 | 600 |
| | | | |
| ***TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT*** | ***6,714*** | ***7,463*** | ***8,067*** |
| | | | |
| **IMPORTS** | | | |
| Import Field Exams/Tests | 100,718 | 120,000 | 140,000 |
| Import Laboratory Samples Analyzed | 23,052 | 26,200 | 26,200 |
| Import Physical Exam Subtotal | **123,770** | **146,200** | **166,200** |
| | | | |
| Import Line Decisions | 9,441,024 | 9,526,745 | 9,613,245 |
| Percent of Import Lines Physically Examined | 1.31% | 1.53% | 1.73% |
| | | | |
| **Prior Notice Security Import Reviews** | | | |
| **(Bioterrorism Act Mandate)** | 80,543 | 80,000 | 80,000 |
| | | | |
| | | | |
| ***STATE WORK*** | | | |
| | | | |
| ***UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS*** | ***8,777*** | ***11,076*** | ***11,575*** |
| ***UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS*** | ***786*** | ***500*** | ***500*** |
| | | | |
| State Contract Food Safety ( Non HACCP) Inspections | 7,791 | 9,797 | 10,297 |
| State Contract Domestic Seafood HACCP Inspections | 914 | 1,148 | 1,148 |
| State Contract Juice HACCP | 50 | 75 | 75 |
| State Contract LACF | 37 | 75 | 75 |
| State Partnership Inspections | 786 | 500 | 500 |
| | | | |
| State Contract and Grant Foods Funding | $9,100,000 | $9,775,000 | $10,400,000 |
| | | | |
| Number of FERN State Laboratories | 16 | 19 | 19 |
| Annual FERN State Cooperative Agreements/Operations Funding | $11,535,000 | $13,450,000 | $10,988,000 |
| | | | |
| **Total State & Annual FERN Funding** | **$20,635,000** | **$23,225,000** | **$21,388,000** |
| | | | |
| **TOTAL FOOD INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)** | | | |
| ***GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS*** | ***16,277*** | ***19,040*** | ***20,143*** |

## Field Cosmetics Program Activity Data (PAD)

| Field Cosmetics Program Workload and Outputs | FY 2008 Actual | FY 2009 Estimate | FY 2010 Estimate |
|---|---|---|---|
| ***FDA WORK*** | | | |
| | | | |
| **DOMESTIC INSPECTIONS** | | | |
| ***UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS*** | ***92*** | ***100*** | ***100*** |
| | | | |
| All Inspections (Domestic and Foreign) | 92 | 100 | 100 |
| | | | |
| **IMPORTS** | | | |
| | | | |
| Import Field Exams/Tests | 1,892 | 2,000 | 2,000 |
| Import Laboratory Samples Analyzed | 301 | 230 | 230 |
| Import Physical Exam Subtotal | **2,193** | **2,230** | **2,230** |
| | | | |
| Import Line Decisions | 1,588,082 | 1,721,372 | 1,865,849 |
| Percent of Import Lines Physically Examined | 0.14% | 0.13% | 0.12% |
| | | | |
| **TOTAL COSMETICS INSPECTIONS (FOREIGN AND DOMESTIC/FDA AND STATE)** | | | |
| ***GRAND TOTAL COSMETICS ESTABLISHMENT*** | ***92*** | ***100*** | ***100*** |