

**FOODS – CENTER FOR FOOD SAFETY AND APPLIED NUTRITION  
(CFSAN)**

	<b>FY 2004 Actual</b>	<b>FY 2005 Enacted<sup>1</sup></b>	<b>FY 2006 Estimate</b>	<b>Increase or Decrease</b>
<b>Program Level</b>	<b>\$167,534,00</b>	<b>\$175,189,00</b>	<b>\$179,434,00</b>	<b>+ \$4,245,000</b>
<i>Total FTE</i>	910	894	881	-13
<b>Budget Authority</b>	<b>\$167,534,00</b>	<b>\$175,189,00</b>	<b>\$179,434,00</b>	<b>+ \$4,245,000</b>
<i>Food Defense</i>	<i>\$11,123,000</i>	<i>\$20,954,000</i>	<i>\$25,776,000</i>	<i>+ \$4,822,000</i>
<i>GSA Rent &amp; Rent Related</i>	<i>\$23,168,000</i>	<i>\$23,187,000</i>	<i>\$23,615,000</i>	<i>+ \$428,000</i>
<i>Administrative Efficiencies</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>-\$232,000</i>
<i>IT Reduction</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>-\$773,000</i>
<i>Total FTE</i>	910	894	881	-13

**For Information Only:**

<b>ORA Field Estimate</b>				
<i>Budget Authority</i>	\$299,341,00	\$319,414,00	\$342,698,00	+ \$23,284,000
<i>FTE</i>	2,172	2,056	1,966	-90

*Includes structure changes to FDA's budget, which displays GSA and Other Rent and Rent Related Activities in the Program line, and the Office of Regulatory Affairs as its own program. ORA estimates are for information purposes only and are not included in the Center program level total.*

<sup>1</sup>*Contains budget authority rescission of 0.8 percent.*

**Historical Funding and FTE Levels**

<b>Fiscal Year</b>	<b>Program Level</b>	<b>Budget Authority</b>	<b>User Fees</b>	<b>Program Level FTE</b>
2002 Actual <sup>1/</sup>	143,178,000	143,178,000	--	924
2003 Actual	147,304,000	147,304,000	--	950
2004 Actual	167,534,000	167,534,000	--	910
2005 Enacted	175,189,000	175,189,000	--	894
2006 Estimate	179,434,000	179,434,000	--	881

*Does not contain GSA Rent or Other Rent and Rent Related Activities.*

<sup>1/</sup>*Includes FDA's FY 2002 Appropriation and the Counterterrorism Supplemental.*

## STATEMENT OF THE BUDGET

The Foods Center Program request is \$179,434,000 to accomplish the following activities:

- Ensure that the food supply, quality of foods, food ingredients, and dietary supplements are safe, nutritious, wholesome, and honestly labeled and that cosmetics are safe and properly labeled;
- Set standards and develop regulations for the food industry;
- Counter terrorism by implementing the White House Homeland Security Presidential Directive/HSPD-9, "Defense of the United States Agriculture and Food;"
- Safeguard the U.S. public by defending the food system against terrorist attacks, major disasters, and other emergencies;
- Take timely and appropriate action on new food ingredients and dietary supplements, infant formula, cosmetics, and bioengineered foods before they go on the market to ensure their safety and effectiveness;
- Research ways to provide the necessary basis for regulatory decisions;
- Identify food-related health hazards;
- Take corrective action to reduce human exposure to food related health hazards and the possibility of food-related illnesses and injuries; and,
- Educate and train consumers and industry on food safety and food security.

### *Scope of Responsibility*

*CFSAN, along with ORA, promotes and protects the public's health by ensuring that the food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled for the public. The program regulates \$417 billion worth of domestic food, \$49 billion in imported foods, and \$59 billion (including \$4 billion imported) in cosmetics and toiletries sold across state lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale, with approximately 60,000 food establishments (including more than 33,000 U.S. food manufacturers and processors and over 22,000 food warehouses) and 2,600 cosmetic firms. The U.S. food supply is among the worlds safest, and FDA will continue to ensure consumer confidence in the food Americans eat.*

## PROGRAM DESCRIPTION

The Foods -- Center for Food Safety and Applied Nutrition (CFSAN) -- program regulates all food except meat, poultry, and frozen and dried eggs, which, are regulated by the USDA. CFSAN, in conjunction with ORA, is promoting and protecting the public's health by ensuring that the Nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled for the public. Additionally, as we enter the 21<sup>st</sup> century, current trends in the food industry promise better nutrition, greater economies and wider choices for the U.S. consumer than ever before. To illustrate:

- The volume and diversity of imported foods has risen dramatically over the last few decades, and foods once considered exotic are now found throughout the U.S.;
- The globalization of the food supply means that foods we consume are being produced by a much larger number of source countries;
- The biotechnology explosion has opened new frontiers in product development, thus providing us the ability to genetically alter foods to make produce more resistant to disease, add desirable consumption characteristics to the foods, and to prolong shelf life; and,
- The dietary supplements industry has grown dramatically, as has consumption of dietary supplements.

Each of these developments presents food safety regulatory and food security/defense challenges for FDA. The Agency's job is to give consumers the confidence to enjoy the benefits of these expanded food choices.

CFSAN's primary responsibilities include: the safety of substances added to food, e.g., food additives (including ionizing radiation) and color additives; the safety of foods and ingredients developed through biotechnology; seafood Hazard Analysis and Critical Control Point (HACCP) regulations; regulatory and research programs to address health risks associated with foodborne chemical and biological contaminants; regulations and activities dealing with the proper labeling of foods (e.g., ingredients, nutrition health claims) and cosmetics; regulations and policy governing the safety of dietary supplements, infant formulas, and medical foods; safe and properly labeled cosmetic ingredients and products; food industry postmarket surveillance and compliance; consumer education and industry outreach; cooperative programs with state and local governments; and, international food standard and safety harmonization efforts. The Center also has the responsibility for development and implementation of food defense provisions outlined in the BT Act of 2002 and implementation of HSPD-9 for safeguarding the nation's food supply. Although our food supply is among the world's safest, the increase in variety of foods and the convenience items available has brought with it public health concerns. Because a growing proportion of the U.S. food supply is imported, CFSAN also works with international organizations and occasionally directly with foreign governments to ensure their understanding of U.S. requirements and to harmonize international food standards.

The Field component, the Office of Regulatory Affairs (ORA) supports the Center for Food Safety and Applied Nutrition. ORA conducts risk-based domestic and foreign postmarket inspections of food manufacturers to assess their compliance with Good Manufacturing Practice (GMP). ORA inspects thousands of domestic firms that have been identified as high-risk food

establishments consisting of manufacturers, packers/repackers, and warehouses processing products. These 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 and 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 staff responds to emergencies and investigates incidents of product tampering and terrorist events or natural disasters that may impact FDA-regulated goods, and in instances of criminal activity, the regular field force is complemented by the Office of Criminal Investigations. ORA is also spearheading the agency’s effort to establish the FERN. In FY 2006, ORA will expend an estimated \$342.7 million in budget authority in support of the Foods Program. Activities that these resources support are displayed in the Program Activities Data Table for Field Activities.

### **CFSAN PERFORMANCE ANALYSIS**

During the latest performance period, FY 2004, CFSAN successfully achieved the targets for three of its four performance goals. The goal that was not met is a two fold goal where the Center was able to exceed in half but was not able to reach the entire goal. CFSAN does expect to achieve its goal in this area in FY 2005. For more detailed explanation of these goals and results, please see their respective section contained in the Detail of Performance Analysis under the Supporting Information tab.

Under the FD&C Act, FDA must review the safety of food and color additives before food manufacturers and distributors can market them. To initiate this review, sponsors are required to submit a petition or notification that includes appropriate test data to demonstrate the safety of the intended use of the substance. The Agency must respond to the sponsor’s notification with a decision within 75 days. The Agency also has a notification program for substances that are GRAS. Finally, the Agency consults with developers of foods derived from bioengineered plants to ensure that all safety and regulatory questions are resolved prior to marketing and FDA has proposed a mandatory premarket notification program for these foods. CFSAN’s key challenge in the premarket area is to expeditiously review new food products without jeopardizing public safety.

**Performance Highlight:**

Goal Target	Context	Results
Complete review and action on the safety evaluation of 75% of food and color additive petitions within 360 days of receipt.	This goal refers to completion of the safety evaluation of food and color additive petitions. This includes a review of the information in a filed petition, and a determination to either approve or disapprove the petition (along with the agency’s rationale and transmittal of the decision to the petitioner).	FDA has met the targets for this performance goal consistently since FY 1999.

## **RATIONALE FOR BUDGET REQUEST**

This request for Budget Authority supports various activities that contribute to the accomplishment of program outputs and performance goals, and presents FDA's justification of base resources and selected FY 2004 accomplishments by strategic goal.

### **PROGRAM RESOURCE CHANGES**

#### **Program Account Restructuring**

##### **GSA Rent and Other Rent Activities Structure Change**

To provide increased flexibility and accountability, eliminate the need for the many reprogramming requests to Congress, place accountability for rental costs within the operating program, and better reflect the total cost of each program. This budget changes the way the GSA Rent and Other Rent-Related Activities budget lines are displayed by incorporating these resources into program level requests.

##### **Office of Regulatory Affairs (ORA) Estimate and Structure Change**

This budget also establishes a single budget line item for the ORA to help the field program provide services more effectively, especially by providing much needed flexibility to respond shifting program priorities. This additional flexibility is essential to allow FDA to respond to emerging situations without being hindered in performing its mission critical activities. These activities have been removed from each program line and the Field estimates will be provided under the Office of Regulatory Affairs to reflect the planned spending for each program area.

#### **Budget Authority**

##### **Counter-Terrorism -- Food Defense: + \$4,822, 000 and 7 FTE**

Funds implement HSPD-9 requiring research and development of new methods for detection, prevention technologies, agent characterization, and dose response relationships for high-consequence agents in food.

-- *New Methods* - FDA fulfills its responsibility of ensuring the safety of the food supply through surveillance and monitoring. New microbiological, chemical, and radiological methods must be developed, validated, and used to detect, enumerate and identify potential non-traditional agents that may threaten the food supply. A particular emphasis is the need to develop biosensors and other technologies to permit continuous monitoring of foods both during production and at import entry sites;

-- *Prevention Technologies* - FDA studies food prevention technologies to improve the safety of food and establish guidelines and or performance standards for industry. Information is needed about new technologies and / or technology enhancements that can increase food safety and protect against potential exposure to non-traditional pathogens, toxins and chemicals during possible high threat situations. For example, critical information is needed

to determine if prevention strategies such as changing pasteurization times and temperatures could be used to safeguard foods and beverages while maintaining the quality that the consumer expects;

-- *Agent Characteristics* - Additional assessments of the abilities of non-traditional microbial pathogens to survive and grow in foods during processing and storage, or the stability and activity of chemical agents while present in foods, and the potential for their inactivation during food processing are essential to improving FDA's ability to detect, quantify and control foodborne pathogens, toxins and chemicals that threaten the food supply; and,

-- *Dose Response Relationships/ Threat Assessments* - An understanding of the dosage amounts needed to inflict human disease or produce adverse reactions, where exposure occurs through consumption of different food matrices, is essential to accurately estimate the threat posed by such exposures. In turn, knowledge of dose response helps determine methods development performance parameters (e.g., sensitivity, ruggedness, statistical confidence) that assure safety and security of the food supply.

### **GSA Rent: + \$428, 000**

To help meet the rising costs of GSA rent, a total of \$4,100,000 is requested, of which \$428,000 is for CFSAN. This will help cover inflation on FDA's current GSA leased facilities.

### **Management Savings: -\$1,005,000 and -4 FTE**

FDA will reduce spending on administrative and IT activities. Specifically, these reductions are:

- **Administrative Efficiencies: - \$232,000 and -2 FTE**  
Administrative efficiency savings will total -\$1,554,000 and -14 FTE, of which CFSAN's share is -\$232,000 and -2 FTE.
- **Information Technology Reduction: - \$773,000 and -2 FTE**  
IT reductions will total -\$5,116,000 and -15 FTE, of which CFSAN's share is -\$773,000 and -2 FTE.

## **JUSTIFICATION OF BASE**

### **USING RISK-BASED MANAGEMENT PRACTICES**

Base resources are used to conduct science-based risk management in all agency regulatory activities so that limited resources can provide the most in health promotion and protection at the least cost to the public. These activities include efforts to:

- Continue FDA's national network of academic centers of excellence to strengthen scientific standards for compliance, threat assessment, and reduction;
- Continue to evaluate the CDC foodborne disease outbreak surveillance system data to identify and analyze outbreaks associated with FDA-regulated products, for the number of

outbreaks, etiologic agents, morbidity and mortality, seasonality, geographic location, site of food preparation, contributing factors and whether the product is domestic or imported;

- Continue to develop food safety prevention standards and guidance to fill the gaps in public health protection from farm to table---modernizing GMP's for food establishments;
- Sustain enhancements to the strategic data systems for surveillance and inspection activities of the food supply that help FDA inspectors focus on and analyze products suspected to have microbiological and chemical contamination;
- Continue to participate in national surveillance and emergency response programs, such as the Foodborne Disease Active Surveillance Network (FoodNet) and PulseNet. FoodNet, a collaborative project with the CDC and USDA, conducts active surveillance for foodborne diseases and related epidemiology studies; while PulseNet is a national network of public health laboratories that performs DNA "fingerprinting" on bacteria that may be foodborne;
- Provide emergency response training in critical areas essential to CFSAN's preparation for and response to potential acts of terrorism against the food supply. Training in FY 2004 included a review of the Center Emergency Response Plan and a case report, involving 641 staff and all Division Directors and Leadership team members. A more intensive training of Situation Room Staff was held in collaboration with DHS/FEMA at the National Fire Training Facility in Emmitsburg, MD. The total number of CFSAN staff trained in Emergency procedures now stands at about 766 out of 875 (87.5 percent);
- Continue to provide the operations and maintenance support necessary for import and domestic product monitoring equipment and information systems, and provide rapid methods to test products in the field; and,
- Enhance coordination of food security and counter-terrorism issues with federal, state, and local governments and other organizations through full participation in the Interagency Food Working Group (IFWG) and sub groups.

### **Food Code**

The Food Code is a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry. FDA will continue to update the Food Code and increase risk management strategies and communication to government, industry and consumers for ensuring the safety of the nation's food supply by quantifying actual performance of the percentage of the total US population that will live in States that have adopted the Food Code.

The Food Code is a component of an even larger effort aimed at decreasing foodborne illness, the National Retail Food Regulatory Program Standards program. Through this program, FDA will:

- Continue to assist state programs and provide oversight in implementing the Standards program;

- Continue to support enrolling new jurisdictions in the program while continuing to provide support and guidance to those jurisdictions already enrolled; and,
- Continue support of conducting audits of those enrolled in the Standards program in accordance with the Standards protocol.

### **Dietary Supplements**

The dietary supplement industry is one of the world's fastest growing with over 1,500 establishments claiming to manufacture dietary supplements and sales of \$17.1 billion in 2000. Between 1994 and 2000, consumer spending on dietary supplements nearly doubled, with over 158 million consumers, and sales growing more than 10 percent per year. Nearly 20 million consumers use dietary supplements with prescription products. FDA is committed to making safe products available to consumers, and has published a dietary supplement strategy that sets clear program goals. It is a science-based regulatory program that will fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA). Base funding will enable FDA to:

- Respond to at least 95 percent of premarket notifications for new dietary ingredients within the statutory time frame of 75 days;
- Review the 30-day postmarket notifications for structure and function claims in a timely manner; and,
- Continue the collaborative effort on dietary supplement research with the National Center for Natural Products Research in Oxford, Mississippi.

### **Bovine Spongiform Encephalopathy (BSE)**

BSE or “Mad Cow Disease” is a deadly chronic, degenerative disorder affecting the central nervous system. BSE and Chronic Wasting Disease (CWD) both belong to a group of fatal progressive degenerative neurological diseases, including those that affect humans such as Creutzfeldt-Jakob disease (CJD). Potential products regulated by the program that can contain these substances are ruminant protein-containing cosmetic products that are packaged and ready for sale, and bovine-derived materials intended for human consumption as either finished dietary supplement products, or for use as ingredients in dietary supplements. Base funding will enable FDA to:

- Continue to identify food and cosmetic products containing brain, spinal cord, and other specific risk materials, including the origin of the animal and country, and infectious agents in foods;
- Continue to conduct research on decontamination or deactivation procedures; and,
- Continue to conduct research on BSE recovery and identification methods from foods and cosmetics.



### **International Codex-Related Activities**

It is important that FDA leverage scarce resources with the international community to provide benefits and incentives for all participants while accomplishing the mission of ensuring the safety of the domestic food supply. FDA will participate in several Codex Committees and Task Forces to help assure that Codex standards provide for the highest level of public health protection and to make Codex standards, to the extent possible, consistent with requirements of the Federal Foods, Drugs, and Cosmetics Act (FFDCA). Such Codex standards, when applied by U.S. trading partners, will increase the safety of their exported food, and help them to meet U.S. requirements.

### **Premarket Activities**

FDA focuses premarket resources to provide for scientifically sound and timely reviews of the safety of food and color additives and food contact substances prior to their entry into the marketplace. To accomplish this, FDA needs to continue to improve the scientific knowledge base that will lead to safer food products and to a better understanding of the complexities of the products the agency regulates. The FDA Modernization Act established a notification process for food contact substances. Since the premarket notification program became fully operational in January 2000, many of the simpler food additive petitions that could have been completed within 360 days are now being handled under the notification program as food contact substance notifications, thus decreasing the workload for this goal. However, since the remaining petitions are usually more complex and time-consuming ones, the Agency anticipated that performance on this goal could decline initially. Once the notification and the recent improvements to the petition review process are well established, FDA expects performance on this goal to increase substantially toward full performance in succeeding years. With base funding, FDA will:

- Continue to reduce the possibility of food-related deaths or injuries and improve the health and well-being of consumers by ensuring that decisions related to approvals of petitions and notifications are scientifically justified and benefit the public health;
- Continue to develop premarket review standards for new products and emerging technologies such as antimicrobial ingredients used in the preparation of processed foods, address the human food safety aspects of genetically modified foods, address the use of novel ingredients added to conventional foods, and ingredients new to infant formulas and medical foods;
- Continue to consult with developers of foods derived from bioengineered plants to ensure that all safety and regulatory questions are resolved prior to marketing;
- Respond to at least 95 percent of premarket notifications for new dietary ingredients within the statutory time frame of 75 days;
- Respond to premarket notifications for food contact substances within the statutory time frame of 120 days;
- Improve the premarket review process for food and color additives using advanced computer and telecommunications technologies and complete review and action on the safety evaluation of 75 percent of food and color additive petitions within 360 days of receipt;

- Continue to provide pre-filing assistance to petitioners through the publication of detailed guidance for food contact substances and food and color additives; and,
- Review 95 percent of premarket notifications for food contact substances within the statutory time limit of 120 days.

### **Other Program Activities**

Under the FFD&C Act, Section 704, FDA is granted general authority to inspect food establishments, and under Section 903, the Agency shall be responsible for research relating to foods and cosmetics in carrying out this Act. FDA will continue to advance egg safety and other compliance and enforcement programs, by continuing research on egg safety as well as education and outreach activities on the proper handling, storage and cooking of eggs. FDA also continues to implement all enforcement efforts of the rule on egg refrigeration/temperature and labeling.

### **Seafood Safety**

FDA continues to provide assistance directly to industry and consumers through provision of information and education activities.

- Continue working with the Interstate Shellfish Sanitation Commission (ISSC) to promote educational and research activities related to shellfish safety, especially *Vibrio vulnificus*.
- Continue to provide expert scientific and technical advice and assistance on the conduct of international seafood activities, including the development and implementation of bilateral agreements.

### **Information Technology**

*CFSAN Adverse Events Reporting System (CAERS)*: Previously, CFSAN had several systems to monitor adverse events: the Adverse Reaction Monitoring System for food and color additives, the Cosmetics Adverse Reaction Monitoring Database for cosmetic products and the Special Nutritional Adverse Event Monitoring System (SN/AEMS) for dietary supplements, infant formulas, and medical foods. In June 2003, after two years of development, these systems were combined into the CFSAN Adverse Event Reporting System (CAERS) database, with which CFSAN staff now track, evaluate, and monitor all adverse events and consumer complaints received about CFSAN regulated products.

Besides mining food and cosmetic adverse event data for patterns, trends and signals, CAERS has put into operation a database search engine capable of responding to a large variety of inquiries from Congress and others, and is capable of generating yearly reports that will describe the voluntary food and cosmetic adverse event reports received. CAERS has become a critical tool for identifying new and emerging food and cosmetic public health problems.

*Food Additives Regulatory Management (FARM)*: FARM provides information management tools for food additive petition reviewers to maximize productivity and expedite the petition review process and subsequent safety decisions. This comprehensive image-based electronic document management and workflow automation system also helps FDA perform associated activities such as responding to and managing Freedom of Information requests and correspondence. All paper and electronic documents are converted to standard formats and stored in an electronic document management system. Each reviewer is able to retrieve documents at their desks using a combination of attribute and full-text search capabilities supported by a thesaurus maintaining nomenclature control.

### **EMPOWERING CONSUMERS FOR BETTER HEALTH**

Base resources will be used to better enable consumers to make informed decisions weighing benefits and risks of FDA-regulated products. FDA will continue to participate in the FDA Task Force on Consumer Health Information for Better Nutrition, which is developing a framework to help consumers obtain accurate, up-to-date, and science-based information about conventional food and dietary supplements; This includes the development of additional scientific guidance on how the "weight of the evidence" standard will be applied, as well as the development of regulations that will give these principles the force and the effect of law.

### **Calories Count – Report of the Working Group on Obesity**

To help confront the obesity epidemic and help consumers lead healthier lives through better nutrition, FDA created the Obesity Working Group (OWG) to outline an action plan. OWG recommendations centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended. The recommendations contained in a report focus on a "calories count" emphasis for FDA actions such as those regarding Food Labeling, Enforcement Actions, and Educational Partnerships.

### **PATIENT AND CONSUMER PROTECTION**

Resources will be used to promote improved patient and consumer safety by reducing risks associated with FDA-regulated products. CFSAN will continue to enhance CAERS, which is designed to compile and assess large numbers of physician, health professional data and conclusions and provide likely associations and causative agents for follow-up through investigation and clinical testing. CAERS will integrate its multiple adverse event reporting systems currently in existence, including the current system for dietary supplements.

### **PROTECTING THE HOMELAND -- COUNTERTERRORISM**

Base resources will be used to strengthen FDA's capability to identify, prepare for, and respond to terrorist threats and incidents.

### **Food Safety and Defense**

FDA helps to protect the safety of the food supply by targeting efforts to minimize health and safety risks facing the U.S. public, and by quickly and accurately assessing and effectively managing those risks. FDA must work to develop profiles of possible or probable food threats and points of attack and must have the capacity to quickly and accurately identify potential or

actual outbreaks at any point in the food chain, and take prompt action to mitigate their effects. Base funding will enable FDA to:

### **Laboratory Preparedness**

- In conjunction with ORA, continue the development of methods science to support the critical infrastructure needed for FERN, which will provide integrated laboratory solutions and disseminated testing capacity to support public health preparedness and response to an act of bioterrorism involving the food supply. FERN will specialize in high throughput/rapid testing of food products for biological, chemical and radiological threat agents using trained personnel who routinely handle food samples and specialize in this discipline. Although some of CDC's LRN labs are multidisciplinary and have some food testing capability, these labs would not have sufficient throughput/ rapid testing capacity to handle requirements should an event threatening the food supply occur. FERN would have microbiological, chemical, and radiological food testing capability/capacity to address over 60,000 different food commodities;
- Continue to support the operation of FERN, including the articulation of interim methods, the development and delivery of training modules, the establishment and integration of laboratory communication systems and protocols, the integration with agency crisis management procedures, establishment of methods validation systems, and the establishment of proficiency programs for microbiological, chemical and radiological detection methods. Resources also enhance the preparedness of CFSAN laboratories that are part of FERN and/or LRN;
- Continue the laboratory accreditation program covering all Center foods facilities for harmonizing practices in food laboratories to ensure acceptance of FDA laboratory results throughout the world (this will include enhanced data quality systems and support for instrument validation);
- In conjunction with ORA, continue diagnostic tests to produce tools that are needed for field and import examinations to determine if a product has been tampered with or is otherwise tainted;
- In conjunction with ORA, continue expanding the number and capabilities of state health and agriculture laboratories, and current laboratories connected to eLEXNET to allow the labs to exchange data on select biological agents (possibly including anthrax, botulinum toxin, brucellosis and other potential infectious diseases) and food pathogens. This system is the first Internet-based food safety system that will link state and local organizations with Federal partners to respond more quickly to outbreak situations;
- Maintain preventative standards, education campaigns and research to improve food safety and security through rapid tests of detection and reduction;
- Continue streamlining techniques for the rapid detection and assessment of bacterial strains of bioterrorist agents (pathogens/chemicals); and,

- Continue to assist in developing irradiation techniques and methods to kill anthrax spores in the mail by participating with industry, which already uses irradiation to sanitize poultry, ground beef, spices, and medical equipment.

**Prior Notice and Foods Registration System**

- In conjunction with ORA, continue regulatory guidance in an expedited time period in order to implement Title III of the BT Act. The FDA is required to propose and issue final regulations for the following four provisions: Section 305 (Registration of Food Facilities); Section 306 (Establishment and Maintenance of Records); Section 307 (Prior Notice of Imported Food Shipments); and Section 303 (Administrative Detention); and,
- Maintain the Food Registration and Prior-Notice system.

**Information Technology**

*FDA Unified Registration and Listing System:* FURLS supports the requirements of the BT Act as it relates to Food Facility Registration, Drug Facility Registration and Listing, and Prior Notice of Food Shipments into the U.S. FDA began FURLS by identifying opportunities for unification between the FDA Drug Facility Registration and Listing requirements with those of the Food Facility Registration Requirements.

**SELECTED FY 2004 ACCOMPLISHMENTS**

**USING RISK-BASED MANAGEMENT PRACTICES**

***“Food Current Good Manufacturing Practices CGMPs”***

*The FDA Food GMP regulations had not been revised since 1986. During the intervening years, important new developments such as food allergens and new pathogens such as Listeria monocytogenes caused us to believe that it was time to make changes to the regulation to address the previously unforeseen concerns.*

*CFSAN conducted research projects related to Food GMP modernization, literature searches and a survey of food recalls from 1999-2003. Based in part on this research, FDA concluded that a modernization of the Food GMPs (21CFR 110) was needed.*

*This initiative will lead to new regulations that will require manufacturers to prevent contamination of foods with undeclared food allergens and strengthen sanitation controls for high-risk foods (those that support the growth of L. monocytogenes). The new regulation will require that all food workers receive training in food safety and GMPs, and that all food manufacturers develop written procedures for cleaning and sanitizing equipment that comes into contact with foods.*

## **Seafood Safety**

***Vibrio vulnificus***: Continued to work with the Interstate Shellfish Sanitation Conference (ISSC) to encourage the post-harvest treatment of Gulf Coast oysters and to monitor progress toward the ISSC illness reduction goals. FDA participates in the ISSC's *Vibrio* Management Committee and various working groups organized under that committee. The ISSC conducted a survey that demonstrates that the shellfish industry's capacity to conduct post-harvest treatment in Gulf Coast oysters well exceeded its goal of 25%, and continued to refine the standardized methods to validate post harvest treatment processes to facilitate industry adoption of the processes.

**Methylmercury Advice**: In FY 2004, FDA and the EPA prepared a joint consumer advisory entitled: "What You Need to Know about Mercury in Fish and Shellfish." The advisory made several recommendations and answers frequently asked questions for selecting and eating fish or shellfish and reducing exposure to high levels of mercury in women who may become or are pregnant, nursing mothers, and young children.

## **Fruits and Vegetables**

**Juice HACCP Guidance**: FDA published a guidance document related to the processing of juice entitled: "Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition," with FDA's views on potential hazards in juice products and actions on how to control such hazards. It is designed to assist juice processors in the development of their HACCP plans.

### **"Safe Produce"**

*Because of the importance of fresh produce in a healthy diet and continuing outbreaks associated with the consumption of fresh produce, FDA developed the Produce Safety Action Plan to minimize foodborne illness associated with these foods and to target microbial food safety hazards (such as bacteria, viruses, and parasites) in or on imported or domestic produce consumed in the U.S. The Action Plan extends to all parts of the food chain from farm through retail or consumer preparation and consumption, as FDA believes that each entity involved in producing, packing, processing, transporting, distributing, or preparing fresh produce has a responsibility to conduct its activities so as to reduce, control, or eliminate microbial contamination of produce. It is intended to cover fresh fruits and vegetables, both in their unpeeled, natural form and raw products that have received some minimal processing (such as peeling, chopping, or trimming).*

*The Action Plan's objectives are:*

- *Prevent Contamination of Fresh Produce with Pathogens;*
- *Minimize the Public Health Impact When Contamination of Fresh Produce Occurs;*
- *Improve Communication with Producers, Preppers, and Consumers about Fresh Produce; and,*
- *Facilitate and Support Research Relevant to Fresh Produce.*

**International Good Agriculture Practices (GAP) Outreach in Conjunction with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN):** FDA and JIFSAN conducted a train-the-trainer program in Guatemala, Honduras, and South Korea on Good Agricultural Practices (GAPs) and GMPs for the production of fresh produce. Participants were trained in good agricultural and manufacturing practices.

### **Transmissible Spongiform Encephalopathies (TSEs)**

**BSE Interim Final Rule:** FDA published an interim final rule: “Use of Materials Derived From Cattle in Human Food and Cosmetics.” Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. To address the potential risk of BSE in human food, including dietary supplements, and cosmetics, FDA is issued an interim final rule to prohibit the use of certain cattle material.

**BSE Risk Assessment:** FDA completed a risk assessment on the potential for variant Creutzfeldt-Jakob Disease (vCJD) in humans from exposure to cosmetics containing cattle-derived protein infected with the BSE agent, and is making this document available to the public to communicate the potential public health risk from cosmetics made with cattle materials that may be contaminated with the BSE agent.

### **Premarket Review of Food Ingredients**

#### **Food and Color Additives**

**Food and Color Additive Petitions – Expedited Review:** for the petition receipt cohort of FY 2003, FDA met its goal to complete within 360 days of filing, the safety evaluation of two of the three food additive petitions that qualify for expedited review. A petition qualifies for expedited review if the food additive is intended to decrease the incidence of foodborne illnesses through its antimicrobial actions against human pathogens that may be present in food.

**Food and Color Additive Petitions – Non-expedited Review:** for the petition receipt cohort of FY 2003, FDA completed within 360 days of filing, the safety evaluation of four (80%) of five food additive petitions that do not qualify for expedited review. This exceeds the goal of completing at least 70% of these petitions within 360 days.

**Biotechnology Consultations:** FDA completed the scientific evaluation of 6 of 7 (85%) biotechnology consultations within 180 days.

**GRAS Notifications:** FDA completed the scientific evaluation of 19 of 23 (83%) GRAS (generally accepted as safe) notifications within 180 days. CFSAN has accepted and filed 157 GRAS notifications since the initiation of the program.

**Food Contact Notifications:** FDA completed the review of all Food Contact Notifications Within the 120-day statutory timeframe.

## **Chemical Contaminants, Pesticides and other Hazards**

**Chloramphenicol:** In FY 2001 and early 2002, the EU and Canada reported finding chloramphenicol (CAP), a banned substance, in honey exported from China. In response, FDA developed new analytical methodology and began testing honey for CAP. From March 1, 2002 through December 31 2003, FDA tested 698 imported honey samples and found 37 positive samples. During 2004, FDA also tested 13 domestic honey samples, all of which were negative. From January 1 through September 2004, FDA tested 108 imported honey samples and found 1 positive sample.

**Pesticides Monitoring:** FDA collected and analyzed over 8,000 food samples for pesticide residues during the FY 2004. FDA must maintain resource levels devoted to the sampling and analyses of pesticide, not only to ensure that the U.S. food supply is safe, but also to reduce dietary exposure.

**FDA's Dioxin Strategy:** FDA continued implementation of its dioxin strategy including monitoring, method development, and identification of opportunities to reduce exposure. Specific accomplishments in FY2004 include:

- Posting data on dioxin-like compounds (DLCs) in 2000, 2001 and 2002 Total Diet Study food samples; and,
- Posting exposure estimates for DLCs in total U.S. population and 14 age-sex subgroup populations.

**Perchlorate Analytical Method:** FDA developed an accurate and sensitive method to determine the perchlorate in selected fruits and vegetables and also in bottled water and milk using ion chromatography-tandem mass spectrometry. The method was posted on the CFSAN website and is successfully being used by FDA and other government and private laboratories.

## **EMPOWERING CONSUMERS FOR BETTER HEALTH**

### **Education**

**Listeria and Methylmercury Education:** Print materials and videos were completed and distributed to targeted audiences in the agency's effort to train health educators teach food safety to pregnant women and women who may become pregnant about the risks of methylmercury in seafood and *Listeria monocytogenes* in refrigerated food.

**Seafood Safety:** Developed and distributed seafood safety education materials, methylmercury advisory information and fotonovellas for *Vibrio vulnificus* in seafood to target audiences.

**Hispanic Outreach:** In FY 2004, CFSAN exhibited and distributed Spanish and English food safety materials at seven Radio Unica health fairs held in San Francisco, Miami, Houston, Dallas, San Antonio, Phoenix, and McAllen, TX. These followed four Radio Unica health fairs in FY 2003 in New York, Los Angeles, Chicago, and Fresno, attracting over 25,000 people, and



the 60-second health messages broadcasted in conjunction with these fairs reached some 14.1 million Hispanic adults.

**Food Safety and Security Health Professionals Program:** FDA, in partnership with the CDC, FSIS, the American Medical Association, and the American Nurses Association (ANA) issued an educational primer entitled: “Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals.” The new primer will assist physicians and other health care professionals be aware of what to look for in relation to foodborne disease, whether accidental or deliberate.

### **Nutrition, Health Claims and Labeling**

**Qualified Health Claims:** FDA published in an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels.

**Consumer Research on Qualified Health Claims:** Completed consumer research to help ensure that qualified health claim messages in the labeling of foods and dietary supplements employ the most effective wording so that the messages are not misleading to consumers.

**Nutrient Content/Health Claims Petitions:** Completed the review of eight nutrient content claim petitions/notifications and twenty-three health claim petitions/notifications within the statutory timeframe.

**Infant Formula Premarket Notifications:** Completed twenty-five 90-day infant formula notifications within the mandated 90-day review period.

**Trans Fat Education:** FDA Public Affairs Specialists were provided a technical presentation promoting *trans* fat education and outreach, including a script about the new labeling requirements to facilitate accurate communication to stakeholders. The FDA Consumer featured a cover story about *trans* fats and all information, including press documents, regulations, Q&A’s, and consumer information was posted on the CFSAN Web site. These documents also were sent to numerous CFSAN stakeholders. FDA also completed a Web-based interactive article in English and Spanish and a new presentation to accompany the consumer article.

## **PATIENT AND CONSUMER PROTECTION**

### **Dietary Supplements**

**75-Day New Dietary Ingredient Notification:** FDA received 49 and responded to 47 notifications for dietary supplements containing new dietary ingredients. The notifications are reviewed for science-based evidence of safety.

**30-Day Nutrient Content/Health Claim Notifications:** Under sec. 403(r) (6) of DSHEA and 21 CFR 101.93(a), nearly 2,000 submissions were received. Each submission identified the claims being made for one or more products. CFSAN sent out 47 letters in response these submissions that addressed one or more issues, such as claims contained in the notifications that were outside the scope of section 403(r) (6), of technical deficiencies of the submission, or that products did not appear to be dietary supplements under current law.

**Substantiation Guidance:** FDA published a draft guidance for industry entitled: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act), to describe the amount, type, and quality of evidence FDA recommends a manufacturer have to substantiate a claim under section 403 (r)(6) of the Act. It does not extend to substantiation issues that may exist in other sections of the Act.

FDA intends to apply a standard for dietary supplements and other health related products of “competent and reliable scientific evidence.” FDA seeks comments on this draft guidance only as they relate to FDA’s use and application of the standard and approach that are described in the guidance. We are not seeking comment on FTC’s application, use, or interpretation of their standard.

### **“Ephedra”**

*FDA issued a final regulation declaring dietary supplements containing ephedrine alkaloids adulterated under the FFD&C Act because they present an unreasonable risk of illness or injury. FDA took action based upon the well-known pharmacology of ephedrine alkaloids, the peer-reviewed scientific literature on the effects of ephedrine alkaloids, and the adverse events reported to have occurred in individuals following consumption of dietary supplements containing ephedrine alkaloids.*

*Ephedrine alkaloids, such as ephedrine, pseudoephedrine, norephedrine, methylephedrine, norpseudoephedrine, methylpseudoephedrine, are chemical stimulants that occur naturally in some botanicals, but can be synthetically derived. Their ingredient sources in dietary supplements include raw botanicals (i.e., plants) and extracts from botanicals. Ma huang, Ephedra, Chinese Ephedra, and epitonin are several names used for botanical ingredients that are sources of ephedrine alkaloids. Other common names used include sea grape, yellow horse, joint fir, popotillo, and country mallow.*

*Over the last decade, dietary supplements containing ephedrine alkaloids have been labeled and used primarily for weight loss, energy, or to enhance athletic performance.*

### **Cosmetics**

**Certified Color Additives:** CFSAN continued to analyze all batches of color additives and determine certification status within an average of 5 working days.

## **PROTECTING THE HOMELAND – COUNTERTERRORISM**

### ***Implementation of Bioterrorism Legislation – Registration, Prior Notice, Recordkeeping, and Administrative Detention***

*FDA published an interim final regulation requiring domestic and foreign manufacturers that pack, or hold food for human or animal consumption in the U.S. to register with FDA by December 12, 2003. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine its source and cause, and will help FDA to quickly notify potentially impacted facilities. When the IFR published, FDA estimated that about 420,000 facilities would register. To date, 236,535 facilities have registered, and FDA believes that most of the facilities required to register have already done so and thus believes that the original estimate was likely an overestimate.*

*Also in accordance with the BT Act FDA published an interim final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S. This allows FDA to know, in advance, when specific food shipments will be arriving and what those shipments will contain. This advance information allows the FDA, working with U.S. Customs, to more effectively target inspections and ensure the safety and security of imported foods. Since this rule was implemented in December 2003, FDA receives an increasing number of notifications about incoming shipment each day, with a current average of 30,000 notifications each day.*

*FDA also has published final rules for the Establishment and Maintenance of Records and Administrative Detention under the BT Act, which protects the U.S. human food and animal feed supply in the event FDA has a reasonable belief an article of food is adulterated and presents a credible threat of serious adverse health consequences or death to humans or animals. These records identify the immediate previous source(s) of all food received, as well as, the immediate subsequent recipient(s) of all food released. The final rule gives FDA the ability to trace back to get to the source of contamination, and to trace forward to remove adulterated food that poses a significant health threat in the food supply.*

*The final rule for the Administrative Detention provision under the BT Act establishes procedures for the detention of food for which the agency has credible evidence or information that it presents a threat of serious adverse health consequences or death to humans or animals. This rule describes how FDA can hold food in place while it initiates legal action to seize and permanently remove it from commerce. All four of these rules are part of the FDA's continuing effort to ensure the safety and security of the nation's food supply.*

## **Food Defense: Implementing the Bioterrorism Act of 2002 (PL 107-188)**

**Food Terrorism Risk Assessment:** FDA completed a risk assessment for food terrorism and other food safety concerns, one of a number of steps the agency is taking to improve its ability to prevent, prepare for, and respond to an incident of food sabotage.

**Food Safety and Security Guidance for the Retail Sector:** FDA published a guidance document related to food security entitled "Retail Food Stores and Food Service Establishments: Food Security "Preventive Measures Guidance." This guidance identifies the kinds of preventive measures that operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

**Food Safety and Security Guidance for Cosmetics:** The "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance" is designed as an aid to operators of cosmetics establishments (e.g., firms that process, store, repack, relabel, distribute, or transport cosmetics or cosmetics ingredients). It identifies the kinds of preventive measures that operators may take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

**Joint FDA/CBP Plan for Prior Notice Timeframes:** FDA and U.S. Customs completed a plan entitled "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes", which describes the process by which FDA and CBP intend to increase integration and coordinate timeframe requirements.

## **Food Defense: Emergency Preparedness**

**Food Emergency Response Network (FERN):** CFSAN and ORA initiated a multi-year effort to support the development of FERN. As such, CFSAN has been involved in multiple activities including:

- Serving as the lead for the proficiency program subcommittee, as the operational laboratory for microbiological proficiency samples, and supporting the activities of the ORA Forensics laboratory for chemical proficiency samples;
- Posting interim methods for priority chemical and microbiological agents on both the FERN and the CDC Laboratory Response Network (LRN) websites;
- Providing training to ORA, USDA, FERN, and LRN labs on detection of priority microbiological agents in a BSL-3 environment and on general food sampling protocols;
- Initiating review of the criteria for the validation of microbiological methods;
- Supporting the development of the organizational structure of FERN including active participation in the Steering Committee and all subcommittees;

- Establishing a “FERN store” for the stockpiling and distribution of kits and specialized reagent to the FERN labs;
- Continuing to identify and address infrastructure, training, and procedural needs for increased preparedness of CFSAN labs including acquisition of key equipment for microbiological and chemical agent detection;
- Completing all requirements for the use of select agents within three of the CFSAN labs, including inspection of laboratories by CDC; and,
- Two additional CFSAN laboratories (NCFST and College Park) into the LRN.

**Food Threat Assessment Evaluations:** FDA produced a "For Official Use Only" (FOUO) version of its classified Operational Risk Management (ORM) vulnerability assessment. CFSAN briefed FDA management, field management, state commissioners of health and agriculture and numerous food trade associations on the content of the document. Beginning October 2004, this document was used during an intensive 6-week assignment by FDA and state inspectors to brief management of targeted food processing facilities on the special risks that their products pose. Because the information in this document is likely to be the greatest detail that could be contained in a non-classified document, FDA has shifted its focus from performance of additional independent vulnerability/threat assessments to working with trade associations to perform their own assessments.

FDA completed training on the CARVER processes for the International Bottled Water Association (IBWA), the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF). With FDA support, IBWA has completed one CARVER analysis and is about to begin a second. IDFA and NMPF are scheduled to begin their first analysis in November 2004.

**Establishment of Prevention Measures:** In an effort to establish prevention measure shields for foods identified as a high security concern, FDA continued to acquire and communicate scientific information to the appropriate sectors in the following areas:

- FDA/CFSAN staff conducted numerous briefings with food industry representatives and State Agriculture and Health Commissioners on its initial food security assessment efforts;
- Through the Institute of Food Technologists, developed and conducted threat assessment training for medium and small food producers nationwide that will lead to improved security of food production facilities and processes;
- Partnered with industry to provide technical assistance in conducting CARVER threat assessments for foods identified as higher concern. CFSAN has four industry partnerships underway: dairy; bottled water; infant formula and produce; and,
- Developed and distributed milk and cosmetic industry security guidance.

**Intramural and extramural research on prevention strategies:** Three activities were initiated:

- (1) CFSAN has initiated a collaborative project with NCFST entitled “Thermal resistance of non-traditional microbial agents.”
- (2) CFSAN is in the planning stages of two collaborative projects with NCFST. The first project is entitled “Decontamination of Food Processing Facilities and Equipment.” The second project is entitled “Effect of Food Processing on the Inactivation of Protein Toxins and *Bacillus anthracis* Spores.” CFSAN and NCFST are presently interviewing post-doctoral candidates, who will be hired to perform these projects in the BSL-3 laboratory and pilot plant that is being built at NCFST.
- (3) FDA has collaborated with the National Institute for Allergies and Infectious Diseases, and the University of Wisconsin to examine the heat stability of botulinum toxin in raw milk.

**Emergency Response Exercises:** CFSAN participated in numerous emergency response exercises that included all levels of government including:

- the TOPOFF 3 Exercise Command Post Exercise Initial Planning Conference;
- an FDA-wide radiological emergency functional exercise to test FDA’s Radiological Emergency Response Plan;
- a Restaurant Association of Maryland Table Top Exercise Steering Advisory Committee Meeting in which representatives from the DHS, USDA, University of Maryland, and various MD state agencies were also present; and,
- an FDA Biochem Exercise.

**Training on the Bioterrorism Final Rules:** Training on two of the four BT Regulations, Food Facility Registration and Prior Notice of Imports, has been completed. A worldwide “Satellite downlink” public broadcast on the two final regulations was held on October 28, 2003. On the 3<sup>rd</sup> and 7<sup>th</sup> of November 2003, FDA held (1) BT Act’s Rules and Procedures – Handling questions (Satellite Downlink); and (2) Implementing the BT Act’s Rules and Procedures.

**Participation in IFWG:** In conjunction with the Interagency Food Working Group (IFWG), FDA/CFSAN served as lead for HHS in helping to establish the Food and Agriculture Sector critical infrastructure protection organization that brings together state officials and industry to further strengthen homeland security in the area of food security.

**Bioterrorism Help Desk:** Implemented the “FDA Industry Systems Help Desk” to respond to general and technical questions about the BT Act with respect to food facility registration and prior notice of imported foods. The Help Desk has responded to over 100,000 inquiries on the BT Act rules.

**Laboratory Upgrade:** CFSAN initiated the upgrade of laboratory facilities at the NCFST to the BSL-3 level, to allow NCFST to conduct food processing and packaging research that is geared to enhance food defense.

**Foods**  
**CFSAN Program Activity Data**

<b>PROGRAM WORKLOAD AND OUTPUTS</b>	<b>FY 2004 Actual</b>	<b>FY 2005 Estimate</b>	<b>FY 2006 Estimate</b>
<b><i>FOOD &amp; COLOR ADDITIVE PETITIONS</i></b>			
Petitions Filed	12	15	15
Petitions Reviewed *	13	16	16
* Number reviewed includes those approved, withdrawn, or placed in abeyance because of deficiencies during the FY.			
<b><i>PREMARKET NOTIFICATIONS FOR FOOD CONTACT SUBSTANCES</i></b>			
Notifications Received	85**	100	110
Notifications Reviewed ***	103	100	110
** Number does not include submissions expedited via FDA's Threshold of Regulation Process. *** Number reviewed includes those that became effective or were withdrawn.			
<b><i>INFANT FORMULA NOTIFICATIONS</i></b>			
Notifications Received <sup>a</sup>	27	30	30
Notifications Reviewed <sup>b</sup>	30	30	30
<sup>a</sup> Number of submissions received in current FY include some received late in the FY. <sup>b</sup> Number of submissions reviewed includes some submissions that were received in the previous FY.			
<b><i>NEW DIETARY INGREDIENT NOTIFICATIONS****</i></b>			
Submissions Received <sup>a</sup>	49	70	75
Submissions Reviewed <sup>b</sup>	47	70	75
FDA Review Time	75 Days	75 Days	75 Days

\*\*\*\* A single notification may address one or more new dietary ingredients. For example, FDA has received at least 15 notifications that contained between 2 to 16 new dietary ingredients in a single notification.

<sup>a</sup> Number of submissions received in current FY includes some received late in the FY that will be completed in the next FY when the 75-day due date occurs.

<sup>b</sup> Number of submissions reviewed in the current FY includes some submissions that were received in the previous FY where the 75-day due date occurred in the current FY.





## PERFORMANCE GOALS AND TARGETS

The following table of performance goals and FY 2006 targets is presented to compliment the sequential display of this program's "outputs" by more closely linking the traditional budget presentation of base and increased activities and workload outputs contained in the Program Activity Data (PAD) charts. Activities discussed throughout this narrative support the accomplishment of outputs (PAD and performance goals) which in turn contribute to the accomplishment of long term outcome and strategic goals. Full cost information for these goals as well as other historical information has been provided in their respective sections in the Detail of Performance Analysis contained in the supporting information tab.

<b>Performance Goals</b>	<b>Targets</b>
<b>Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements. (11001)</b>	FY 06: Complete review and action on the safety evaluation of 75% of food and color additive petitions within 360 days of receipt.
<b>Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the nation's food supply. (11010)</b>	FY 06: 84% of 49 states -- Increase the percentage of the U.S. population that will live in states that have adopted the Food Code.

**BLANK PAGE**