FOODS

The FY 2009 program level budget request for the FDA Foods Program is $542,534,000. The following table shows a three-year funding history for the Foods Program.

FDA Program Resources Table

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Program Level	**$457,104,000**	**$509,867,000**	**$542,534,000**	**$32,667,000**
Center	*$159,095,000*	*$172,035,000*	*$182,087,000*	*$10,052,000*
FTE	*763*	*780*	*811*	31
Field	*$298,009,000*	*$337,832,000*	*$360,447,000*	*$22,615,000*
FTE	*1,806*	*1,853*	*1,999*	*146*
Program Level FTE	**2,569**	**2,633**	**2,810**	**177**
Budget Authority	**$457,104,000**	**$509,867,000**	**$542,534,000**	**$32,667,000**
Center	*$159,095,000*	*$172,035,000*	*$182,087,000*	*$10,052,000*
Field	*$298,009,000*	*$337,832,000*	*$360,447,000*	*$22,615,000*
Food Protection (non-add)			*$32,667,000*	*$32,667,000*
Budget Authority FTE	**2,569**	**2,633**	**2,810**	**177**

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.*)
Foods 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*

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

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 FDA's field force, is responsible for protecting and promoting the public health by ensuring that the nation's food supply is safe, sanitary, wholesome, and properly labeled and that cosmetic products are safe and properly labeled. The 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's 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 Practice (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, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. ORA's Field Foods Program is funded by appropriated dollars that allow ORA to perform inspections and fund inspections through State contracts.

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

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

Ensuring Food Protection

FDA's Food Protection Program, encompassing both food safety and food defense, is a comprehensive and integrated strategic approach that involves multiple parts of the FDA and CFSAN. The program goal is to keep the nation's food supply safe from both unintentional and deliberate contamination. The program builds in safety measures focusing FDA's 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 Food Protection Program aims to identify potential hazards and counter those before they can do harm.

Currently, close to 15 percent of the food consumed in the U.S. is imported and the percentage is rising each year. To address the concern of protecting imported food, CFSAN and ORA Food Program have been involved in two major initiatives, one focused on China specifically and one focused more broadly on all imported products. In FY 2007, FDA and its Chinese counterparts began developing agreements to increase cooperation and information sharing between the U.S. and Chinese governments. This effort culminated in the establishment of two formal Memoranda of Agreement between the United States and China to improve the safety of food (including feed) as well as feed, drugs and medical devices.

Recent outbreaks of foodborne illness in the United States have shaken consumer confidence in the safety of the food supply. This is well illustrated with the 2006 outbreaks of *E. coli* O*157:H7* linked to spinach and lettuce. These outbreaks resulted in decreased consumption of the implicated fresh produce at a time when increased consumption is critically important to maintaining a healthy diet.

In FY 2007, FDA worked with the California Department of Public Health to identify additional risk factors leading to contamination of produce as part two of the 2006 Leafy Greens Initiative. The results of this on-going work have improved FDA's guidance and policies aimed at minimizing future outbreaks of illness. FDA launched a Tomato Safety Initiative in the Eastern United States that addressed all points in the supply chain and strengthened collaborative relationships with federal, state, and local public health officials. FDA continued its international "Train-the Trainer" program on Good Agricultural Practices, conducting workshops in Guatemala and Peru. In addition, FDA issued guidance to minimize microbial food safety hazards of fresh-cut fruits and vegetables and held two public hearings on the safety of fresh produce to gather data and information from industry and other stakeholders. Finally, FDA issued guidance to processors of low acid juice on the prevention of botulinum toxin formation in response to an outbreak of botulism associated with carrot juice consumption in October 2006.

FDA has given priority to the review and authorization of substances and treatments used in the processing and production of food that may mitigate contamination with foodborne pathogens. Examples of such products permitted to enter the market in the past eighteen months include several uses of novel bacteriophages to reduce levels of *Listeria monocytogenes* on a variety of foods. Nearly a dozen additives have been authorized to reduce the opportunity for cross contamination of foods during processing including meat and poultry, fish, fruits and vegetables. In FY 2007, novel packaging was authorized to facilitate the irradiation of some packaged foods

to prevent foodborne illness. FDA continues to expedite the review and approval of similar applications that may have potential public health benefit.

The risk to human health from consuming poultry, hogs, and fish that consumed animal feed that contained melamine and melamine-related compounds became an important FDA health priority in FY 2007. FDA led a multi-agency effort to conduct and make public a peer-reviewed safety/risk assessment of the risk to human health associated with animals inadvertently fed animal feed contaminated with melamine and its analogues. FDA posted data from its exploratory survey of perchlorate in foods on its website together with a preliminary peer-reviewed exposure assessment. FDA also issued guidance for industry on lead levels in candy.

FDA continues its efforts to prevent the transmission of Transmissible Spongiform Encephalopathies (TSEs) into the food supply or any FDA regulated product. In FY 2007, FDA published a final rule on Bovine Spongiform Encephalopathy (BSE) recordkeeping and completed a final rule on prohibited cattle materials. In addition, FDA completed a risk assessment for chronic wasting disease as a human health risk.

Food Protection Program – ORA Activities

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

In 2006 and 2007, ORA, in conjunction with federal, state, and local counterparts, investigated a number of foodborne outbreaks that resulted in traceback investigations to determine the implicated products. These investigations enabled the swift removal of associated products from store shelves across the United States. These outbreaks included *E. coli* in lettuce and raw spinach and a snack food contaminated with *Salmonella wandsworth*.

In addition to ORA's domestic food work, ORA conducted 94,743 import food field exams in FY 2007 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 33 percent. 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 early June 2007, ORA launched a three-month pilot test of the prototype system. 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 – Center Activities

The principal mission of FDA's 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 choices to improve their health and help them reduce the risk of chronic disease. CFSAN conducts research, issues guidances 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 OMB's Program Assessment Rating Tool (PART) evaluation of FDA's mission. 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.

CFSAN recently initiated two education efforts. First, with the Cartoon Network, FDA released a public service campaign for tweens to "Spot the Block" which 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 September 2007, FDA issued guidance on the appropriate use of "sugar free" claims. FDA published a proposed rule to revise the existing labeling requirements for foods that have been irradiated. In November 2007, FDA published an advanced notice of proposed rulemaking (ANPRM) to solicit comments on updating the Nutrition/Supplements Facts label, including the Daily Values. In response to the new labeling requirements and other directives of the Food Allergen Labeling and Consumer Protection Act of 2004, FDA issued a series of guidances to assist manufacturers in implementing the labeling requirements and published a proposed rule for use of the term "gluten-free" in labeling.

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 infant formulas. Serious health problems arise from inadequate nutrition in infants including increased rates of insulin dependent diabetes mellitus, asthma, and eczema. ORA collects and performs nutrient analyses of samples on this "high-risk" food product in order to ensure adherence to dietary guidelines set forth in the Infant Formula Act of 1980.

Improving Dietary Supplement Safety – Center 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's regulation of dietary supplements is 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 will conduct cGMP inspections of both domestic and foreign dietary supplement manufacturing facilities based on the 2007 final cGMP rule.

FDA also continues the operation and further development of its voluntary adverse events reporting database called CAERS (CFSAN Adverse Events Reporting Systems). 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 4,500 reports of adverse events and/or consumer complaints a year with a total of 39,000 reports entered to date. In 2006, for example, a breakdown of reports shows: 220 cosmetic, 100 seafood, 2200 conventional food, 130 dietary supplement, 100 infant formula and medical foods, and 2000 food ingredient reports.

In FY 2008, CAERS prepared for newly mandated reporting requirements, commencing on December 22, 2007, and received its first mandatory adverse event report for a dietary supplement under the Dietary Supplement and Nonprescription Drug and Consumer Protection Act of 2006. FDA developed guidance on reporting serious adverse events associated with dietary supplements and used its post-market Safety Review Program to monitor medical literature for signals of potential adverse reactions to dietary supplements and ingredients.

FDA published a final rule on "per day" labeling for dietary supplements. In FY 2007, FDA also reviewed 91 New Dietary Ingredient Notifications, and more than 2,500 Structure Function Claim Notifications, and completed methods to isolate and purify major components in two dietary supplements of safety concern, blue cohosh, and teucrium.

<u>Improving Dietary Supplements – ORA Activities</u>
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 September 2007, FDA issued a warning to consumers not to use Baby's Bliss Gripe Water (apple flavored) due to the presence of the parasite *Cryptosporidium parvum* that was linked to intestinal infections in infants. Nearly 18,000 bottles of the product were distributed nationwide or sold over the Internet between November 2006 and September 2007.

<u>Improving Cosmetics Safety – Center Activities</u>
The FDA Cosmetics Program's mission 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 two laws.

The domestic cosmetic industry has annual U.S. sales exceeding $62 billion, 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. In 2006, cosmetics accounted for 9% of all imports under FDA's jurisdiction, which in turn represented a 19% increase in cosmetics imports over the preceding year. 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's effort to develop guidance for industry on this issue and to protect public health, FDA is conducting collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and their potential health hazards when used in cosmetics. In FY 2007, FDA officials also gave over 15 invited presentations at meetings of scientific and trade societies on nanotechnology-related research and/or regulatory perspectives as applied to cosmetics.

FDA implements 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% over FY 2006 levels. FDA continues to provide industry training on the VCRP. The current annual level of product registration is now more than 15 times higher than with the prior paper-based system.

The safety of cosmetics should be 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 FDA's 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.

Some dental products are included in the list of FDA-regulated cosmetics. In the summer of FY 2007 FDA found the poisonous chemical Diethylene Glycol (DEG) in numerous dental products

imported from China. FDA's field force issued public warnings to consumers and recalls of over 40 different dental products began in June and continued through October of 2007. ORA continues to investigate this problem and will take further action as required to address this important public safety issue.

Five Year Funding Table with FTE Totals

Fiscal Year	Program Level	Budget Authority	Program Level FTE
2005 Actuals	$435,517,000	$435,517,000	2,943
2006 Actuals	$438,721,000	$438,721,000	2,774
2007 Actuals	$457,104,000	$457,104,000	2,569
2008 Enacted	$509,867,000	$509,867,000	2,633
2009 Request	$542,534,000	$542,534,000	2,810

Budget Request

The FY 2009 President's Budget requests $542,534,000 in program level funding for the Foods Program, including the support of 2,810 FTE. The CFSAN portion of the request is $182,087,000 and 811 FTEs, an increase of $10,052,000 and 31 FTEs. The Field portion of the request is $360,447,000 supporting 1,999 FTEs, an increase of $22,615,000 and 146 FTEs. The request provides additional budget authority to implement Food Protection Plan goals and to provide the cost of living pay raise for the Foods Program.

Protecting America's Food Supply Initiative

The FY 2009 budget request for the Protecting America's Food Supply Initiative in the Foods Program is $537,777,000, an increase of $32,667,000 over the FY 2008 enacted level. Base funding for the Protecting America's Food Supply Initiative encompasses nearly all of the Foods Program and its goals for ensuring the safety of the Nation's food supply.

The FY 2009 budget requests an increase of $32,667,000 for the protecting America's food supply. Of this amount, $8,619,000 is for the cost of living pay increase and $24,048,000 will fund program enhancements implementing the FDA Food Protection Program and its mission to reduce and prevent the incidence of foodborne illness. The CFSAN portion of the cost of living pay increase is $2,502,000 and the Field portion is $6,117,000 The cost of living pay increase will allow FDA to retain the highly trained professionals to achieve FDA's performance commitments and to anticipate and respond to public health emergencies.

The Protect America's Food Supply initiative will allow FDA to accomplish its mission of ensuring the safety of domestic and imported food by implementing priority components of the

Food Protection Plan, FDA will use this funding to continue implementing the FDA Food Protection Program and its mission to reduce and prevent the incidence of foodborne illness associated with the consumption of fresh produce. The initiative will provide a risk-based, production-to-consumption strategy for food and feed safety and defense.

The funds for this initiative will allow CFSAN target FY 2009 increases in five major areas.

- *Preventing Contamination: +$2,000,000*: Establish a framework to develop new methods for growers, handlers and processors to prevent food contamination; develop new standards to address effectively and efficiently the incidences of microbial contamination of produce in the U.S. food supply; conduct and participate in emergency preparedness exercises; develop training videos and use media to expand communication to the farmer and industry on food safety technologies, safe farming techniques, and smart packaging to prevent contamination, and to increase outreach to American consumers.

- *Prevention through Mitigation: +$2,000,000*: Establish preventative measures that focus on understanding the optimum steps to prevent contamination throughout the farm-to-table continuum and conduct outreach and meetings with the food industry to achieve corporate responsibility.

- *Import Enhancements: +$1,000,000*: Address safety concerns associated with increases in imports of FDA-regulated products from foreign countries by improving their food protection systems; providing assistance with the development of safety programs through audits, other cooperative efforts and the sharing of laboratory and risk-assessment methodologies to eliminate significant health concerns associated with intentional or unintentional food contamination.

- *Surveillance: $550,000*: Expand traceback capabilities and strengthen the ability of FDA to work with state and local agencies and teams of federal and state investigators to facilitate traceback and farm investigations; improved food safety and food defense training for state and local agencies; and provide assistance in analyzing food protection data identifying sources of contamination and make recommendations to prevent future contamination..

- *Prevention through Research: $2,000,000*: Develop a risk-driven research plan to determine mitigation steps necessary to prevent food and feed contamination; validate rapid screening and detection methods to identify pathogens in food samples; develop interventions and preventative control measures at the producer, processor, food service and retail levels, and improve risk assessments; and address gaps in the understanding of pathogens.

The funds for this initiative will allow the Field Foods Program to expand the number of food safety inspections and import examinations. ORA will conduct an additional 1,507 domestic food safety program inspections, 90 domestic low acid canned food/acidified food inspections, and 20,000 import field exams in FY 2009. Moreover, it will provide the means to develop the Rapid Response Teams which are developed as a FDA-States partnership through the mechanism of State Cooperative Agreements. These Rapid Response Teams and associated activities support intervention and response initiatives outlined in FDA's Food Protection Plan and are an essential

element of a comprehensive risk-based food safety and food defense strategy. This supplemental funding will decrease the risk of unsafe food products from entering into the U.S. marketplace.

Foods Outputs / Outcomes Table

#	Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 1: Increase access to safe and nutritious new food products.									
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) (output)	89% of 9	100% of 7	70%	87% of 7	50%	10/08	60%[1]	60%
Long-Term Objective 2: Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.									
2.1	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 (214101) (outcome)	120 enrolled	185 enrolled	NA	259 enrolled	240 enrolled	302 enrolled	317[2] enrolled	332 enrolled
2.2	Percentage of the enrolled jurisdictions which meet 2 or more of the Standards. (214102) (outcome)	NA	NA	NA	24%	26%	32%	32%[3]	32%
Long-Term Objective 3: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.									
3.1	Increase consumer understanding of diet-disease relationships (dietary fats and CHD) Increase by 40 percent the percentage of American consumers who correctly identify that trans fat increases the risk of heart disease. (212401)	32%	NA	NA	NA	45%	1/09	NA	NA
3.2	Increase by 10 percent the percentage of American consumers who correctly identify that saturated fat increases the risk of heart disease. (212402)	74%	NA	NA	NA	81%	1/09	NA	NA

[1] FY 2008 target increased from 50%.
[2] FY 2008 target increased from 255 enrolled because enrollment was better than expected.
[3] FY 2008 target increased from 26% meet 2 standards because enrollment was better than expected.

3.3	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. (212403)	31%	NA	NA	NA	34%	1/09	NA	NA
Long-Term Objective 4: Detect safety problems earlier and better target interventions to prevent harm to consumers.									
4	Number of prior notice import security reviews. (214201) (output)	33,111	86,187	45,000	89,034	60,000	84,088	80,000[4]	80,000
5	Number of import food field exams. (214202) (output)	70,926	84,997	73,376	94,545	71,000	94,743	85,000[5]	105,000
6	Number of Filer Evaluations. (214203) (output)	1,745	1,407	1,000	1,441	1,000	1,355	1,000	1,000
7	Number of examinations of FDA refused entries. (214204) (output)	4,905	5,655	3,000	5,846	3,000	5,510	4,000[6]	4,000
8	Number of high risk food inspections. (214205) (output)	7,597	7,568	5,963	6,795	5,625	6,421	5,700	6,100
9	Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214303) (outcome)	NA	NA	NA	NA	NA	NA	5 data entry labs	5 data entry labs
10	Establish and maintain accreditation for ORA labs. (214206) (outcome)	1 lab	6 labs	13 labs	13 labs	13 labs	13 labs	13 labs	13 labs
11	Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week) (214305) (outcome)	NA	0	1,200 chem	1,200 chem	1,000 rad & 1,200 chem	1,000 rad & 1,200 chem	2,500 rad & 1,200 chem[7]	2,500 rad & 1,200 chem

[4] FY 2008 target increased to 80,000 to better align with recent historical actual data.
[5] FY 2008 target increased to 85,000 to better align with recent historical actual data.
[6] FY 2008 target increased to 4,000 to better align with recent historical actual data.
[7] The FY 2008 target was reduced to 1,200 chemical samples per week because the FY 2007 RCR funding level did not fund the three new Chemical Labs.

Other Outcome Indicators Measured in the HHS Strategic Plan

Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 3: Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.								
Reduce the incidence of infection with key foodborne pathogens: *Campylobacter* species.	12.8 cases/ 100,000	12.7 cases/ 100,000	NA	12.7 cases/ 100,000	TBD	09/08	TBD	TBD
Reduce the incidence of infection with key foodborne pathogens: *Escherichia coli* O157:H7.	0.9 cases/ 100,000	1.1 cases/ 100,000	NA	1.3 cases/ 100,000	TBD	09/08	TBD	TBD
Reduce the incidence of infection with key foodborne pathogens: *Listeria monocytogenes*.	0.27 cases/ 100,000	0.30 cases/ 100,000	NA	0.31 cases/ 100,000	TBD	09/08	TBD	TBD
Reduce the incidence of infection with key foodborne pathogens: *Salmonella* species.	14.6 cases/ 100,000	14.5 cases/ 100,000	NA	14.7 cases/ 100,000	TBD	09/08	TBD	TBD

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 has been 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. Our performance targets for FY 2008 and FY 2009 are based on our current level of certainty that program submissions will not dramatically increase during FY 2008 or FY 2009.

Performance: In FY 2008 and FY 2009, FDA hopes to maintain performance close to or at the FY 2007 level. However, although this program has reached or exceeded its performance goal each of the last three years, program resources have continued to shrink. One reason goals have continued to be met is that the actual number of submissions has fallen off over that time period. Even a slight increase in the number or complexity of incoming submissions could dramatically reduce performance. This goal is based in part on the assumption that the FCN program will be funded adequately in FY 2008 and FY 2009.

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 FY07 target by enrolling 43 additional state, 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 302. 97 of these 302, or 32%, of the enrolled jurisdictions reported meeting at least 2 of the 9 Program Standards, based on their own self assessments. The FY 2008 and FY 2009 targets in the Outputs Table are based on an expectation of enrolling fifteen additional enrolled jurisdictions each year. 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 FY08 and FY09 is to maintain the current percentage of those enrolled jurisdictions that meet 2 or more of the Standards at 32%.

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 protocol for implementing the Health and Diet Survey is under review.

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. The FY 2008 and FY 2009 targets have been increased to 80,000 security reviews to better reflect recent historical actuals for this goal. However, they are still lower than the FY 2007 actuals since it is unknown how many entries will be flagged for review as a potential security or public health risk in a given year. 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: In FY 2007, FDA exceeded this goal of 60,000 by conducting 84,088 import security reviews. The FDA Prior Notice Center collaborated with Customs and Border Protection to direct field personnel to hold and examine five (5) suspect shipments of imported foods; refused 390 lines of imported food for prior notice violations; conducted 333 informed compliance calls, responded to 29,490 phone and e-mail inquiries; and conducted the 84,088 intensive security reviews of the 9,804,001 Prior Notice submissions received in order to detect and intercept contaminated products before they enter the food supply. Explanation of why this goal was significantly exceeded: This goal is a difficult goal to set targets for because it is not known in advance how many food/feed entry lines will require an import security review, but FDA is required to review all of them. Therefore, FDA must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed the goal even if the number of lines requiring an import security review in a given year decreases from historical averages. FDA has concluded that future targets should be adjusted upward based on actual performance data for the last several years. The change in target should have minimal impact on FDA's ability to identify and prevent imported food and feed products that may be intentionally contaminated with biological, chemical or radiological agents, or which may pose a significant health risk to the American Public from entering the US.

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 9.3 million line entries of imported food out of an estimated 15.9 million lines of FDA regulated products in FY 2007. In FY 2009, FDA expects approximately 10.4 million line entries of imported food within a total of more than 18.2 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. The FY 2008 target is lower than the FY 2007 actuals because the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in the next year. In FY 2009, FDA will use additional Food Protection resources to increase the number of import food field exams by 20,000 exams.

Performance: In FY 2007, FDA exceeded this goal of 71,000 by completing 94,743 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 must estimate a conservative target number each year to assure that there is still a reasonable opportunity to exceed 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 2009 target is being maintained even though it is lower than the FY 2007 actuals because the historical accomplishments for this goal have decreased every year.

Performance: In FY 2007, FDA exceeded this goal of 1,000 by performing 1,355 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 2008 and FY 2009 targets have been increased to 4,000 examinations to better reflect the recent historical actuals for this goal.

Performance: In FY 2007, FDA exceeded this goal of 3,000 by performing 5,510 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 2008 and FY 2009 targets have been increased over the FY 2007 target but are lower than the FY 2007 actuals because the available inventory of firms for this goal is highly variable. Also, the FY 2007 actuals reflect unplanned Agency initiatives and emergencies that may not occur in subsequent years.

Performance: In FY 2007, FDA exceeded this goal of 5,625 by performing 6,421 inspections of high-risk domestic food establishments.

9. Convert laboratories that participate in eLEXNET via manual data entry to automated data exchange. (214301)

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. To date, 135 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: FDA exceeded the previous FY 2007 goal by creating informational reports on 8 specific analytes and 5 select agents. eLEXNET automatically sends recurring reports regarding 8 analytes including salmonella in peanut butter, colors in all products, pesticide residue in all products, elemental analysis in all products, antibiotic residues in all products, E. coli in spinach, Shigella in all products, and results of FDA's protein surveillance assignments. eLEXNET also routinely sends reports to FERN laboratories on 5 select agents including Bacillus anthracis, clostridium botulinum, clostridium perfringens, aflatoxin, and ricin. The FY 2008 target reflects the new goal to convert manual data entry to automated for which accomplishment data will not be available until the end of FY 2008.

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 2007, 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. Philadelphia District Lab underwent a renewal assessment in November 2007.
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.

Performance: In FY 2007, FDA met this performance goal when the 2 State Radiological Laboratories funded in FY 2006 were provided equipment and training to support their analytical surge capacity of 1,000 radiological samples per week. FDA also maintained the surge capacity for 1,200 chemical samples (known analyte) per week. Also in FY 2007, FDA awarded Cooperative Agreements to 3 State Radiological Laboratories to increase the capacity to respond to radiological attacks on the food supply. These 3 laboratories are the basis for the increase of 1,500 radiological samples per week in the FY 2008 surge capacity goal.

CFSAN Program Activity Data

PROGRAM WORKLOAD AND OUTPUTS	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
FOOD AND COLOR ADDITIVE PETITIONS			
Petitions Filed	7	12[1]	12[1]
Petitions Reviewed [1]	7	9[1]	9[1]
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES			
Notifications Received	105[3]	100[4]	100[4]
Notifications Reviewed[2]	115[3]	100[4]	100[4]
INFANT FORMULA NOTIFICATIONS			
Notifications Received[5]	29	35	35
Notifications Reviewed [6]	27	32	35
FDA Review Time	90 Days	90 Days	90 Days
NEW DIETARY INGREDIENT NOTIFICATIONS [7]			
Submissions Received [8]	94	64	64
Submissions Reviewed [9]	62	64	64
FDA Review Time	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] Due to a planned strategic re-deployment in FY 2007, this program was intended to be eliminated and result in the statutorily mandated safety review for food contact substances having to be submitted through the rulemaking process for food and color additives. Because the above redeployment did not take place under the FY 2007 CR or the current FY 2008 CR notifications have continued to be received. This number is greater because it includes those submissions received late in the previous fiscal year where the 120-day statutory timeframe begins in FY 2006 but ends in FY 2007.
[4] Our current estimates assume continued funding of the FCN program in FY 2008 and FY 2009.
[5] Number of submissions received in current FY includes some received late in the FY.
[6] Number of submissions reviewed includes some submissions that were received in the previous FY.
[7] 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.
[8] 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.
[9] 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.

ORA Foods Program Activity Data

Field Foods Program Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
DOMESTIC INSPECTIONS			
Domestic Food Safety Program Inspections	3,148	4,000	5,057
Imported and Domestic Cheese Program Inspections	360	360	450
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	448	450	542
Domestic Fish & Fishery Products (HACCP) Inspections	1,954	1,950	2,000
Import (Seafood Program Including HACCP) Inspections	408	500	500
Juice HACCP Inspection Program (HACCP)	416	415	500
Interstate Travel Sanitation (ITS) Inspections	1,112	1,555	1,755
State Contract Food Safety (Non HACCP) Inspections	7,398	8,973	9,300
State Contract Domestic Seafood HACCP Inspections	1,103	1,145	1,010
State Contract Juice HAACP	57	51	75
State Contract LACF	0	60	75
State Partnership Inspections	634	700	700
Total Above FDA and State Inspections	**17,038**	**20,159**	**21,964**
State Contract and Grant Foods Funding	$7,372,000	$8,825,000	$9,600,000
Number of FERN State Laboratories	13	13	13
Annual FERN State Cooperative Agreements/Operations Funding	$8,385,000	$7,435,000	$7,480,000
Total State & Annual FERN Funding	**$15,757,000**	**$16,260,000**	**$17,080,000**
Domestic Field Exams/Tests	2,438	4,925	4,925
Domestic Laboratory Samples Analyzed	11,683	9,880	9,955
PROGRAM OUTPUTS-			
IMPORT/FOREIGN INSPECTIONS			
All Foreign Inspections	96	150	200
Import Field Exams/Tests	94,743	85,000	105,000
Import Laboratory Samples Analyzed	24,588	26,000	26,075
Import Physical Exam Subtotal	**119,331**	**111,000**	**131,075**
Import Line Decisions	9,356,074	9,853,234	10,376,812
Percent of Import Lines Physically Examined	1.28%	1.13%	1.26%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	84,088	80,000	80,000

Field Cosmetics Program Activity Data

Field Cosmetics Program Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
DOMESTIC INSPECTIONS			
All Inspections (Domestic and Foreign)	114	100	100
PROGRAM OUTPUTS-			
IMPORT/FOREIGN INSPECTIONS			
Import Field Exams/Tests	2,095	2,000	2,000
Import Laboratory Samples Analyzed	229	230	200
Import Physical Exam Subtotal	2,324	2,230	2,200
Import Line Decisions	1,465,113	1,579,607	1,703,048
Percent of Import Lines Physically Examined	0.16%	0.14%	0.13%