FOODS

Introduction

FDA's Foods Program summarizes the budget program requirements that justify a $466,726,000 request for FY 2008. The Foods program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Center for Food Safety and Applied Nutrition and related Field support from the Office of Regulatory Affairs
- effects of the full year FY 2007 continuing resolution on the Foods Program
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Foods Program funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 budget request.

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget	Increase or Decrease
Program Level	**$438,721,000**	**$438,721,000**	**$449,687,000**	**$466,726,000**	**$17,039,000**
Center	*$153,470,000*	*$153,568,000*	*$148,363,000*	*$154,588,000*	$6,225,000
FTE	*812*	*771*	*748*	*756*	8
Field	*$285,251,000*	*$285,153,000*	*$301,324,000*	*$312,138,000*	$10,814,000
FTE	*1,962*	*1,842*	*1,940*	*1,946*	6
Total FTE	**2,774**	**2,613**	**2,688**	**2,702**	**14**
Budget Authority	**$438,721,000**	**$438,721,000**	**$449,687,000**	**$466,726,000**	**$17,039,000**
Center	*$153,470,000*	*$153,568,000*	*$148,363,000*	*$154,588,000*	$6,225,000
Field	*$285,251,000*	*$285,153,000*	*$301,324,000*	*$312,138,000*	$10,814,000
Pay Increase	--	--	--	*$7,539,000*	$7,539,000
Strengthening Food Safety	--	--	--	*$9,500,000*	$9,500,000
Total FTE	**2,774**	**2,613**	**2,688**	**2,702**	**14**

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2004 Actuals	$407,052,000	$407,052,000	--	3,082
2005 Actuals	$435,517,000	$435,517,000	--	2,943
2006 Actuals	$438,721,000	$438,721,000	--	2,774
2007 Continuing Resolution	$438,721,000	$438,721,000	--	2,613
2007 President's Budget	$449,687,000	$449,687,000	--	2,688
2008 President's Budget	$466,726,000	$466,726,000	--	2,702

Statement of the Budget Request

The Foods Program is requesting $466,726,000 in program level resources in order to complete mission-critical activities:

- ensuring that the U.S. food supply is safe, secure, sanitary, wholesome, and honestly and otherwise properly labeled
- taking corrective action to reduce human exposure to food related health hazards and the possibility of food-related illnesses and injuries
- defending the U.S. food system against terrorist attacks, major disasters and other emergencies as mandated by Presidential Directives such as HSPD-9 to assure the best protection to the American consumer
- conducting safety evaluations of new food ingredients to ensure that any food ingredient intended to have a technical effect in food or any color additive for use in foods is deemed safe
- taking corrective action to reduce human exposure to cosmetic related health hazards and the possibility of cosmetic-related illnesses and injuries
- identifying substances and issues of safety concern for color additives and their raw material

- developing and evaluate methods to identify and quantify potentially harmful ingredients and contaminants in color additives.

Research to Measure Electrical Conductivity: Simple Ways of Preventing Attacks on Our Food Supply

Food facilities are vulnerable to tampering and terrorist acts by individuals who may infiltrate a company's workforce. An "inside" job could be difficult to prevent once an employee has access to the plant. Looking for practical solutions, FDA scientists examined whether something as simple as the ability of a liquid food to conduct electricity or its visual appearance could be used to determine if a toxic chemical had been added to liquid food (for example, milk, juices, bottled water). Measuring the electrical conductance with a simple meter before and after adding toxic levels of a number of highly toxic compounds showed that they produced significant changes. Likewise, many of the toxic compounds produced measurable changes in the visual appearance of liquid foods, particularly juices. FDA researchers demonstrated that by first developing the normal characteristics of a product, a manufacturer could easily and inexpensively monitor the conductance or color of their products. Deviation from that norm would be a strong signal to the manufacturer to investigate why its product had changed. In addition to this simple but effective technique serving as an early warning that a product may been tampered with, it may also be a useful tool for manufacturers to monitor the quality of their products. The development of such applications by FDA researchers is particularly important for small businesses that cannot afford research efforts in food defense.

Program Description

The Center for Food Safety and Applied Nutrition (CFSAN) administers the program, with the assistance from the Office of Regulatory Affairs' Field offices nationwide. Together, CFSAN and ORA's field staff are responsible for protecting and promoting the public health by ensuring that the nation's food supply is safe, secure, sanitary, wholesome, and honestly and otherwise properly labeled. FDA is also responsible for ensuring that cosmetic products are safe, secure, and honestly and otherwise properly labeled.

The Foods Program operates by successfully joining forces with academia, industry, and other government agencies to protect and promote the public health by maintaining a safe food and cosmetics supply. CFSAN's food safety program also involves a number of intramural and extramural efforts. The coordination and communication among these groups has also allowed the Foods Program to leverage efficient use of resources and expertise to address food and cosmetics related safety concerns, and prepare for new and emerging issues

Current trends in the food industry promise better nutrition and a wider range of choices for the U.S. consumer than ever before. However, despite these encouraging developments, the foods program still faces many challenges. The volume and diversity of imported foods continues to rise, with foods once considered exotic now found throughout the United States. The globalization of America's food supply means that

foods we consume are being produced by a much larger number of source countries whose regulatory infrastructure may not be as sophisticated as our own. FDA must continue to seek innovative ways to target high-risk imported foods and increase enforcement action against firms continuing to manufacture or import violative foods.

The dietary supplement industry and the consumption of these products continue to grow. FDA must continue to emphasize enforcement activities to protect Americans against dietary supplement products bearing fraudulent or unsubstantiated claims, and on activities to identify ingredients or products that create safety problems and to respond with appropriate regulatory actions.

One of the major focuses related to cosmetic safety is the rise in popularity of tattoos in the United States. Adverse events associated with tattoo inks have heightened CFSAN's concerns about the safety and use of certain inks. FDA is committed to providing consumers with information about the health hazards associated with the cosmetic and other personal care products used daily.

The Foods program is responsible for the development and implementation of the food defense provisions outlined in the Bioterrorism Act of 2002 (BT Act) and implementing Homeland Security Presidential Directive-9 (HSPD-9) to safeguard the food supply. Because a growing proportion of the U.S. food supply is imported, we also work with international organizations and occasionally directly with foreign governments to ensure their understanding of U.S. requirements and to harmonize international food standards.

Scope of Responsibility

CFSAN, along with ORA, regulates $417 billion worth of domestic food, $49 billion in imported foods, and $59 billion (including $4 billion imported) in cosmetics sold across state lines. FDA's regulatory responsibility takes place from a product's point of U.S. entry or processing to the product's point of sale, with approximately 300,000 food establishments and 3,500 cosmetic firms.

Field Foods Activities

Through risk-based domestic and foreign inspections of food establishments conducted by ORA, FDA assesses industry compliance with cGMP and HACCP requirements for myriad products. In particular, ORA inspects thousands of domestic firms identified as high-risk food establishments consisting of manufacturers and packers and repackers processing products. These products include modified atmosphere packaged products, acidified and low acid canned foods, seafood, custard filled bakery products, soft, semi-soft, soft-ripened cheese and cheese products, un-pasteurized juices, sprouts or processed leafy vegetables, fresh vegetables shredded for salads, processed root and tuber vegetables, sandwiches, prepared salads, infant formula, and medical foods.

In addition to overseeing 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, FDA's Office of Criminal Investigations (OCI) complements the regular field force.

Effects of the Full Year FY 2007 Continuing Resolution

The analysis in this justification assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for the Foods Program. For comparison purposes, FDA budget tables also include a column that reflects an FY 2007 Continuing Resolution (CR) level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Foods Program:

- There will be a slowing of the development of preventative strategies needed to minimize the likelihood of recurring produce-related outbreaks. Slowing of response capabilities needed to detect and respond to outbreaks of foodborne illness.

- FDA will have to decrease inspections and testing of domestic food products, resulting in fewer products identified with microbial organisms, pesticides, and industrial chemical contaminants, and filth problems, which could lead to an increase in foodborne illnesses and death.

- FDA will have to reduce inspections and sample analysis of imported food products and inspections for current Good Manufacturing Practice and Hazard Analysis Critical Control Point compliance.

- The work that was scheduled to begin this year to develop safeguards to ensure that foods do not serve as a vehicle of transmission for avian influenza cannot be initiated.

- There will be increased risk to public health as the agency becomes less able to ensure the safety of animal feeds and drugs consumed by animals produced for food.

- FDA will have fewer resources available to ensure the safety of infant formula. All infant formula manufacturing plants are inspected yearly because of the public health consequences of adulterated infant formula. Annual inspections cannot be assured with diminished resources.

- Americans will be at greater risk of developing drug resistance and other adverse health effects during a pandemic influenza because FDA cannot detect and enforce illegal use of human antiviral drugs in poultry or the proper disposal of infected animals to ensure they do not enter the food supply.

Field Foods Program

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Field Foods Program:

- ORA will limit its Food Emergency Response Network (FERN) funding to the maintenance of the ten State laboratories; FDA's resources to support training, proficiency testing and planned expansions of the FERN system will be limited by reduced operating funds and fewer experienced analytical staff in ORA laboratories.

- The number of high risk foods performance goal inspections planned for FY 2007 will be reduced by almost 20 percent [-1,015 inspections] from the President's budget proposal; firms making high risk products that received annual inspections in previous years will be inspected on a biennial schedule instead.

- Routine Cosmetics inspections will be eliminated and ORA will perform cosmetics inspections only on a "for cause" basis, where a product or firm is suspected of being out of compliance.

- ORA will not be able to fund inflationary increases in State inspection costs and the number of State inspections will decline from the President's budget level, possibly damaging FDA's relationships with the States.

- Domestic and Import Laboratory Samples Analyzed will decline by 2,000 samples below the President's budget level.

- Funding under the continuing resolution causes a loss of 120 FTE for the Field Foods Program.

If FDA receives the CR funding rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Foods Program. FY2008 performance projected off the funding off the FY 2007 Presidents Budget will need to be revised. CFSAN will need to develop a risk management strategy to handle the highest risk incidents

Field Foods Program

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Field Foods Program:

- Any new hires are unlikely to exceed 25 percent of typical productivity which means that FY 2008 inspection and laboratory analysis targets may not be met and ORA work will include a higher proportion of entry level tasks than in FY 2006.

- Despite ORA's desire to pursue risk based activities, newly hired employees will require intensive coaching and supervision and may need to assist an experienced ORA specialist for several months before assuming responsibility for complex risk based activities.

- Although ORA should be able to award contracts and grants for the increased sums authorized in the FY 2008 budget, reduced staffing will delay activities funded by the contracts and grants.

Program Resource Changes

Budget Authority

Pay Increase: +$7,539,000
The FDA request for pay inflationary costs is essential to accomplish our public health mission. Eighty percent of FDA's budget supports the agency workforce. Of this, payroll costs account for almost sixty-percent of our total budget. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. Maintaining the FDA workforce provides stability for the organization and allows FDA to maintain the current level of coverage for its premarket and postmarket activities. Without these funds, FDA must reduce FTE levels in order to have adequate resources to cover it payroll, which will lead to corresponding reductions in programs that protect public health. The total request for cost of living pay increases in FY 2008 is $21,773,000. The Foods portion of this increase is $7,539,000**.**

Strengthening Food Safety (CFSAN): +$4,000,000 and +8 FTE
FDA proposes a total of $10,644,000 for food safety activities, $4,000,000 of which is for CFSAN, to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks. The resources would also improve FDA's ability to protect the public health by enhancing our ability to respond to possible foodborne outbreaks. CFSAN resources would develop better scientific tools to detect and attribute foodborne illness outbreaks related to produce, permitting more rapid detection of disease-causing microorganisms in fresh produce. This activity allows for quicker intervention to reduce illnesses and deaths from contaminated food and quicker resumption of marketing of uncontaminated food. The request would also increase sampling and traceback capabilities, fund development of cost-effective regulations and/or guidance to prevent and reduce foodborne outbreaks, and obtain additional expertise in the production and processing of fresh produce, with emphasis on microbiological safety issues.

Strengthening Food Safety (Field): +$5,500,000 and +6 FTE
FDA proposes a total of $10,644,000 for food safety activities, $5,500,000 of which is for ORA, to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks. The resources would also improve FDA's ability to protect the public health by enhancing our ability to respond to possible foodborne outbreaks. The request would help ORA develop the capacity for more rapid traceback of produce-

related outbreaks, and improve the capacity to more quickly determine the root cause of an outbreak. The request would also allow FDA to accelerate the development of an integrated import decision making IT system capable of detecting high-risk shipments of FDA regulated products before they are admitted or released into U.S. commerce. In addition, ORA would begin formal integration of this technology into the Mission Accomplishment and Regulatory Compliance Services (MARCS) system.

User Fees

Proposed User Fees

Reinspection User Fee (Mandatory): $5,517,000 and 44 FTE (Non-Add)

The FY 2008 budget includes $23,276,000 in budget authority for reinspection related activities. The Budget also proposes a new mandatory user fee to support reinspection activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

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. 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. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the Agency in FY 2008 are $23,276,000, with $5,517,000 of the collections being allocated to the Field component of the Foods program.

Food and Animal Feed Export Certification User Fee: $3,674,000 and 23 FTE (Non-Add)

The FY 2008 budget includes $3,741,000 in budget authority for export certification related activities. The Budget also proposes a new mandatory user fee to support export certification activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

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 collecting 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 the Agency's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary

appropriations. The total proposed collections for the Agency in FY 2008 are $3,741,000, with $3,674,000 of the collections being allocated to the foods program.

Justification of Base

The Foods Program has five overarching areas of responsibility:

1. **Ensuring Food Safety** – Current Good Manufacturing Practices (cGMP) compliance; Seafood Hazard Analysis and Critical Control Point (HACCP), and Juice HACCP regulations; Good Agricultural Practices; Safety of food ingredients and packaging (including ionizing radiation) and color additives

2. **Ensuring Food Defense** – protect consumers against deliberate attempts to contaminate food at any point along the food production, processing, and distribution chain

3. **Improving Nutrition** – regulations and activities dealing with the proper labeling of foods (for example, ingredients, nutrition health claims) and cosmetics

4. **Improving Dietary Supplement Safety** – regulations and policy on the safety of dietary supplements; dietary supplement industry postmarket surveillance and compliance

5. **Improving Cosmetic Safety** – regulatory and research programs to address the safety of cosmetic products.

The chart below displays the five program areas of the Foods Program, and shows their broad support for FDA's strategic goals.

	FDA Strategic Goals		
	Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products	Increase Access to Innovative Products and Technologies to Improve Health	Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight
Program Area			
Ensuring Food Safety	X		X
Ensuring Food Defense	X		X
Improving Nutrition	X		
Improving Dietary Supplement Safety	X		X
Improving Cosmetic Safety	X		X

Ensuring Food Safety

For more than a century, FDA has had the responsibility of protecting the food supply and promoting public health. During this time, the world of food safety has seen significant changes. Food safety issues have become more refined. FDA can focus on specific contaminants rather than broad categories of hazards. Available scientific information has increased FDA's awareness of specific hazards. Changes in knowledge such as the emergence of new foodborne pathogens and changes in society such as technology advancements, human demographics and behavior, global travel and trade, and more food coming from distance places have had an effect on our food safety systems. These changes have impacted our regulatory policies and environment and FDA is adapting to these changes. FDA's past philosophy has revolved around a "command and control" approach. The new philosophy is moving toward an approach that titrates the degree of "regulatory control" to the risk to public health and focuses on end results (for example, is the food safe?). CFSAN ensures food safety through the performance of 17 activities:

1. responding to and investigating foodborne outbreaks

2. addressing produce safety by developing assisting in the development of, additional produce guidance

3. issuing guidance on recommended maximum level of lead in candy consistent with the FDA's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practicably can be obtained

4. addressing egg safety issues by developing a final rule to prevent contamination of shell eggs during production

5. enrolling sixty-two different states, local and tribal retail food inspection programs in the Voluntary National Retail Food Regulatory Program Standards bringing the total number of enrolled jurisdictions to 252 at the end of FY 2006

6. publishing and distributing to states and other interested parties the 2005 Pasteurized Milk Ordinance (PMO) with benefit of recent time/temperature/microbial growth research data surrounding dairy products

7. addressing molluscan shellfish safety issues such as red tide and *Vibrio vulnificus*

8. addressing food allergen and related public health issues by evaluating and/or validating test kits for food allergen contamination

9. taking enforcement action against products and/or manufacturers that violate the Federal Food, Drug, and Cosmetic Act and other laws

10. defining microbial pathogen risks associated with foods by examining the emergence of these risks in the food supply, adapting to the barriers that are traditionally used to keep food safe, and rapid detection

11. "fingerprinting" pathogens in food; studying unique intervention technologies to prevent contamination; and arraying all this information, using risk assessment techniques, to inform risk managers

12. conducting studies of how heat, ultraviolet light, irradiation, and high pressure processing can improve the safety of cheese, sprouts, juice, and eggs

13. conducting studies to provide criteria for prevention, reduction, or elimination of safety hazards affecting seafood within the unique HACCP requirements regulating this program and/or the cooperative National Shellfish Sanitation Program with industry

14. continuing the development of enhanced sampling and detection methods for surveillance for priority chemical, microbiological, and radiological agents in vulnerable foods

15. developing risk assessments, risk assessment techniques, and critical scientific data needed to ensure that international food safety standards are based on sound science

16. modernizing and incorporating advances in science and technology into cGMPs for food

Research on Sprouts: Saving Small Producers

Over the past decade, an ever increasing number of American consumers have enjoyed including sprouted seeds (e.g., mong bean, alfalfa, clover, and radish) as one of the fresh produce items that they consume with their salads. However, few of them are aware that this industry, which also includes small producers, was in jeopardy just a few years ago. This was because fresh sprouts were increasingly being linked to outbreaks of salmonellosis and life-threatening *E. coli* infections. Responding to this emerging public health concern, FDA mobilized its scientists to work with the industry to find innovative solutions that fit the small business nature of this industry. Taking advantage of its government/academic/industry consortium, the National Center for Food Safety and Technology, the FDA formed a research taskforce so that its scientists could work with the industry under realistic production conditions. In less than two years, the FDA scientists and their academic and industry partners had developed methods for improved detection of contaminated seeds, effective means for disinfecting the seeds while maintaining their viability, techniques for monitoring the irrigation water to determine if a batch of sprouts had become contaminated, and effective post-sprouting treatments to reduce pathogens that might have been missed. The success of this program has been outstanding; outbreaks associated with this group of products have been largely eliminated, the vitality of this segment of the fresh produce industry has never been better, and the American consumer has had an uninterrupted access to a desired food.

17. providing the U.S. Delegate or Alternate Delegate to, or participating in 10 U.S. Codex Committees and related activities; CFSAN's leadership in these activities is critical to the development of scientifically sound international public health standards.

Ensuring Food Safety: Food Allergens

In the area of Food Allergens, three activities are performed:

- making available a report summarizing the current state of scientific knowledge regarding food allergens and celiac disease, including information on dose-response relationships for major food allergens and for gluten, respectively

- revising guidance to industry relating to food allergens and questions and answers about the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2)

- issuing guidance on the labeling of certain uses of lecithin derived from soy.

Ensuring Food Safety: Premarket Review of Food Ingredients

Food additives play a vital role in today's food supply. Food additives perform a variety of useful functions, ranging from improving safety to increasing shelf life, providing flavor or texture, or adding to the desirability of the product. The use of a new food additive is prohibited until its sponsor establishes its safety and FDA authorizes its use. To ensure food additives are safe, FDA performs six activities:

- reviewing and approving direct food additives, i.e., substances added to a particular food for a specific purpose

- reviewing and approving indirect food additives, i.e., substances that become part of the food in trace amounts because of their use in or on food packaging or food processing equipment

- consulting with developers of foods derived from bioengineered plants to ensure that safety and regulatory questions are resolved prior to marketing

- encouraging the kind of marketplace where healthy foods can compete readily among all foods available

- providing guidance to industry on chemistry issues pertaining to the use of recycled plastics in food packaging

- providing guidance to industry on procedures for submitting an early food safety evaluation of new plant varieties, including bioengineered plant varieties.

Ensuring Food Safety: The National Center for Food Safety and Technology (NCFST):

The National Center for Food Safety and Technology is a unique consortium composed of scientists from FDA, academia, and food related industries. NCFST provides a neutral ground where industry, academia and government scientists can pool their scientific expertise and institutional perspectives to address food safety issues in a proactive and creative manner. This is accomplished through four activities:

- fostering scientific and technical exchange among diverse segments of the food science community
- providing a better understanding of the science and engineering behind food safety
- conducting research to promote the safety and quality of the U.S. food supply
- conducting research needed to answer regulatory questions related to food safety.

Food Safety – Field Activities

The Office of Regulatory Affairs (ORA) assures the safety of marketed products through inspections and surveillance of the food supply. Consumers rely on the FDA to prevent dangerous and unreliable products from entering commerce. ORA's efforts focus on five areas:

- identifying the food source and contaminant of foodborne illness outbreaks ranging from chemical and microbiological to physical hazards
- analyzing food samples for pesticides and environmental contaminants
- funding State contracts, partnerships, and grants to permit the States to inspect the foods industry
- conducting State contract audit inspections to ensure consistent application of regulations during FDA and State inspections of food establishments
- providing criminal investigations of reported product tampering, counterfeit products, and other fraudulent criminal activities involving regulated products.

Ensuring Food Safety: Laboratory Analyses

FDA is committed to providing consumers with information about safe food handling practices. Many food safety problems cannot be addressed solely through the use of regulations, enforcement, and research. CFSAN plays a vital role in educating consumers, particularly at-risk or vulnerable populations, about the safe handling of

food. Major education efforts are undertaken tp inform consumers:

- prevention and education programs focusing on the prevention of foodborne illness for pregnant women

- education and labeling programs focusing of the prevention of *Salmonella Enteritidis* from shell eggs

- education programs focusing on safe food handling following national disasters

- educating consumers through the FightBAC! Initiative— a food safety initiative that educates millions of consumers about the four simple steps -- clean, separate, cook, and chill -- they can take to reduce their risk of foodborne illness; this initiative was created through the Partnership for Food Safety Education

- distributing education/media materials throughout the United States as part of a consumer education campaign to increase consumer understanding and awareness about the major food allergens in the U.S. food supply

- co-sponsoring food safety conferences to reach "At-Risk" audiences

- publishing consumer information on safe seafood handling.

FDA/CFSAN developed the Lettuce Safety Initiative as a response to the recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce. The Initiative is intended to reduce public health risks by focusing on the product, agents, and areas of greatest concern. An important goal of the Initiative is to demonstrate FDA's commitment and concern about the safety of lettuce to the industry. The Initiative supports the goals of the 2004 FDA Produce Safety Action Plan, which is intended to minimize the incidence of foodborne illness associated with consumption of fresh produce. On August 28, 2006, CFSAN issued the "Fall Lettuce Safety Assignment," which includes inspections of processors and assessments of growers, harvesters, coolers, and packers. FDA, in coordination with the State of California, has completed the majority of the inspections of fresh cut processors.

In conjunction with State Officials, FDA initiated inspections of lettuce farming and processing operations located in Salina Valley, California. The inspection of this California $2-billion-a-year lettuce industry began in late August and will continue through the fall. Lettuce and spinach grown in the valley have been connected to eight of 19 outbreaks of *E. coli* O157:H7, associated with such produce since 1995. The eight outbreaks sickened at least 217 people in eight states, including two who died at a retirement home in Northern California, in 2003. This issue was intensified when at least 34 people in Minnesota were sickened last year after consuming packaged Dole salad from the Salinas Valley. FDA developed a Lettuce Action Plan to assist State

Officials and Industry with correcting identified issues. In addition to the lettuce and spinach investigations, significant shifts in resources were warranted in 2006 in order to address the Taco Bell and Taco John outbreaks.

Outbreaks of E. Coli

Between August 1 and early October 2006, an outbreak of E. coli O157:H7 linked to bagged spinach infected at least 204 persons in 26 states. Three patients died and one hundred and two individuals were hospitalized, including 31 patients who suffered hemolytic uremic syndrome (HUS). HUS is a serious complication associated with *E. coli* O157:H7 infection that can lead to a potentially fatal form of kidney failure.

Ensuring Food Defense

FDA remains concerned about the possibility of food products being used as a vehicle for a terrorist attack. Production of food is so extensive that, if even a few agents were intentionally introduced into a part of the food chain, a staggering number of human illnesses and deaths, and catastrophic economic losses, could result.

Obtaining critical knowledge about the characteristics and dose response relationships of specific agents is a critical aspect of preventing and responding to intentional adulteration of the American food supply. In response to this need FDA/CFSAN completed the construction of its BSL-3 laboratory suite. The primary purpose of this laboratory is to directly assist CFSAN, the Food Emergency Response Network (FERN), and the Laboratory Response Network (LRN) in the development of methods for the isolation and identification of bio-threat agents from foods. In addition, this laboratory will function as a support laboratory for the Office of Regulatory Affairs, FERN, and LRN in the event of natural or deliberate contamination of the food supply.

FDA/CFSAN established a repository of *E. coli* 0157:H7 from varied geographical locations and sources and a supporting relational database as a reference collection for the Department of Homeland Security (DHS). This information was developed at the request of the National Bioforensic Analysis Center (NBFAC) and will be used by FDA and DHS to provide standards for detection and analysis of pathogenic E. coli isolates. The database will help both DHS and the FDA in the identification and forensic tracing of outbreak strains of pathogenic *E. coli*.

FDA/CFSAN also developed a set of tools including DNA microarray, genome optical mapping, and bioinformatics analysis for forensic identification of *E. coli* O157:H7. These tools and the information generated by these tools were developed in response to the need to identify individual isolates of *E. coli* O157:H7 and other pathogenic bacteria beyond traditional microbiological identification methods. Microarrays and genome mapping will be used to identify geographic, temporal, and nucleotide allele

variants in O157:H7 and other pathogens to discriminate individual isolates of these bacteria and determine their source.

CFSAN has focused its food defense efforts on assessing vulnerabilities in our food safety systems, establishing and maintaining the capacity to respond to an attack on our food supply. FDA/CFSAN conducted eight CARVER + Shock vulnerability assessments with industry and State partners in the following commodities: baby food, bottled water, frozen pizza, fruit juice, powdered infant formula, milk, fresh-cut produce and yogurt.
The CARVER + Shock Assessment is a tool that helps identify, assess and distinguish between real and perceived food defense vulnerabilities in specific food products, commodities or activities.

FDA is engaged in eight efforts to develop and promote food defense measures:

- providing technical assistance to State and local governments and to the industry on the process and mechanics for conducting a vulnerability assessment

- evaluating the public health consequences (risk) of product-agent-activity combinations associated with tampering or terrorist activity

- identifying preventative measures that companies can take to minimize the risk that food or cosmetics under their control is the target or subject of a terrorism event

- developing methods for ensuring that critical food production and manufacturing infrastructure can be rapidly and effectively decontaminated in the event of a terrorist attack

- determining the behavior of microbiological, chemical, radiological, and biologically-derived toxic agents in priority vulnerable foods during the stages of production, distribution, marketing, and preparation; this information is critical to the development of more effective intervention technologies and to conducting vulnerability assessments

- maintaining relationships with state partners to ensure laboratory capacity and capability in response to a food terrorism event

- developing and conducting outreach and education to inform industry and consumers of the potential risks and steps to take in the event of a terrorist attack on the food supply; this includes surveys to assess consumer understanding of the risks and messages

- collaborating with Federal, state, and local governments to protect the food and agriculture critical infrastructure.

Microbial Forensics Research: Being Able to Catch the Bad Guys

The attack on the mail system with anthrax taught the U.S. many lessons including how difficult it is to capture a technologically sophisticated attacker. The scientists at FDA have been called upon by the Department of Homeland Security (DHS) and the FBI to help them develop the microbial forensics capability for being prepared to investigate terrorist threats if an attacker attempts to use enteric bacteria (e.g. *Escherichia coli* O157:H7, *Shigella dysentariae*) as a weapon of mass destruction. Using advanced techniques in microbiology, molecular biology, genetics, and microbial physiology, the FDA scientists have applied their expertise to being able to "fingerprint" in amazing detail the identity of individual strains of these pathogens for which we were asked to take responsibility. The methods have become so accurate that they can distinguish the same strains that have been maintained in different laboratories. The initial successes have been so effective that DHS has designated FDA/CFSAN's MOD I facility at the Muirkirk Research Campus as a National Center of Excellence for Microbial Forensics of Enteric Pathogens. They are encouraging the FDA scientists to build on their initial successes to develop the methods, expertise, and databases that the country needs to be able to investigate and prosecute terrorist events involving microbiological agents if they were to occur.

Food Defense – Field Activities

FDA must have the capacity to quickly and accurately identify and respond to potential terrorist events occurring at any point in the food chain and take prompt action to mitigate their effects. In the event of an identified threat, FDA will work with other federal, State, and local agencies to eliminate or contain the hazard, reduce public health risk, and identify those who perpetrated the attack. ORA efforts will focus on five areas:

- continuing to fund previously awarded Food Emergency Response Network (FERN) State cooperative agreements for increased laboratory surge capacity and the National Surveillance Sampling Program

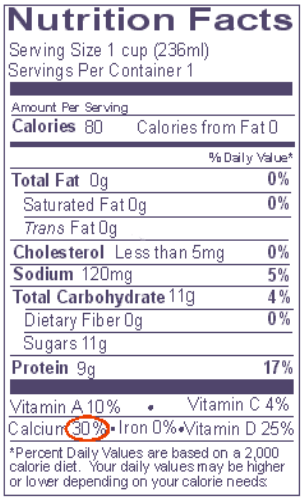
- maintaining the electronic Laboratory Exchange Network, eLEXNET, a system that collects lab analytical data on chemical, microbiological, and other contaminants and links federal, State, and other laboratories

- reviewing products offered for import into the U.S. for safety and security issues and collaborate with Customs and Border Protection (CBP) to monitor the importation of regulated products and follow-up on the status of products refused entry

- continuing development of the National Biosurveillance Integration System (NBIS), the departmentally recognized standard for communication in the health arena.

Improving Nutrition

Science is exploring opportunities for improving the health consequences of nutrition that range from a better understanding of the impact of general dietary patterns for the US population as a whole to the specific understanding of how an individual's genetic makeup interacts with food and the environment, offering the possibility of "designing" foods and diets for individuals to maximize health. Increasing health information and increasing consumer understanding of nutrition and the importance of eating a healthy diet is at the forefront of this evolution.



Health messages on product labels that may influence consumer knowledge and enhance dietary choices fall into three major categories. All three have important consequences for consumer behavior. Health claims provide information about the relationship between a food or food substance and reduction of risk of a disease and are reviewed and authorized by FDA. "Structure/function" claims highlight how a food substance works within or otherwise supports the body. A general "dietary guidance" statement focuses on general dietary patterns, practices, and recommendations that promote health.

Developments in the law, as well as critical public health considerations such as the nation's dramatic rise in obesity in adults and children, call for FDA to take appropriate steps to provide critical and needed information for consumers to make informed choices and to protect consumers from false and misleading information.

Since the late 1980s, adult obesity has steadily increased in this country. About 64 percent of Americans are overweight and more than 30 percent are obese. As apart of the Transform the Health System Goal in the DHHS Secretary's 500 Day Plan, the Department has committed to comprehensive, novel early prevention and detection strategies to increase the potential for a healthy life including the reduction of obesity and its consequences. To help tackle what FDA is calling the "nation's obesity epidemic," the FDA has developed and is focusing on both long- and short-term recommendations (*Calories Count Report)* based on the scientific fact that weight control is mainly a function of caloric balance. That is, calories in must equal calories out. CFSAN has in place many activities to deal with this issue.

<u>Improving Nutrition: Preventing Obesity</u>

In preventing obesity, CFSAN's efforts focus on four areas:

- providing recommendations for improving consumer's ability to manage calorie intake from foods prepared ad purchased away-from-home

- developing new learning tools that will help consumers use the Nutrition Facts label to choose nutritious food and achieve healthy weight management

- developing and disseminating better information for consumers about the health consequences of their diet—helping consumers lead healthier lives through better nutrition

- assisting the public in making wise dietary choices that benefit long-term health through promotion of healthy dietary practices and increasing awareness of U.S. Dietary Guidelines for Americans.

Improving Nutrition: Food Labeling

For Food Labeling, CFSAN's efforts focus on six areas:

- implementing food label education campaigns to promote healthy lifestyles and combat childhood obesity

- publishing a new regulation to update the names and the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States and clarifying guidelines for the voluntary nutrition labeling of these foods

- reviewing and authorizing "health claims" to be used on food labels that describe the relationship between a substance and a disease

- reviewing and monitoring the use of "structure/function" claims that highlight how a food substance works within or otherwise supports the body to ensure the claims are truthful, substantiated and not misleading

- reviewing and monitoring the use of "dietary guidance" statements on food labels to ensure the statements are truthful and not misleading

- modernizing the food label to improve the public availability and consumer understanding of nutrition and ingredient information provided and increasing the public's ability to use food label information to help identify foods that contribute to a healthy total diet.

Improving: Nutrition: Infant Formula

On the matter of Infant Formula, CFSAN solicits public comment on the FDA proposal to revise current good manufacturing practice requirements for infant formula.

Improving Nutrition: Consumer Research

To further improving nutrition, CFSAN conducts consumer research to evaluate food safety messages and corresponding changes in behavior.

Enterobacter sakazakii research: Protecting our youngest consumers

Modern pediatric medicine increased the number of premature infants that survive and ultimately thrive. However, it has also produced new challenges in terms of protecting this most sensitive of populations from potentially infectious agents. These findings led to the confirmation that *Enterobacter sakazakii*, a ubiquitous bacterium that can occur in powdered infant formula, can lead to life-threatening infections in infants, particularly premature or immunocompromised infants. Ever since CDC and FDA scientists unequivocally established the link between this pathogen and contaminated infant formula, FDA researchers have been on the forefront in the development of tools for controlling its presence in dehydrated and rehydrated formula. For example, FDA scientist have developed and validated methods for the detection of *E. sakazakii* from powdered infant formula. This was critical as an initial first step in finding ways to ensure that contaminated lots do not enter commerce. Furthermore, FDA's characterization of this newly identified pathogen was instrumental in demonstrating the microorganism's ability to survive for years in dehydrated formula, and then resume growth when the product is rehydrated. The information generated by FDA scientists on the thermal resistance of this microorganism has been critical to providing practical guidance to developing countries. Without this research capability, FDA may not have rapidly provided scientifically based guidance to both the industry and consumers worldwide. The research expertise that FDA was able to bring to bear rapidly has directly contributed to the significant reduction in *E. sakazakii* outbreaks in our most susceptible of consumers that has occurred during the last two years.

Improving Dietary Supplement Safety

The dietary supplement industry is one of the world's fastest growing industries. In the United States, over 158 million consumers use dietary supplements and 20 million of these consumers use dietary supplements in conjunction with prescription products. FDA plays a vital role in ensuring the safety of new dietary ingredients by reviewing of new dietary ingredients to ensure the sufficiency of the safety evidence.

FDA is also committed to providing consumers with more timely access to important information about nutrition and disease risk-reduction at earlier stages of scientific knowledge as long as that information is truthful and not misleading. CFSAN performs six major actitives to improve dietary supplement safety:

- reviewing and monitoring dietary supplements to ensure they contain the ingredients listed on the label
- educating manufacturers and distributors about their responsibilities under DSHEA regarding label claims for dietary supplements
- completing steps to establish current good manufacturing practice requirements

for dietary supplements to ensure product quality and safety

- using a risk-based approach to prioritize and take enforcement actions against firms that are marketing or distributing dietary supplements with false or misleading claims
- taking strong enforcement actions against dietary supplement manufacturers or distributors illegal dietary supplement products such as Ephedra
- reviewing and monitoring adverse event reports and take appropriate action.

The Consumer Health Information for Better Nutrition initiative is designed to foster two complementary goals concerning the labeling of food and dietary supplements:

- encourage makers of conventional foods and dietary supplements to make accurate, science-based claims about the health benefits of their products
- help to eliminate bogus labeling claims by taking regulatory action against those dietary supplement marketers who make false or misleading claims.

ORA will ensure that enforcement activities focus on products with the following marketing strategies: unapproved new drugs containing prosteroids and precursor steroids such as dietary supplements; dietary supplements with unsubstantiated structure function claims (examples include treatments for autism, treatments for mental retardation and epilepsy, sports performance enhancement, and aging); and dietary supplements containing prescription drug ingredients.

Ensuring Cosmetic Safety

There are approximately 3500 cosmetic firms in the United States and each year, $62 billion worth of cosmetics are sold across state lines. FDA is committed to providing consumers with information about the health hazards associated with the cosmetic and other personal care products they use daily. Tattoos are an old form of body art that has been used for millennia. Tattoo popularity in the United States is on the rise. Adverse events associated with tattoo inks have heightened CFSAN's concerns about the safety and use of certain inks. To ensure cosmetic safety, CFSAN undertakes six activities:

- providing outreach information about the health hazards associated with specific tattoo inks
- providing information to consumers about the health hazards and adverse events associated with various cosmetic products
- taking appropriate enforcement action against adulterated or misbranded cosmetics in interstate commerce

- implementing a new Voluntary Cosmetic Registration Program making it easier for cosmetic companies to submit cosmetic industry establishment and cosmetic product formulation data so that FDA staff can more easily assess cosmetic ingredient usage

- implementing a new color certification electronic system to provide essential information to the cosmetic industry about that status of their samples and account information.

Selected FY 2006 Accomplishments

Management
CFSAN completed a reorganization of the entire Center. As a result of the reorganization, CFSAN can align all of its activities under five overarching program areas and build the Center's overall budget around these areas. The overarching program areas are: Food Safety, Food Defense, Nutrition, Dietary Supplements and Cosmetics. This restructuring of CFSAN's organizational units enables the Center to meet its priorities while maintaing alignment with the goals of the DHHS and the Administration. CFSAN also used a Zero-Based Budget (ZBB) process again FY 2006 to align resources with the highest public health priorities using the Center's priority setting criteria.

Ensuring Food Safety

Premarket Review of Food Ingredients
In the area of Premarket Review of Food Ingredients CFSAN demonstrated results by posting guidance for industry, "Use of Recycled Plastics in Food Packaging: Chemistry Considerations."

Food Allergens
CFSAN published a proposed rule to require the declaration of cochineal extract and carmine on the label of all food and cosmetic products that contain these color additives. The proposed rule responds to reports of severe allergic reactions, including anaphylaxis, to cochineal extract and carmine-containing food and cosmetics and would allow consumers who are allergic to these color additives to identify and thus avoid products that contain these color additives.

Food Allergens
CFSAN demonstrated results for in the Food Allergens area in three activities:

- revised report: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; report summarizes the current state of scientific knowledge regarding food allergens and celiac disease, including information on dose-response relationships for major food allergens and for gluten, respectively

- announced in the Federal Register (70 FR 76463) the availability of a revised guidance document for industry entitled: "Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2)

- published guidance for industry: "Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) the Federal Food, Drug, and Cosmetic Act."

Allergen Education Campaign

As part of the Allergen Education Campaign, CFSAN distributed in late FY 2006 education/media materials throughout the United States as part of a consumer education campaign to increase consumer understanding and awareness about the major food allergens in the U.S. food supply.

Bioengineered Plants Guidance

To further the program goals of the Food Safety Program, CFSAN published guidance to industry: "Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use."

Lead in Candy

To further FDA's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that practicably can be obtained, CFSAN published draft guidance for industry entitled ``Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy."

Voluntary National Retail Food Regulatory Program Standards

In FY 2006, 57 different state, local and tribal retail food inspection programs enrolled in the Voluntary National Retail Food Regulatory Program Standards. This brings the total number of enrolled jurisdictions to approximately 240. As of July 2006, 60 jurisdictions reported meeting at least 2 of the 9 Standards. 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 increases in enrollment and use of the Standards reflects a growing recognition of the value that the Standards have in helping programs to identify ways to most significantly affect food safety in foodservice and retail food establishments.

2005 Pasteurized Milk Ordinance:

CFSAN published and distributed to States and other interested parties the 2005 Pasteurized Milk Ordinance (PMO) with benefit of recent time/temperature/microbial growth research data surrounding dairy products. It will soon be available on CFSAN's web site.

Codex Committees

CFSAN provided the U.S. Delegate or Alternate Delegate to, or participated in 10 U.S. Codex Committees and related activities: Codex Alimentarius Commission, General Principles, Food Additives/Contaminants, Food Import and Export Inspection and Certification Systems, Nutrition and Foods for Special Dietary Uses, Food Labeling, Methods of Analysis and Sampling, Pesticide Residues, Milk and Milk Products, and Fish/Fish Products. CFSAN's leadership in these activities is critical to the development of scientifically sound international public health standards.

Produce Safety
CFSAN published draft Guidance for Industry: "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables." This document complements FDA's current good manufacturing practice (CGMP) regulations by providing specific guidance on the processing of fresh-cut produce in order to minimize microbial food safety hazards.

Food Safety Conference
CFSAN co-sponsored in conjunction with USDA, CDC and NSF/WHO Collaborating Center on Food Safety a conference entitled, "Reaching At-Risk Audiences and Today's Other Food Safety Challenges."

Ensuring Food Defense

Research
The construction phase of the BSL-3 suite has been completed. The primary purpose of these laboratories is for the direct support of FDA, CFSAN, the Food Emergency Response Network (FERN) and the Laboratory Response Network (LRN) in the development of methods for the isolation and identification of bio-threat agents from foods. In addition, these laboratories will function as support laboratories for the Office of Regulatory Affairs, FERN, and LRN in the event of natural or deliberate contamination of the food supply.

CFSAN also established a repository of *E. coli* 0157:H7 from varied geographical locations and sources and a supporting relational database as a reference collection for the Department of Homeland Security (DHS). This information was developed at the request of the National Bioforensic Analysis Center (NBFAC) and will be used by FDA and DHS to provide standards for detection and analysis of pathogenic E. coli isolates. The database will help both DHS and the FDA in the identification and forensic tracing of outbreak strains of pathogenic *E. coli*.

Finally, CFSAN developed a set of tools including DNA microarray, genome optical mapping, and bioinformatics analysis for forensic identification of *E. coli* O157:H7. These tools and the information generated by these tools were developed in response to the need to identify individual isolates of *E. coli* O157:H7 and other pathogenic bacteria beyond traditional microbiological identification methods. Microarrays and genome mapping will be used to identify geographic, temporal, and nucleotide allele variants in O157:H7 and other pathogens to discriminate individual isolates of these bacteria and determine their source.

Preventive Measures
CFSAN conducted CARVER + vulnerability assessments in eight food products/commodities in FY 2006. The CARVER + Shock Assessment is a tool that helps identify, assess and distinguish between real and perceived food defense vulnerabilities in specific

food products, commodities or activities. CFSAN exceeded its goal of conducting at least six CARVER assessments in FY 2006.

Improving Nutrition

Preventing Obesity

CFSAN staff participated in all three of the Keystone Forum dialogue plenary sessions that led to the development of the Keystone report entitled: "The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity." The report provides recommendations for improving consumers' ability to manage calorie intake from foods prepared and purchased away-from-home. It offers recommendations related to 1) understanding and influencing consumer behavior, 2) increasing the availability of lower-calorie products, menu items, and meals, and 3) providing consumers with nutrition information.

CFSAN also developed two new learning tools that will help consumers use the Nutrition Facts label to choose nutritious food and achieve health weight management. The tools are, "*Make Your Calories Count*," a web-based learning program with an animated character, "*Labelman*," and a new *Nutrition Facts Label* brochure.

Food Labeling

CFSAN implemented a food label education campaign in an effort to promote healthy lifestyles and combat childhood obesity. The first phase of the campaign focusing on children and obesity via media began September 20, 2006.

CFSAN published a regulations updating the names and the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the U.S. and clarifying guidelines for the voluntary nutrition labeling of these foods.

CFSAN published Guidance for Industry and FDA Staff: Whole Grain Label Statements." The draft guidance is intended to provide guidance to industry about what the Agency considers to be ``whole grain" and to assist manufacturers in labeling their products.

Infant Formula

CFSAN developed an improved bacteriological testing method for *Enterobacter sakazaki* has been developed. After validation, FDA intends to use the method for detection of *Enterobacter sakazaki* in infant formula.

Cosmetic Safety

CFSAN coordinated with National Center for Toxicological Research (NCTR) an FDA Science Forum session entitled: "Body Marking: Tattoos, Permanent Make-up and Laser Removal." The session included presentations by medical professionals and the results of an epidemiology study by CDC. CFSAN revised the FDA webpiece on tattooing and worked with the Office of Women's Health (OWH) to produce literature for public dissemination.

CFSAN fully implemented an electronic system to support industry participation via the internet in CFSAN's Voluntary Cosmetic Registration Program (VCRP). In addition to making it much easier for companies to submit cosmetic industry establishment and cosmetic product formulation data, the new web-based system enables staff to more easily assess cosmetic ingredient usage and industry participation in the program.

CFSAN launched a web-based information system for the Color Certification Program. The new system provides essential information to industry about the status of their samples and account information, as well as updates from FDA.

Foods Program Activity Data (PAD)

PROGRAM WORKLOAD AND OUTPUTS	FY 2006 Actuals	FY 2006	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget
FOOD & COLOR ADDITIVE PETITIONS[1]					
Petitions Filed	7	12	8	25[1]	50[1]
Petitions Reviewed[2]	8	12	8	15[1]	18[1]
[1] Beginning in FY 2007, this program includes petitions for food contact substances. We expect the number of petitions received to increase in subsequent years to at least 60-90 incoming petitions, because of the elimination of the food contact substance notification program. [2] Number reviewed includes petitions approved, withdrawn, or placed in abeyance because of deficiencies during the FY.					
PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES[6]					
Notifications Received	88	110	0	0	0
Notifications Reviewed[4]	73	100[5]	0	0	0
[4] Number reviewed includes notifications that became effective or were withdrawn. [5] FDAMA established a notification program for food additives that are food contact substances (e.g. packaging materials). The number of "notifications reviewed" appears to be the same, in some instances, because under the provisions of this notification, a food contact substance may be marketed 120 days after notification unless the agency objects. [6] Due to strategic re-deployment, beginning in FY 2007, this program in intended to 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. The FY 2007 Congressional Justification anticipates that food contact notifications submitted within the last 120 days of the end of FY 2006 is expected to be reviewed as food additive petitions (see note 1 above, because the FCN program ends on September 30, 2006).					
INFANT FORMULA NOTIFICATIONS					
Notifications Received[7]	28	30	35	35	35
Notifications Reviewed[8]	23	30	35	33	32
FDA Review Time	90 Days	90 Days	90 Days	90 Days	90 Days
[7] Number of submissions received in current FY includes some received late in the FY. [8] Number of submissions reviewed includes some submissions that were received in the previous FY.					
NEW DIETARY INGREDIENT NOTIFICATIONS [9]					
Submissions Received [a]	53	78	60	91	64
Submissions Reviewed [b]	49	78	60	86	64
FDA Review Time	75 Days	75 Days	75 Days	75 Days	75 Days
[9] 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 [a] 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. [b] 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.					

FOODS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY 2006 Actuals	FY2007 Continuing Resolution	FY2007 President's Budget	FY2008 President's Budget
Domestic Food Safety Program Inspections	3,833	3,000	3,400	3,400
Imported and Domestic Cheese Program Inspections	401	200	300	300
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	477	300	400	400
Domestic Fish & Fishery Products (HACCP)	2,308	2,000	2,330	2,330
Import (Seafood Program Including HACCP)	529	250	500	500
Juice HACCP Inspection Program (HACCP)	441	100	300	375
Interstate Travel Sanitation (ITS) Inspections	1,175	1,000	1,550	1,550
State Contract Food Safety (Non HACCP) Inspections	6,680	7,780	8,400	8,400
State Contract Domestic Seafood HACCP Inspections	1,006	1,010	1,010	1,010
State Contract Juice HAACP	58	47	47	47
State Partnership Inspections	822	900	900	900
Total Above FDA and State Inspections	**17,730**	**16,587**	**19,137**	**19,212**
State Contract and Grant Foods Funding	$6,378,774	$6,378,774	$6,825,288	$7,303,058
Number of FERN State Laboratories	10	10	16	16
Annual FERN State Cooperative Agreements/Operations Funding	$7,105,000	$7,195,000	$12,535,000	$10,285,000
Total State & Annual FERN Funding	**$13,483,774**	**$13,573,774**	**$19,360,288**	**$17,588,058**
Domestic Field Exams/Tests	2,455	2,500	2,500	2,500
Domestic Laboratory Samples Analyzed	11,706	9,965	10,465	10,465
All Foreign Inspections	125	100	100	100
Import Field Exams/Tests	94,545	71,000	71,000	71,000
Import Laboratory Samples Analyzed	20,662	26,980	28,480	28,480
Import Physical Exam Subtotal	115,207	97,980	99,480	99,480
Import Line Decisions	8,883,999	9,101,004	9,101,004	9,323,310
Percent of Import Lines Physically Examined	1.30%	1.08%	1.09%	1.07%
Prior Notice Security Import Reviews (Bioterrorism Act Mandate)	89,034	60,000	60,000	60,000

COSMETICS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY 2006 Actuals	FY2007 Continuing Resolution	FY2007 President's Budget	FY2008 President's Budget
All Inspections	151	25	100	100
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Import Field Exams/Tests	2,441	2,000	2,000	2,000
Import Laboratory Samples Analyzed	280	230	230	200
Import Physical Exam Subtotal	2,721	2,230	2,230	2,200
Import Line Decisions	1,358,918	1,611,326	1,611,326	1,910,616
Percent of Import Lines Physically Examined	0.20%	0.14%	0.14%	0.12%

Performance Analysis

During FY 2006, which is the latest performance period for which data are available, the Foods Program successfully achieved or exceeded 9 out of 10 targets for its FY 2006 performance goals. The remaining target is expected to be met when data become available later in FY 2006. For more information about these performance goals and results, please see the Performance Detail section.

The Voluntary National Retail Food Regulatory Program Standards are a key component of FDA's effort to decrease foodborne illness and represents a successful federal/state/local/tribal partnership in improving food safety. FDA continues to encourage jurisdictions to enroll in the Program Standards while continuing to provide support and guidance to those jurisdictions already enrolled.