PERFORMANCE BUDGET OVERVIEW

Agency Mission Overview

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA) is responsible for promoting and protecting the health of the U.S. public. These responsibilities cover a wide range of regulatory activities.

FDA's Mission

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, Nations food supply, cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, to provide the public accurate, science-based information needed regarding medicines and foods to improve their health. FDA plays a significant role in addressing the Nation's counterterrorism capability and ensuring the security of the food supply.

FDA decisions affect virtually every American on a daily basis. Annually, consumers spent nearly $1.5 trillion, or more than 20 percent of all consumer expenditures, on FDA-regulated products. By operating as a knowledgeable and efficient agency responsive to our customers, FDA can provide better protection for consumers and more effectively promote their health with accurate health information.

FDA works to achieve its broad mission by managing efforts toward a comprehensive set of long-term strategic goals, continuing to place greater emphasis on linking program performance to budgetary resources. To achieve these goals, FDA focuses its resources toward five broad strategic goals that are supported by the Agency's annual performance goals. These goals are:

FDA Strategic Goals
Improving FDA's Business Practices (Formally: More Effective Regulation through a Stronger Workforce)
Using Risk-Based Management Practices (Formally: Efficient Risk Management: The Most Public Health Bang for our Regulatory Buck)
Empowering Consumers for Better Health (Formally: Empowering Consumers: Improving Health Through Better Information)
Patient and Consumer Protection (Formally: Improving Patient and Consumer Safety)
Protecting the Homeland -- Counterterrorism (Formally: Protecting America from Terrorism)

Annual performance goals that are discussed in this overview continue to contribute toward achieving long-term outcome goals that have a significant impact on the health of the U.S. consumer.

FDA's strategic goals fully support the Department's strategic goals and priorities which include:

- enhancing health science research;
- improving health care services;
- responding to bioterrorism and other public health challenges; and,
- enhancing management practices.

The following table demonstrates the relationships between Departmental goals and priorities and those of the FDA.

FDA STRATEGIC AND OUTCOME GOALS ALIGNED BY HHS STRATEGIC GOALS & FY 2006 SECRETARIAL PRIORITIES

HHS STRATEGIC GOALS	SECRETARY'S FY 2006 PRIORITIES	FDA STRATEGIC GOALS	FDA OUTCOME GOALS
Achieve Excellence in Management Practices	Strengthening Management	Improving FDA's Business Practices	Reduce administrative overhead at FDA by reducing the number of administrative staff.
Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	Preventing Disease / Illness	Using Risk-Based Management Practices	Reduce the average time to marketing approval for safe and effective new drugs, biologics, devices, and generic drugs.
Improve the Quality of Health Care Services	Accelerating the Adoption of Information Technology in Health Care	Patient and Consumer Protection	Reduce adverse drug events related to medication dispensing and administration errors. Increase the patient population covered by active surveillance of medical product safety.
		Empowering Consumers for Better Health	Increase consumer understanding of diet-disease relationships.
Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges.	Responding to Bioterrorism and other Public Health Emergencies	Protecting the Homeland -- Counterterrorism	Increase FDA's capacity to effectively analyze food samples for biological, chemical and radiological threat agents in the event of a terrorist attack.

Overview of FDA Performance

This section describes FDA's planning process, strategic goals and strategies used to achieve them, the results of the OMB program assessments in developing long-term outcome goals, and the relationship between the performance planning and traditional budget presentation.

FDA Strategic Goals

FDA's five strategic goals focus resources to accomplish its mission. These goals are:

Improve FDA's Business Practices -- This goal focuses on the critical infrastructure that provides scientific support and administration to FDA's programs. Managerial and operational efficiencies being pursued under this goal support the President's Management Agenda; the Secretary's FY 2006 priority of strengthening management by creating a more streamlined, cost-effective, and accountable organization; and the DHHS strategic goal of excellence in management practices.

Current strategies to align FDA activities with these initiatives include:

- Using competitive sourcing to maximize cost-effective performance of functions;
- Developing more robust program performance data to demonstrate progress in meeting long-term outcome goals;
- Creating flexible human resource policies and programs to recruit, reward, and retain state-of-the-art scientists and health professionals; and,
- Creating a modern and efficient infrastructure, and operating the Office of Shared Services, to support mission-critical activities.

To Improve FDA's Business Practices, the key performance goal in FY 2006 is:

Improving FDA's Business Practices

Performance Goal

- Increase the percentage of contract dollars allocated to performance-based contracting.

Using Risk-Based Management Practices -- This strategic goal focuses on the safety and effectiveness of FDA-regulated products, while emphasizing risk management efficiencies. Developing and applying approaches that provide the most health protection at the least cost both improves agency cost-effectiveness and supports better industry efficiency and market competition. Ultimately, the improvements will help control health care costs.

In pursuing this goal, FDA uses the best available data and analytic methods to assess risk and target cost-effective risk management, for both pre- and post-market regulation, with continued evaluation of program performance.

FDA is employing four strategies to achieve this goal:

- Provide a timely, high quality, and cost-effective process for review of new technologies/premarket submissions;

- Provide high quality, cost-effective oversight of industry manufacturing, processing and distribution;

- Ensure the safety and security of the U.S. food and cosmetics supply to protect consumers; and,

- Identify the most effective and efficient risk management strategies and optimize regulatory decision-making.

For Risk-Based Management Practices, key FY 2006 goals include:

Risk-Based Management Practices

Outcome Goals

- Reduce average time to marketing approval for safe and effective new drugs and biologics;

- Reduce average time to marketing approval or tentative approval for safe and effective new generic drugs;

- Reduce average time to marketing approval for safe and effective new medical devices.

Performance Goals

- Ensure that a safe and effective drug supply is available to the public;

- Increase risk-based compliance and enforcement activities to ensure product quality; and,

- Provide premarket reviews within statutory time frames to assure the safety of food ingredients, bioengineered foods and dietary supplements.

Empowering Consumers For Better Health – This strategic goal focuses on providing the best available information of the risks and benefits of using FDA-regulated products to patients, consumers, and health professionals.

FDA believes that well-informed consumers and health professionals can bring about improved health if they have accurate and timely information to make informed decisions on diet, nutrition, and health care. FDA believes that significant public health benefits will result when consumers have access to, and use, information to aid them in their purchases, information that goes beyond just price, convenience and taste, but extends to include science-based health factors. More scientifically based information about the nutritional content and health benefits of foods can help consumers make tangible differences in their own long-term health by lowering their risk of numerous chronic disease, particularly those caused by obesity.

Strategies employed to achieve this strategic goal include:

- Developing an understanding of what information consumers need to make informed product choices;

- Developing the mechanisms necessary to communicate to a variety of audiences;

- Assuring that information communicated to consumers is based on sound scientific evidence; and,

- Determining the impact of FDA communications on constituents' understanding, behavior, and health outcomes.

Empowering Consumers For Better Health

Outcome Goal
- Increase consumer understanding of diet-disease relationships

Performance Goal
- Increase risk management strategies and communication to government, industry and consumers in order to ensure the safety of the Nation's food supply.

Patient and Consumer Protection - This strategic goal focuses on improving the identification, resolution, and communications of health risks to health care professionals and to patients.

FDA strives to minimize adverse health events involving FDA-regulated products. While it is rare that risks associated with medical products are fully revealed during the premarket review process, adverse events may emerge after use in wider patient and consumer population. Some of these potential adverse health effects may be prevented if systems are upgraded to improve the speed in which risks are identified.

To accomplish this goal, FDA is pursuing these strategies:

- Enhancing the ability to quickly identify risks associated with FDA-regulated products;
- Developing analytical capability to identify and quantify medical product risk;
- Enhancing the capability to quickly resolve medical product risks; and,
- Increasing communication of risks to educate health care professionals and patients about problems and solutions associated with appropriate product use.

Patient and Consumer Protection

Outcome Goals
- Increase the patient population covered by active surveillance of medical product safety; and,
- Reduce adverse drug events related to medication dispensing and administrative errors.

Performance Goal
- Improve the safe use of drugs in patients and consumers

Protecting The Homeland -- Counterterrorism - This strategic goal focuses on FDA's preparation and response to potential acts of terror. Specific strategies are:

- Facilitating the development and availability of medical countermeasures to limit the effects of an attack on civilian or military populations;
- Enhancing FDA's emergency preparedness and response capabilities to be better able to respond to a terrorist attack;
- Ensuring the safety and security of FDA personnel, physical assets, and sensitive information; and,
- Implementing Homeland Security Presidential Directive-9 and the

Bioterrorism Act of 2002 to protect the security of foods and animal feeds.

Protecting The Homeland -- Counterterrorism

Outcome Goal

- Increase the capacity to effectively analyze food samples for biological, chemical and radiological threat agents in the event of a terrorist attack; and,

Performance Goals

- Enhance the Agency Emergency preparedness and response capabilities to be better able respond in the event of a terrorist attack.

Role of the OMB Program Assessments in Developing Long-Term Outcome Goals - In the FY 2004 PART evaluation, OMB identified two key areas in which the FDA should strengthen its results orientation:

- Develop specific long-term outcome goals that tie to improved public health and safety; and,

- Develop efficiency goals to demonstrate more streamlined government operations.

In response, FDA developed eight long-term outcome goals (including an efficiency goal) that were then included in the FY 2005 PART review and FY 2005 Performance Plan.

As a result, OMB's FY 2005 PART evaluation yielded a much improved score, with a rating that improved to "moderately effective." FDA leadership developed baseline information for the eight outcome goals to help measure progress.

FDA Strategic Action Plan and Agency Follow-up - To meet the strategic goals' performance commitments specified by the annual performance and outcome goals, Agency leadership also developed a Strategic Action Plan (issued in August 2003) which provided the framework for meeting these commitments.

To monitor the strategic action plan's objectives and the Government Performance and Results Act performance commitments, FDA established a senior level Strategic Planning Council was established to ensure timely progress.

In January 2004, this Council agreed to establish a performance framework to systematically link an array of program activities, outputs, and outcomes to support and demonstrate progress in meeting long-term outcome goals, and directed that OMB and DHHS be informed of FDA's progress in achieving these goals. During the spring, the Council also used performance and budget information to make decisions on FY 2006 funding priorities.

Relationship Between the Strategic Action Plan and the Performance Budget - The five strategic goals outlined above constitute the foundation for both the Strategic Action Plan and the FY 2006 Performance Budget that is aligned by strategic goal within each program's justification of base presentation.

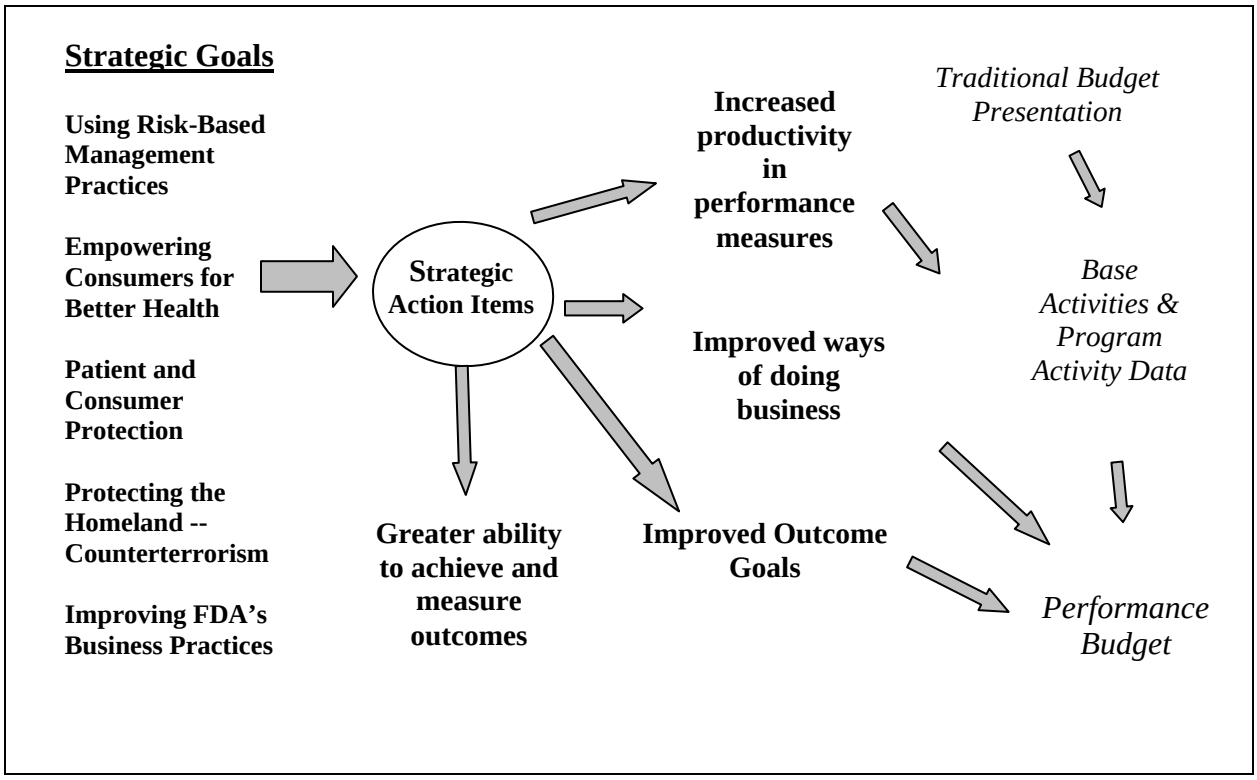
Action items emerging from the Strategic Action Plan will have several beneficial effects on performance planning. First, several of these items constitute improved ways of conducting the FDA's core business. Second, many of the action items enhance FDA's ability to identify, measure, and influence public health outcomes, resulting in a greater proportion of future performance goals being outcome-oriented.

In addition, budget and performance integration efforts have more consciously linked resources with results, presenting a more complete picture.

The presentation order in this performance budget is: base activities (Justification of Base); FY 2004 accomplishments; program activity data (PAD); and performance targets. The resource request funds base activities that in turn support the accomplishment of discrete workload outputs (PAD and performance goal targets) which contribute to achieving long term public health outcomes and strategic goals. The diagram below illustrates the relationship among strategic action planning, performance planning and budget presentation.

Flow of Performance Information into Performance Budget

From Strategic Goals through Action Items, Outcome Goals, Performance Measures, Program Activity Data, and Base Activities to Performance Budget



FY 2006 Budget Request

In accordance with FDA's strategic plan, certain activities require increased funding in order to achieve key goals. The proposed increases will allow FDA to maintain performance at current levels while supporting important new initiatives and facing new challenges that fall within its mission.

This request includes the following programmatic changes:

FY 2006 Summary of Change
Program Level
(Dollars in $000)

Increase Area	Total
Food Defense	$30,074
Medical Device Review	$5,996
The Office of Drug Safety	$5,000
GSA Rental Payments	$4,100
White Oak Consolidation	$4,128
Buildings and Facilities	$7,000
Administrative Efficiencies	($1,554)
Information Technology Reduction	($5,116)
User Fees	$31,320
Total	**$80,948**

Food Defense: + $30,074,000

To build upon gains that will be achieved with funds appropriated for food defense in FY 2005, FDA and the USDA, in conjunction with the White House Homeland Security Council, have continued to develop a joint food defense budget to protect the agricultural and food sectors. Within this initiative, FDA's request encompasses the following cross-cutting Administration priorities:

1. Establishing a national network known as the Food Emergency Response Network (FERN) to increase analytic surge capacity in the event of terrorist attack by developing adequate laboratory testing capacity for biological, chemical and radiological threats;

2. Targeted food defense research efforts, including prevention technologies, methods development, determination of infectious dose for certain agents when ingested with food, and agent characteristics within specified foods;

3. More effective targeted, risk-based inspections using data from FDA's Prior-Notice system as authorized in the 2002 BT Act;

4. Improved coordination and integration of existing food surveillance capabilities with the Department of Homeland Security's (DHS) integration and analysis function, as part of the government-wide Bio-Surveillance Initiative; and,

5. Upgrading Crisis/Incident Management capabilities.

This request will enable FDA to effectively address our laboratory, research, inspectional, biosurveillance and crisis management needs. FDA and USDA are developing a national laboratory network that will enable us to test thousands of food samples within a matter of days in the event of an act of terror or other emergency. This network must be undergirded by a strong research program to ensure that we can detect or inactivate certain agents if they are present within foods. This requested increase will also support the

Administration's biosurveillance initiatives and improve our incidence management capabilities.

The events of September 11th heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures, such as the food supply. As a result of this awareness, FDA has made fundamental changes in how we implement our mission of protecting the food supply, so that all Americans can have confidence that their food is not only safe but also secure. With this request, the Agency can continue to make progress in achieving our food defense goals.

With the continued rapid growth in food imports, FDA has become aware that pursuing food safety through import field exams alone is not the most effective strategy. The Bioterrorism Act of 2002, which established Prior Notice requirements, provided an additional tool to assess the risks of imported food and improve the focus of import food risk assessment. To complement FDA's import exams, Prior Notice Import Security Reviews receive and evaluate notices of imported foods prior to their arrival at our borders. These notices describe what each shipment contains and provides additional information such as country of origin, so that FDA is better situated to know what products are entering, whether they are of concern and if so, to conduct an examination at the port. The Prior Notice Center (PNC) operates side-by-side with the intelligence arm of the Customs and Border Protection to integrate and supplement this information.

Once an item is targeted, a security review is conducted. The PNC will receive feedback from import field exams and filer evaluations and begin targeting firms that continuously violate the law. They will also target commodities based on immediate and potential threats to the integrity and security of the food supply chain.

Medical Device Program: +$5,996,000

To strengthen FDA's medical device review process, the Medical Device User Fee and Modernization Act (MDUFMA) was authorized in FY 2002. MDUFMA is a multi-year effort to improve the quality and timeliness of the medical device review process, by authorizing the collection of user fees and creating an aggressive set of performance goals. This legislation only allows the Agency to collect user fees if a number of "triggers" are met, including achieving a certain level of budget authority for the Medical Devices and Radiological Health program. The ability to collect this user fee is critical to strengthen the medical device review process and to meet the medical device review goals by 2007.

FDA is requesting a $5,996,000 increase for medical device review, along with $40,300,000 in additional user fees for the Devices and Biologics Program. This will allow the Agency to meet the minimum statutory appropriation level of $220,823,000 for FY 2006. Without this increase, our ability to continue to collect user fees would be jeopardized.

The Office of Drug Safety: +$5,000,000

FDA's Center for Drug Evaluation and Research (CDER) is responsible for ensuring that America's drug product supply is, safe and effective, and of the highest quality. Ensuring drug product safety is a mission-critical function of CDER. Drug safety analysis and decision-making is the result of collaborative efforts among offices across the Center. CDER's Office of Drug Safety (ODS) is one such office involved in the overall drug safety function.

The $5,000,000 increase in funding will be used to strengthen the drug safety functions within ODS by: hiring additional staff to manage and lead safety reviews; increasing the number of staff with expertise in critical areas such as risk management, risk communication, and epidemiology; and, increasing access to a wide range of clinical, pharmacy and administrative databases.

GSA Rental Payments: +$4,100,000

This increase will help cover inflationary costs on properties that FDA occupies nationwide and increased rent costs at White Oak, will support the "Improving Business Practices" strategic goal and, will minimize the need to redirect resources from core programs to cover rental cost increases.

In this budget, FDA has revised its display of the GSA Rent and Other Rent and Rent-Related Activities budget lines by incorporating these costs into program-level requests. This display change will increase flexibility, eliminate many reprogramming requests to Congress, place accountability for rental cost within the operating programs, and better reflect the total cost of each program.

White Oak Consolidation: +$4,128,000

We are working with GSA to consolidate FDA at the government owned White Oak site in Montgomery County, Maryland. The new buildings will eventually replace all the existing fragmented facilities which support the Office of the Commissioner, ORA, CDER, CDRH, CBER, and CVM offices. Funding is needed to ready and occupy the project's next phase, which includes the CDRH Engineering/ Physics Laboratory and the consolidation of FDA's data center facilities. Funding will be used to equip and make the laboratory ready for occupancy. The consolidation of existing data centers will reduce the number of such facilities currently operating across FDA and will result in cost savings.

Building and Facilities: +$7,000,000

In FY 2005, the Agency did not request funding for building and facilities in order to fund other higher priority initiatives, but is now challenged to continue to sustain these buildings, some of which are over 50 years old, are in poor condition and which have deferred maintenance.

This increase will help cover the cost of repairs and improvements to existing owned or leased facilities that FDA occupies in 49 states and in the District

of Columbia and Puerto Rico. This includes approximately 40 buildings in 16 separate locations in Maryland; five regional offices, 19 field District complexes including 19 administrative and 13 specialized laboratory facilities nationwide and more than 120 field resident posts, eight field criminal investigation offices, two distinct program laboratory complexes outside the Washington D.C. Metro area; and the National Center for Toxicological Research complex in Jefferson Arkansas.

Management Savings: -$6,670,000

Management savings will accrue as a result of FDA's effort to continue to meet the President's Management Agenda goals by streamlining administrative and information technology (IT) service costs. Proposed management savings will result in a $1,554,000 reduction in administrative efficiencies and a $5,116,000 decline in informational technology spending. The effect of which is a loss of 29 FTE.

User Fees: +$31,320,000

This budget request includes user fee increases of $20,938,000 for prescription drug review, $6,362,000 for medical device review, $2,964,000 for animal drug review, $254,000 for mammography inspections, $24,000 for export certification, and $778,000 for color certification.

FOOD DEFENSE – COUNTERTERRORISM -- $30.074 Million

Desired Outcome

Safeguard the public by defending the food system against terrorist attacks, major disasters, or other emergencies.

Program Objectives

U.S. agriculture and food systems are vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or that are intentionally delivered by acts of terrorism. This system is extensive, open, and interconnected. FDA strives to provide the best protection possible against an attack on the food system, which could have catastrophic health and economic effects.

FDA, USDA's Food Safety & Inspection Service (FSIS), and the White House Homeland Security Council are implementing Homeland Security Presidential Directive-9 (HSPD-9), which established a national policy to defend the food supply from terrorist attacks. In this budget, the Administration requests $30,074,000 for FDA to implement this homeland security initiative.

The request, which continues food defense and counter-terrorism activities previously funded in FY 2005, supports the following HSPD-9 goals:

- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing response and recovery procedures; and,
- Enhancing screening procedures for domestic and imported products.

Based on the Administration's priorities, this request is focused primarily on five major cross-cutting initiatives:

- Establishing a national network known as the Food Emergency Response Network (FERN) to increase analytic surge capacity in the event of terrorist attack by developing adequate laboratory testing capacity for biological, chemical and radiological threats;
- Targeted food defense research efforts, including prevention technologies, methods development, determination of infectious dose for certain agents when ingested with food, and agent characteristics within specified foods;
- More effective targeted risk-based inspections using data from FDA's Prior-Notice system as authorized in the 2002 BT Act;
- Improved coordination and integration of existing food surveillance capabilities with the Department of Homeland Security's (DHS) integration and analysis function, as part of the government-wide Bio-Surveillance Initiative; and,
- Upgrading Crisis/Incident Management capabilities.

Requested Increases for FY 2006
(Dollars in $000)

Program	Center	Field	Total
CFSAN	4,822		4,822
Field/ORA		22,752	22,752
Other Activities	1,500		1,500
NCTR	1,000		1,000
Total	7,322	22,752	30,074

Lab Preparedness

FERN--$20.0 million
FERN, which is managed by ORA, is a multiyear effort to establish a comprehensive network of Federal and state laboratories across the U.S. that will enable FDA to test thousands of food samples within a matter of days in the event of an act of terrorism or other emergency.

The requested increase, in conjunction with base funding, will provide an additional 19 FDA-funded state laboratories, adding to the six that were funded in 2005 and to the 10 FDA laboratories that are already up and running. Currently, 93 labs in 42 states and Puerto Rico have satisfactorily completed the FERN Laboratory Qualification Checklist, which provides vital information to determine if a lab meets the criteria for participation in FERN and is eligible for Federal funding (see map at the conclusion of this section).

These funds will also permit FERN's National Program Office to manage the laboratory response in the event of a food related emergency and coordinate the FERN support programs which provide validated food testing methods, proficiency testing for laboratories, electronic communications, and training programs for laboratory personnel.

FERN, developed in accordance with HSPD-9, integrates the nation's laboratory infrastructure to detect and identify biological, chemical or radiological threat agents in food at the local, state, and Federal levels. Its primary objectives include prevention (Federal and state surveillance sampling programs); preparedness (strengthen laboratory capacity and capabilities); response (surge capacity to handle terrorist attacks or a national emergency involving the food supply); and, recovery (support recalls, seizures, and disposal of contaminated food to restore confidence in the food supply). FERN resources are leveraged by collaborating and coordinating with other lab networks including the Laboratory Response Network (LRN) and the National Animal Health Laboratory Network.

Food Defense Research--$5.574 million

This applied and targeted research initiative addresses the significant need for research funding to ensure our ability to detect or inactivate a broad range of agents that could pose serious threats to the food supply. These funds will:

- expand and accelerate the food defense research plan by identifying additional agent/commodity combinations which will effect the relevant food defense research thrusts of methods development, agent characteristics, prevention technologies, and dose-response relationships;

- provide the required base support from FDA for the microbial forensics program that the Interagency Agreement with the DHS/National Biodefense Analysis and Countermeasures Center specifies; and,

- help to maintain the foods defense research enterprise infrastructure (equipment maintenance and repair, BSL-3 labs, select agent inspections, animal care inspections, and LRN labs).

In the food defense area, mission-critical knowledge gaps are addressed through an integrated portfolio of intramural, extramural, and consortia-based programs, which address the need to anticipate, prevent, detect, respond, and recover from a terrorist attack on the food supply. This requires research activities in:

- knowledge of the behavior and susceptibility of the population to microbiological, chemical, radiological, and biologically-derived toxic agents in priority vulnerable foods during the stages of production, distribution, marketing, and preparation;

- identification and/or development of new techniques for "shielding" priority vulnerable foods through the development of new prevention and/or security technologies;

- development of enhanced sampling and detection methods for priority agents in vulnerable foods including field deployable and in-line sensor-based screening, analytical, and investigational (forensic) technologies;

- development of effective methods for ensuring that critical food production and manufacturing infrastructure can be rapidly and effectively decontaminated if a terrorism event were to occur;

- assessments of vulnerabilities of foods and identifying areas where enhancements in preventive measures could increase the security of the food supply, and,

- knowledge of consumer behaviors and the critical role consumers play in preventing illness associated with an attack on the food supply, to ensure timely and relevant information about threats and/or an attack is understood by consumers.

The mission critical needs require that the research not stop at the generation of new knowledge and technologies, but also include the validation of those approaches under realistic conditions that reflect the diversity of the food industry, and the transfer of that technology to the appropriate sectors of the food industry.

<u>Crisis Management: Emergency Operations Network Project and Incident Management System--$1.5 million</u>

The request also supports the Emergency Operations Network/Incident Management System Project to provide

a comprehensive system for managing emergencies and related incidents in FDA's centers and field offices. The development of this system conforms to HSPD-5, "Management of Domestic Incidents", and the establishment of a National Incident Management System.

The Emergency Operations Network Incident Management System (EON IMS), managed by the FDA Office of Crisis Management, is the central hub for exchanging and relaying all emergency-related information into, within, and outside of FDA. One of its overarching objectives is to integrate multiple data streams from other electronic systems – such as the FERN, eLEXNET, Epidemic Information Exchange (EPI-X), and from FDA laboratories/investigators and external agencies -- into a coherent fashion during critical decision points. This improved information management will create a safety net that significantly reduces the probability that terrorists will achieve their aims and minimize the impact of these threats if they occur. The EON IMS is important in all emergencies and exercises requiring efficient receipt and dissemination of large volumes of information to our stakeholders, including the public and other federal and state agencies. This system will provide a web-based connection for all FDA offices and our partners, through which accurate real-time information about various incidents can be shared and discussed.

The EON IMS, which is critical for the agency to manage, plan for, and respond to emergency situations, has three components: incident tracking and contact management, a collaboration and knowledge management tool for meetings and document management, and a Geographic Information System (GIS) for mapping and impact assessment.

By developing and incorporating agency-wide guidance in the EON IMS, FDA will ensure that its emergency response is uniform, consistent, and coordinated. Participants coordinating an emergency will be able to provide input and access real-time data regarding a specific emergency, Agency operating plans and procedures, contact databases, and analysis tools which will enhance the agency's capability of responding in the most efficient way possible.

For example, during a hurricane, EON IMS would provide a central location for FDA to disseminate real-time information about the storm. Using the GIS module, we will be able to view the locations of FDA regulated firms that have been severely impacted by the storm's path. That data can then be used by FDA to implement a targeted assessment and response of those industries that would have been the most severely impacted by the storm. Forecast advisories, health-related statistics, and other facts would be posted in the incident records for all users to view. Emergency contact information would be available for FDA representatives throughout the agency, including temporary information for those individuals deployed as part of an on-site response. These contacts would be sorted by their respective office or program area, and allow coordinators to track down experts as needed.

The EON IMS also provides a system for incident management to strenghthen preparedness capabilities of FDA. The

system will also be used during emergency preparedness and response exercises, establishing vital links with federal, state and local partners in accordance with HSPD-8, "National Preparedness."

In 2004, several outbreaks of Salmonellosis associated with Roma tomatoes affected approximately 400 people in over 15 states. FDA traceback and farm investigations with CDC and the respective state and local public health and agriculture agencies were coordinated by the FDA using a pilot version of EON. It was used to manage and create tools for the investigation, including a map of locations for the onsite investigations, a contact list of investigation participants, and a log of significant investigation activities. As demonstrated during this outbreak, the EON will be used to manage the large volume of incident related information and disseminate that information to interested stakeholders in an efficient manner.

Biosurveillance/NBIS--$3.0 million

The DHS is leading the development of the National Biosurveillance Integration System (NBIS), which is intended to integrate systems that monitor health, environment, and intelligence information in order to provide early detection of threats, guided responses to events, and information sharing among agencies. eLEXNET and FERN data capture system, have been identified as a food sector specific surveillance and detection system that is a candidate system to participate in NBIS. FDA's ORA will contribute to the Administration's Bio-Surveillance Initiative by developing nationally recognized standards for data messaging and communication in the health area and by establishing the appropriate connectivity with the NBIS.

Import Field Exams and New Prior-Notice Security Review Performance Goals – Redirection of Base Resources to Risk-based Prior-Notice Security Reviews

FDA is taking advantage of the capabilities developed by the Prior-Notice Center (PNC) that was established under the BT Act of 2002. The PNC will additively complement existing efforts applied to import exams. The risk based model developed by this center is being used to identify high-risk food imports based on available intelligence and information gained from Prior-Notice requirements that collectively will enable FDA to identify and interdict suspect products.

The events of September 11th heightened the nation's awareness of security and placed a renewed emphasis on ensuring the safety of the food supply. Import food field exams, along with laboratory analyses, were FDA's major tool to physically monitor imports prior to the BT Act. Under this approach, FDA steadily increased the number of import field exams from 12,000 in FY 2001 to a target of 60,000 per year in 2004.

FDA has become aware that import field exams are not singularly the most effective approach to ensure import safety. The BT Act, which established Prior-Notice requirements, provided FDA with an additional tool to assess the risks of imported food and improve the focus of import food risk assessment. These new Prior-Notice Import Security

Reviews are just one example of the expanded targeting and follow through on potentially high risk import entries that FDA is developing to complement the import field exam.

The PNC receives and evaluates notices of imported foods prior to their arrival at our borders. These notices describe what each shipment contains and provides additional information, such as country of origin, so that FDA is better situated to know what products are entering, whether they are of concern and if so, to direct inspectors to conduct an examination at the port. The PNC operates side-by-side with the intelligence arm of the Customs and Border Protection to integrate and supplement this information.

Once an item is targeted, a security review is conducted. The PNC will receive feedback from import field exams and filer evaluations and begin targeting those firms that continuously violate the law. In addition, broader surveillance of products imported from countries considered to be at a higher risk for terrorist activities can be incorporated into targeting goals. Strategies used to ensure effective targeting will include:

- Intelligence regarding countries, commodities, and information specific to shipment or shipping entities;
- Information gleaned from Foreign and Domestic Establishment Inspection Reports that identify security breaches**;**
- Sample collection and analysis for counterterrorism; and,
- Prior-Notice discrepancies reported during import field exams.

By prioritizing some resources from field import exams to Prior-Notice Security reviews in FY 2006, FDA will implement a better tool to protect the food supply. As shown below, even with this redirection, the number of imported food entry reviews would remain roughly the same as our previous FY 2006 target. FDA believes this new system, which complements the field food exams, provides for risk based targeting and follow through on potentially high risk import entries. We believe this system places FDA in a better position to keep up with rising import volume.

Performance goal	**FY 05 target under previous system**	**FY 05 Target in New Risk-Based System**	**FY 06 Target in New Risk-Based System**
Import Field Exams	97,000	60,000	60,000
Prior-Notice Security Reviews	--	38,000	38,000

Why is FDA's Contribution so Important?

The Administration has designated the food supply as part of the nation's critical infrastructure. An attack on the food supply could pose severe public health and economic impacts, while damaging the public's confidence in the food we eat. FDA is making progress on many fronts, such as working with industry as well as state and local

food we eat. FDA is making progress on many fronts, such as working with industry as well as state and local governments, to provide sound guidance on food defense and conducting its own threat assessments.

Consequences of Not Achieving the Objective

The events of September 11th heightened the nation's awareness and placed a renewed focus on ensuring the protection of the nation's critical infrastructures. Several food incidents since the Fall 2001 highlight the significance of FDA's food security activities.

On February 27, 2004, the Office of Criminal Investigations was advised by FDA Emergency Operations of a tampering and extortion complaint received in Cincinnati, Ohio. A British citizen was convicted of trying to extort $180,000 from a Supermarket chain by threatening to place contaminated baby food on store shelves.

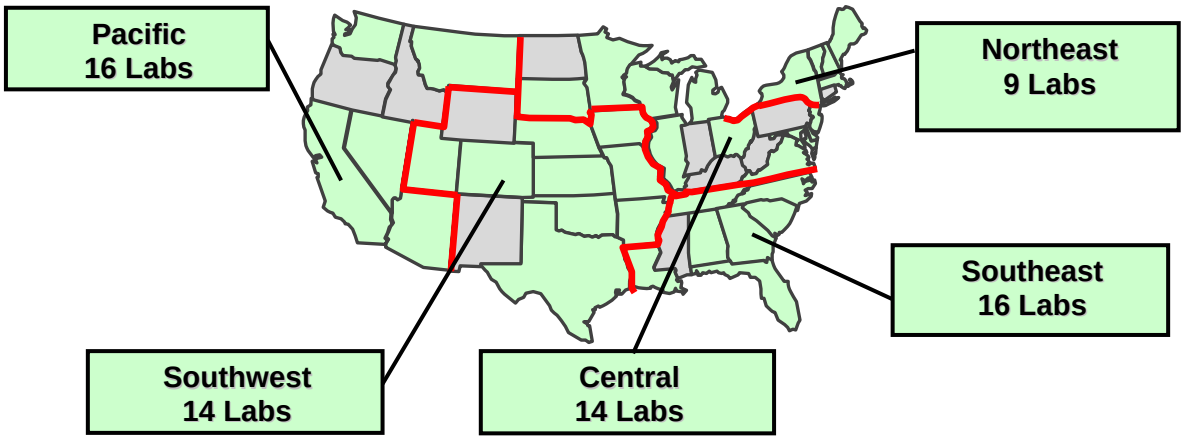
PNC collaborated with CBP in FY 2004 to direct field personnel to hold and examine 20 suspect shipments of imported food. In addition, the PNC responded to 20,430 inquiries and conducted 33,111 intensive reviews of prior notice submissions in order to intercept contaminated products before entering the domestic food supply.

As a result of new threats to the food supply, FDA has made fundamental changes in how we implement our mission of protecting our food supply, so that all Americans can have confidence that their foods are not only safe but also secure. In these efforts, the FDA and the USDA's FSIS will continue to work with the White House Homeland Security Council, DHS, and other federal agencies to further enhance our ability to detect, deter, and respond to an attack on our food supply.

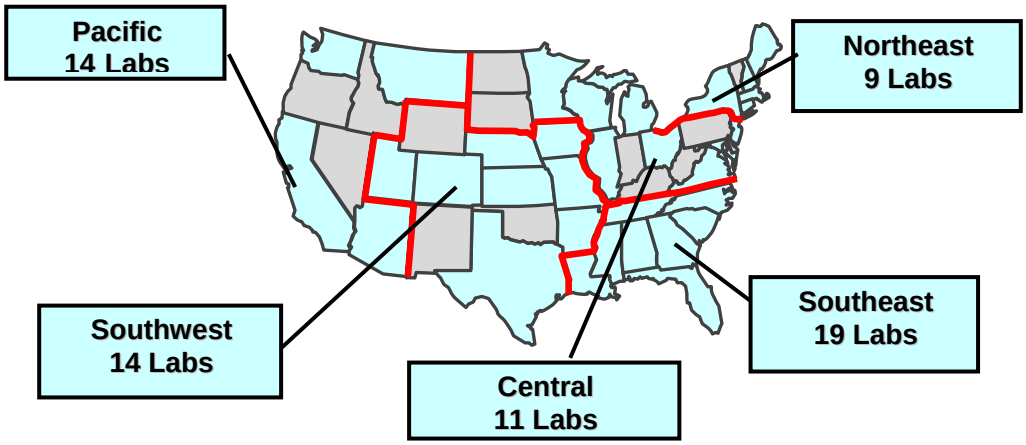
In FY 2006, FDA expects to expend $180,026,000 on Food Defense.

Food Emergency Response Network (FERN)

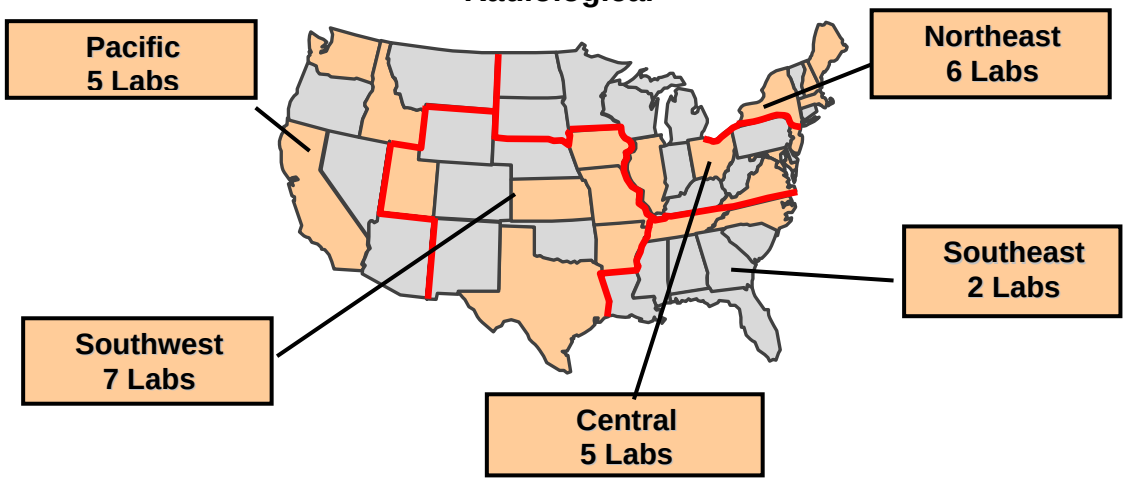
Microbiological



Chemical



Radiological



NOTE: Total lab numbers reflect laboratory capabilities for microbiological, chemical, and radiological analysis rather than actual laboratory locations because some laboratories will have capability to analyze samples for several types of agents at one location.

MEDICAL DEVICE PREMARKET REVIEW

Desired Outcome

To improve the quality and reduce the cumulative review time required to approve 510(k) and traditional Pre-Market Approval Applications (PMA), while ensuring the safety of products approved for the market.

Program Objective

To achieve the Agency's FY 2006 Medical Device User Fee and Modernization Act (MDUFMA) performance goals for prompt review, so patients can enjoy the benefits of safe and effective medical devices to diagnose, treat, and prevent disease.

The medical device review program supports the FDA Strategic Plan in the area of "Using Risk Based Management Practices." This goal is aimed at providing the most health protection at the least cost to the public by making the review process more efficient through the use of a third party review program.

Why is FDA's Contribution so Important?

Sound, risk-based review processes are imperative to ensure that medical devices on the market are safe and effective. These devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices.

Because of the complexity of many medical devices, a 510(k) or PMA is required to market the product. A 510(k) is a premarketing submission made to FDA 90 days before a company proposes to begin marketing a new or modified device. A 510(k) demonstrates that a device to be marketed is safe and effective, and is substantially equivalent to a device that is currently legally marketed.

The PMA is required for new Class III medical devices that must be approved by FDA before the products can be marketed. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Premarket review entails the scientific and regulatory evaluation of the PMA to assure the safety and effectiveness of the product.

To strengthen FDA's Premarket review process, Congress enacted MDUFMA as a multi-year effort to improve the quality and timeliness of the medical device review process. It authorizes the collection of user fees to supplement the appropriated portion of the medical device review program for the review of medical device applications. The user fee is collected from device manufacturers that submit premarket applications, certain supplements to those applications, and premarket notifications.

The implementation of MDUFMA makes available new revenue for completing more timely and complete device reviews, reducing the cumulative approval time, reducing the number of review cycles, encouraging and supporting high quality applications, and providing a more efficient resolution of outstanding issues. The viability of the MDUFMA program is essential for the success of the medical device review program.

Requested Increases - Budget Authority

MDUFMA specifies a minimum amount of budget authority that must be provided each year in the Device and Radiological Health line of FDA's appropriation. FDA's budget has undergone a structure change since the passage of MDUFMA and the Device and Radiological Health line of FDA's appropriation is equivalent to the Center for Devices and Radiological Health (without Rent) plus the Devices and Radiological Health Estimate under the Office of Regulatory Affairs.

The minimum amount is the FY 2003 base appropriation of $205,720,000, multiplied by the April Consumer Price Index for Urban areas for each year thereafter. FDA estimates that adjustment factor for FY 2006 is 1.0734 percent, [1/] which would yield a minimum that must be appropriated for the Devices and Radiological Products Program for FY 2006 of $220,823,000 plus the $138,000 in FY 2005 make up funds for a total of $220,961,000.

This legislation also requires that any appropriation shortfalls below the specified level in fiscal years 2003, 2004 and 2005 be made up, or the program will cease to operate on October 1, 2005. Recognizing this requirement, the OMB Director issued a letter on October 29, 2003 to the Speaker of the House, committing the Administration to budget requests at a level that would satisfy this MDUFMA requirement for FY 2005 through 2007. For FY 2005 Congress appropriated a level approaching the trigger level in the FY 2005 Omnibus Appropriation and the Administration anticipates that Congress will take up the legislation during FY 2005 that will forgive the Appropriation triggers for FY 2003 and FY 2004, thus allowing the MDUFMA program to maintain operations and continue to efficiently review the safety and effectiveness of medical devices.

[1/] As specified in MDUFMA, the adjustment factor for FY 2006 is the Consumer Price Index for all urban consumers, U.S. city average (CPI/U) for April of FY 2005 divided by the CPI/U for April of 2002 (179.8). The adjustment factor for FY 2006 is based on the CPI/U for FY 2005 from the Economic Assumptions for the FY 2006 Budget. This estimate will be adjusted for actuals in mid May of FY 2005 when the Bureau of Labor and Statistics releases the April 2005 CPI/U.

FY 2005 Request
Budget Authority Increase
(Dollars in $000)

Program	Center	Field	Total
Devices and Radiological Health	$1,796	$4,200	$5,996

The requested budget authority increase of $5,996,000 will allow FDA to:

- Meet all of the performance goals specified in MDUFMA for FY 2005-2007;
- Maintain the level of investigators conducting inspections; and,
- Allow the field to meet the third party inspection trigger for the MDUFMA program.

Consequences of Not Achieving the Objective

Without the ability to collect fees, FDA would lack the resources needed to meet agreed upon performance goals from FY 2003 to 2007. Failing to meet these goals would negatively impact public health by delaying improvements in the medical device review process and denying patients access to innovative new medical

procedures and treatments. The current request, in conjunction with the MDUFMA user fees, will allow FDA to meet the aggressive FY 2005-2007 medical device review performance goals.

How are we Doing?

Overall the requested budget authority of $5,996,000 for the Devices and Radiological Health Program, in conjunction with the $40,300,000 in MDUFMA user fees, will allow FDA to:

- Acquire and train staff to meet a set of aggressive FY 2005 - 2007 performance goals to expedite the review of medical device applications, which were formally submitted by the Secretary of Health and Human Services to the Congress;

- Promote public health with major improvements in the review of breakthrough medical technologies and improvements in review of expedited device submission; and,

- Make major improvements in review performance in areas where fees are collected, while maintaining performance in other areas.

Specifically, the FY 2006 FDA premarket device review performance goals include:

- Complete review and decision on 80 percent of Expedited PMA Actions within 300 days;

- Complete Review and Decision on 80 percent of 180 day PMA supplement actions within 180 days;

- Complete Review and Decision on 75 percent of 510(k) (Premarket Notification) within 90 days; and,

- Conduct 295 domestic and 15 foreign BIMO inspections with an emphasis on scientific misconduct, data integrity, innovative products, and vulnerable populations.

In FY 2006 a total of $220,961,000 is requested for the Devices and Radiological Health Program (CDRH (without rent) and the Devices and Radiological Health Estimate under the Office for Regulatory Affairs) for both premarket and postmarket activities related to MDUFMA.

OFFICE OF DRUG SAFETY (ODS)

Desired Outcome

Reduce preventable deaths and injuries associated with the use of medical products by increasing and enhancing the Office of Drug Safety's (ODS) review and analysis of both pre-marketing and post-marketing safety information on all products regulated by the Center for Drug Evaluation and Research (CDER).

Program Objectives

CDER has a central public health role to ensure that drug and biological therapeutic products are demonstrated safe and effective prior to marketing, and that these products continue to be safely used once approved and marketed.

Although products are required to be safe, safety does not mean zero risk. A safe product is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available. All participants in the product development and delivery system have a role to play in maintaining this benefit-risk balance by making sure that products are developed, tested, manufactured, labeled, prescribed, dispensed, and used in a way that maximizes benefit and minimizes risk.

Ensuring drug product safety is a mission-critical function of CDER. Drug safety analysis and decision-making is the result of collaborative efforts among offices across the Center.

ODS is one such office involved in the overall drug safety function, by playing the following roles in drug safety:

- Collaborating with CDER's Office of New Drugs (OND) in pre-market risk management analysis to:
    - Learn about and understand new drugs and its safety issues;
    - Make recommendations about potential additional population studies to be pursued after a drug is approved; and
    - Participate in advisory committee meetings
- Collaborating with OND to play a key role in safety signal (potential safety issue) identification and epidemiological analysis by:
    - Collecting and analyzing adverse event reports after a drug has been marketed; and
    - Performing epidemiological analysis to determine what a signal may mean using data from internal and external databases.
- Helping prevent medication errors and monitor previously identified errors by consulting on drug name and labeling issues; and,
- Acting as CDER's resource for epidemiological expertise for various analyses and population studies.

This initiative focuses on bolstering the drug safety functions within ODS by:

- increasing the professional staff in ODS who manage and lead safety reviews;
- increasing the number of staff with expertise in critical areas such as risk management, risk communication, and epidemiology; and,

- applying funding to increase access to a wide range of clinical, pharmacy and administrative databases.

Why is FDA's Contribution so Important?

FDA's contribution, as laid out in the Federal Food, Drug, and Cosmetic Act, is devoted largely to pre- and post-marketing drug risk assessment. The approval/nonapproval decision is the Agency's central risk management action. FDA must ensure that beneficial medical products are available and labeled with adequate information on their risks and benefits while protecting the public from unsafe products or false claims.

FDA approves a product when it judges that the benefits of using a product outweighs its risks for the intended population and use. A major goal of the pre-marketing review is to ensure that products are truthfully and adequately labeled for the population and use. Labeling is given considerable emphasis because it is the chief tool the Agency uses to communicate risk and benefit to the healthcare community and patients. Once medical products are on the market, however, ensuring safety is principally the responsibility of healthcare providers and patients, who make risk decisions on an individual, rather than a population, basis. They are expected to use the labeling information to select and use products wisely, thereby minimizing adverse events.

FDA has assumed a significant watchdog role regarding post-market surveillance. When FDA approves drugs and other medical products, it takes every precaution to ensure these products are safe when they are marketed. However, product safety continues throughout the product's lifetime. Because the clinical trials that help gauge product safety are conducted on relatively small groups of patients--usually ranging from a few hundred to several thousand--problems can remain hidden, only to be revealed after hundreds of thousands or even millions of people use the product over a prolonged period. For these reasons and more, FDA relies on MedWatch and MedSun to provide a significant amount of data on post-marketing surveillance of medical products to identify safety concerns and take necessary action. These programs depend on doctors, dentists, nurses, pharmacists, and other health professionals to provide FDA details of serious adverse reactions and medical product problems.

Requested Increases for FY 2006
(Dollars in $000)

Program	Center	Field	Total
Human Drugs	$5,000	$0	$5,000
Total	**$5,000**	**$0**	**$5,000**

With the $5,000,000 increase, ODS will:

- Hire 6 FTE to:
  - Establish policies and processes regarding safety reviews and risk management;
  - Manage communications with the Office of New Drugs; and,
  - Support patient safety initiatives and external partnerships with CMS, AHRQ, and other HHS Agencies.
- Hire 10 FTE in the 3 operating divisions of ODS to:
  - Handle the increased workload of monitoring biologic therapeutics;
  - Increase communication and coordination of safety review activities within the divisions; and,
  - Increase focus on medical error signal detection and address current

backlog of unaddressed potential signals

- Hire 4 FTE to increase staff dedicated to evaluating and communicating drug safety risks to the healthcare community and the American Public; and,
- Apply funding to increase access to a wide range of clinical, pharmacy and administrative databases. Given the highly fragmented healthcare system in the U.S., there is no single healthcare database that the Agency can rely upon to widely monitor drug adverse events. As each drug has its own indication(s) that may result in its differential use in different populations, it is essential that the CDER have access to a wide range of databases to adequately assess drug safety.

Consequences of Not Achieving the Objectives

Recent drug safety issues have resulted in questions regarding the capability and credibility of FDA's drug safety program. Without additional resources to help achieve our stated objectives, FDA may continue to be perceived as unable to ensure the safety of marketed drugs.

How Are We Doing?

Learning about the relative safety of a drug product starts from the earliest development of a chemical entity and continues throughout the clinical development and review. Once a drug is approved for marketing in the U.S. and available for general distribution, there are two fundamental ways to continue the assessment of both the safety and safe use of a medicinal product. These two approaches include 1) monitoring of adverse drugs events and medication errors as they occur in individual patients, and 2) formally studying in populations the occurrence of such events.

The FDA currently relies primarily on the reporting and analysis of instances of adverse events. In 2003, we received over 370,000 such reports, a third of which (over 144,000) where serious in nature. The strengths and limitations of our Adverse Event Report System (AERS), which now contains over 2.5 million reports, are well known. We have made vast improvements in the way we manage and analyze this large data set over the last 7 years, using a variety of electronic and statistical tools that have increased our ability to get information to safety evaluators in a timely manner.

Improvements in drug safety must begin well before the drug is approved, while the product sponsor is evaluating the safety of candidate products and deciding which will be moved forwarded to each successive stage of testing. For example, FDA is collaborating with NIH to develop common data standards for electronic reporting of adverse event in clinical trials, to assist and facilitate rapid analysis of safety findings. FDA work to improve identification of safety issues early in drug development includes efforts to mine FDA data to create predictive software that uses structure-activity relationships to help identify compounds with potentially significant adverse properties, so they can be eliminated as lead compounds earlier in development.

FDA published the *Draft Guidance for Industry: Pharmacogenomic Data Submissions* to encourage drug and biologic developers to conduct pharmacogenomic tests during drug development. Among the many potential uses of this data is identification of early signals of product toxicity. FDA scientists developed a new technique to detect the presence of

contaminating virus in small pox vaccine products; this technique can be applied to other vaccine and cell-based products.

During FY 2005 and 2006, FDA plans a variety of activities focused on increasing and enhancing the review and analysis of both pre-marketing and post-marketing safety information on all products regulated by CDER. FDA's actions during this timeframe will focus on establishing a "drug safety net", a comprehensive effort that ultimately will require that FDA have:

- Access to large clinical and drug use data sets for detecting adverse events and medication errors, and for conducting population-based safety studies;
- Linkage of these data sets to increase the "power" to detect problems;
- Development of strong analytic tools to rapidly identify "signals"; and,
- Timely, thoughtful and actionable communication of information to healthcare providers and consumers.

FDA will continue its efforts to improve the timeliness and availability of drug safety information and will be seeking alternative strategies for managing drug safety issues as well as increasing its use of external experts in evaluating post-marketing safety issues. FDA actions will be harmonized with the emerging results of an Institute of Medicine (IOM) Study of the drug safety system. In this study, IOM will evaluate the effectiveness of the U.S. drug safety system with emphasis on the post-market phase to assess what additional steps could be taken to learn more about the side effects of drugs. The committee will examine FDA's role within the health care delivery system and recommend measures to enhance the confidence of Americans in the safety and effectiveness of their drugs.

In FY 2006, FDA anticipates it will expend $22,900,000 on the Office of Drug Safety.

GSA RENT

Desired Outcome

Improve management of and provide for rising GSA rent costs without redirecting resources from core, mission-critical activities. This activity includes charges for all of FDA's GSA space, both Government-owned and GSA-leased.

Program Objective

The requested increase will assist in meeting the Improving FDA's Business Practices strategic goal, and will minimize the need to redirect resources from core programs to cover rental cost increases.

The Agency occupies over 4.6 million square feet of space including parking. Nearly half of the GSA rent charges are for government-owned or GSA-leased space in the Washington, DC area with the largest individual charges for the Parklawn complex, Module II in Beltsville, and CFSAN's new College Park location. In addition, there is the Regional office and laboratory in Jamaica, NY. The balance of the charges would affect the Regional Offices, District Office/Laboratory complexes, and over 130 leased offices, which serve as resident posts for strategically placed field investigators.

GSA Rent and Other Rent and Rent-Related - FY 2006
(Dollars in $000)

Item	
GSA Rent - BA	$113,479
Other Rent and Rent-Related - BA	$35,758
FY 2006 Increase - BA	*$4,100*
Subtotal - BA	$153,337
GSA Rent - UF	$15,421
Other Rent and Rent-Related – UF	$686
FY 2006 Increase – UF	*$1,950*
Subtotal - UF	$18,057
TOTAL GSA Rent and Other Rent	**$171,394**

Why is FDA's Contribution So Important?

The FY 2002 supplemental provided many FDA programs with substantial staffing increases in response to bioterrorism and emergency preparedness needs. To house these staff, additional space has been acquired. Also, FDA anticipates a fairly significant increase in GSA rental costs plus a final rent estimate for the White Oak facility is still pending.

Plan to Change GSA Rent and Other Rent-Related Activities Display

FDA proposes changing the way the GSA Rent and Other Rent and Rent-Related Activities budget lines are displayed. While these are currently tracked at the agency-level, FDA proposes eliminating these budget lines and incorporating rent into program-level requests.

Under the current budget structure, if rent needs unexpectedly change, a reprogramming request to Congress is

required. Displaying rent at the program-level would eliminate the need for many such requests, would place accountability for these costs with the programs, and would more accurately portray the full cost of operating each program.

Including rent in the program-level totals would provide FDA with increased flexibility to respond to unpredicted needs such as new regulatory initiatives that require additional staff and office space, safety initiatives, natural disasters, or other emergencies. Currently, a reprogramming would most likely be needed to respond to any increased rent needs resulting from these types of scenarios.

In addition, this budget structure change would strengthen our ability to respond to unexpected rent increases. Rent appropriations for a given year are estimated 16 to 28 months before the rent bills are due. Rent bills are often higher than the amount appropriated for rent. Including rent in the program-level totals would enable the transfer of funds within a center to meet an unexpected increase in rent.

This change would also better align the "full cost" of each program with strategic goals and performance measures. In addition, this change will improve accountability for the Center on how they manager their rent space.

FDA HEADQUARTERS CONSOLIDATION AT WHITE OAK

Desired Outcome

Consolidating of FDA's headquarters a decade's long effort, was made possible when Congress passed the FDA Revitalization Act (P.L. 101-635) that was enacted on November 28, 1990. In 1994, OMB approved a consolidation plan for laboratory, office and support space to be located in Silver Spring, Maryland.

Program Objective

The consolidation of the remaining FDA headquarters is occurring at the government-owned White Oak site. The design and construction of the new buildings at White Oak are funded through General Services Administration (GSA) appropriations in the same manner as the CFSAN facility with FDA paying for building fit-out and move costs. The White Oak campus will replace all existing fragmented facilities with new laboratories, office buildings and support facilities. The last part of the White Oak consolidation is scheduled to be ready for occupancy in 2010.

Why is FDA's Contribution so Important?

This project will help provide FDA with the required modern facilities to best perform its mission. The White Oak consolidation will ensure that it has state-of-the-art laboratories and facilities that will enable FDA to better respond to the Nation's drug review, approval and supply needs.

The new facility is designed to provide an environment that encourages efficiency, creativity and superior performance. This will help attract and retain top quality scientists by enabling them to do top-quality work as part of an effective team. This is even more critical as we face new challenges in ensuring that FDA regulated products are not used as a vehicle for terrorism.

Requested Increases

The FY 2006 total request of $21,974,000 will be used to fund the additional relocation needs that are not covered by the design and construction budget for the CDRH Engineering and Physics Laboratory and the new Central Shared Data Center.

The 128,000 square foot CDRH Engineering and Physics laboratory will house approximately 160 CDRH employees. These high tech laboratories will evaluate electromagnetic and medical devices, and radiological instruments and consumer appliances generating radiological signals. The facility consists of numerous vibration isolation slabs, electromagnet shielding, an anechoic chamber and laser devices especially dedicated to the program science.

Construction of the Central Shared Use Data Center began in October 2004. Consolidating the Data Center will reduce the number of such facilities currently operating within the Agency, thus resulting in cost savings. To implement this data center, FDA has

embarked upon an aggressive IT modernization strategy to enable information sharing and improved IT effectiveness, while reducing redundancy and minimizing costs. The first phase of this building, including the cafeteria, fitness center and security command center is scheduled for completion in spring 2006.

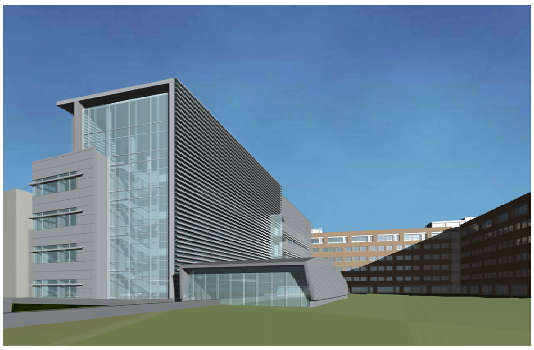
Requested Increase for FY 2006
(Dollars in $000)

Recurring Budget Authority	$17,846
FY 2006 BA Increase	$4,128
Total Increase	**$21,974**

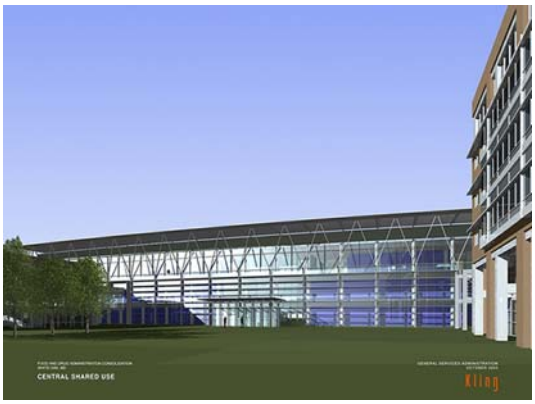
The request will be used for the CDRH Engineering and Physics laboratory and the Shared Data Center move which include:

- Internal communication needs, including equipment, cabling and audiovisual;
- Security, including infrastructure and equipment;
- Information technology and telecommunications cabling;
- Modular furniture and other equipment to furnish the building for occupancy; and,
- Relocation costs, including records management consolidation, relocation coordination and moving.

CDRH Engineering and Physics Laboratory



Central Shared Use Data Center Rendering



Consequences of Not Receiving the Resources to Complete the Move

Without this increase, FDA will be unable to prepare the space for occupancy and could delay the centralization of the new space and associated cost savings. This delay would extend the time that the Agency would be required to pay rent at its existing locations while also paying rent at the new building which will greatly impact the GSA Rent appropriation.

How Are We Doing?

The White Oak consolidation plan, which has received recognition in many different areas, estimates that over 7,700 staff will be housed in 2.3 million square feet of space. By end of 2005, the campus will have almost 700,000 sq. ft. completed with 1,850 staff on-site. The first laboratory building on the campus was dedicated on December 11, 2003.

Improving Management:

One of the first priorities of the President's Management Agenda is to make government citizen-centered. The White Oak consolidation will do just that by providing a readily identifiable location for citizens to interact with FDA. The project will also allow FDA to standardize and modernize document handling, use shared facilities such as libraries and conference areas, reduce redundancies in a wide range of administrative management tasks, and allow conversion to a single computer network. This will create a strong FDA by reducing operating costs, reducing travel time between organizations and increasing the convenience of access to FDA by the public.

Energy Savings:

As part of this project, in October 2002, GSA awarded a 20-year, $98 million, energy-services contract to Sempra Energy Solutions to construct a central utility plant that will utilize energy-saving cogeneration technology to provide electricity, heat and air conditioning. Sempra is financing the plant and recovering its costs through an energy-savings performance contract. The second phase of this contract will go into effect in 2005. FDA will be able to realize substantial annual operating savings and benefits from this energy-saving program and maintain a safe and healthful work environment for both its employees and the community. The Federal Government can lead the nation in energy efficient building design, construction and operation and can foster energy efficiency, water conservation, and the use of renewable energy products.

Design:

In 2004, FDA and Kling won an Honor Award for Design from the American Institute of Architects for the design of the Central Shared Use Building.

The award was based on project's architectural design quality, the integration into a pedestrian campus concept, the successful relationship of a new building to a historic structure, and the implementation of numerous sustainable design features into a large, significant federal project. The project received one of only two Honor Awards out of 77 entries. This award was given to the entire FDA and GSA team, plus the local community and stakeholders,

who have been very supportive and involved in the project.

GSA Funding:

From FY 2000 through 2004, Congress appropriated a total of $225.8 million to GSA for demolition, design and construction of CDER laboratories, the CDRH Engineering and Physics laboratory and offices for CDER and CDRH.

In FY 2005, the GSA request for White Oak is $88.7 million, for construction of the second CDER Office Building, internal roads and bridges, construction of parking garage, and fit-out of the Central Shared Use building. In FY 2006, GSA has requested a total of $127.8 million to complete the next phases of the consolidation plan.

FDA Funding:

In FY 2002, FDA received two-year funding of $4,000,000 to equip and occupy the laboratory for CDER. These funds partially supported actual moving costs, IT design and decommissioning costs and other associated expenses.

In FY 2004, FDA received $5,986,000 ($2,361,000 in budget authority, and $3,625,000 in PDUFA carryover funds) to equip and prepare to occupy the CDER office facility. These funds were used for telecommunication and data cabling requirements and other infrastructure costs and represent the second installment to relocate and consolidate most of CDER's headquarters activities in one location. The building is expected to be completed in April 2005.

In FY 2005, FDA received $32,937,000 to relocate approximately 1,700 CDER review staff, with increases of $15,503,000 in new budget authority, $2,343,000 in recurring move costs from the FY 2004 enacted level, $3,000,000 from new PDUFA funds and $12,092,000 from PDUFA carryover balances from previous fiscal years.

BUILDINGS AND FACILITIES

Desired Outcome

To Implement the President's Management Agenda by improving FDA operations and the quality of its facilities. Buildings and Facilities funding is for greatly needed repairs and improvements to existing owned or leased facilities all across the U. S.

Program Objective

The $7 million requested increase is for construction, improvement and repair of FDA facilities. This includes approximately 40 buildings in 16 separate locations in Maryland; plus five regional offices, 19 field District complexes including 19 administrative and 13 specialized laboratory facilities nationwide; more than 120 field resident posts, eight field criminal investigation offices, two distinct program laboratory complexes outside the Washington D.C. Metro area; and the NCTR complex in Jefferson Arkansas. Overall, FDA maintains offices and staff in 49 states, and in the District of Columbia and Puerto Rico.

In FY 2005, the Agency did not request funding for building and facilities in an effort to fund other higher priority initiatives, but is now challenged to continue to sustain these buildings, some of which are over 50 years old, are in poor condition and which have deferred maintenance.

Requested Increases for FY 2006
(Dollars in $000)

Item	Dollars
Building and Facilities - BA	$7,000

Why is FDA's Contribution So Important?

FDA's field laboratories provide critical laboratory and analytical support to the domestic and import inspection effort and are a key element to the FDA science base. FDA's large laboratories provide a cost-effective critical mass of scientific expertise in the fields of chemistry, microbiology, pesticide chemistry, animal drug research and total diet research areas.

Consequences of Not Achieving the Goal

Without this increase, FDA will have to continue delaying completion of projects, which will cause additional operating costs to support personnel and equipment in different buildings and postponing planned inter-center research projects. The Agency would also be in a position of having to shut down critical laboratories and buildings due to safety issues, with field operations bearing the brunt of any such closures. Given the one-year pause in Building and Facilities funding in FY 2005, this restoration is especially important, and not receiving these resources will only lead to rising costs due to the continued delays in maintenance and deterioration of the FDA facilities.

MANAGEMENT SAVINGS

Desired Outcome

To support the Administration's goals by reducing administrative and information technology costs.

Program Objective

By implementing the President's Management Agenda and Secretarial reform initiatives, FDA has achieved increased efficiencies by streamlining its organizational structure, improving the delivery of administrative and IT services, and through a re-invigorated and strategic-orientated IT plan linking mission critical programs with performance outcomes and cost-effective IT solutions.

Management savings were achieved during FY 2004 with the creation of the shared services organization, results from competitive sourcing competitions, and consolidation efforts by the Department. These savings, which are continuing in FY 2005, have permitted FDA to meet its Administration goals for reducing spending and administrative staff by 15 percent.

The total aggregate savings has amounted to over $80 million and a loss of 204 FTE. While some costs savings may be achieved in FY 2006, FDA will not be able to replicate the degree of savings previously achieved. Further staff and resource reductions will directly impact on FDA's programs.

FY 2006 Management Savings
(Dollars in $000)

Item	Dollars	FTE
Administrative Efficiencies	($1,554)	(14)
Information Technology Reduction	($5,116)	(15)
Total	**($6,670)**	**(29)**

Why is FDA's Contribution So Important?

Human and IT resources are essential to accomplishing FDA's mission, as it is more people-intensive than many government agencies, with payroll accounting for more than 60 percent of its total budget. Critical IT systems allow FDA to handle the large amounts of data used for applications review processes as well as monitoring post-marketing surveillance of regulated products. Mission critical work includes:

- The Agency's regulatory mandate to protect the public health. Interpretation and enforcement of this mandate is an inherently governmental function;
- Inspectional responsibilities which require hands-on coverage domestically and abroad;
- Product review functions which require numerous interdependent specialists in product areas who interact with industry on a regular basis;

- Regulatory responsibilities which require staff to monitor the entire life cycle of all FDA-regulated products; and,

- Review an estimated 14.4 million import line entries in FY 2005 of FDA regulated products for admissibility into domestic commerce.

USER FEES -- $31,320,000

User Fee Overview

This budget requests a $31,320,000 increase. This increase is based on a current service estimate and does not account for workload adjustments or payroll adjustments. The increase includes $20,938,000 for Prescription Drug User Fee Act (PDUFA) fees, $6,362,000 for Medical Device User Fee Modernization Act (MDUFMA) fees, $2,964,000 for the recently enacted Animal Drug User Fee Act (ADUFA) fees, $254,000 for Mammography Quality Standards Act (MQSA), $24,000 for Drugs/Devices Export Certification and $778,000 for Color Certification.

The user fees FDA collects support the following FDA strategic goals:

- Enhance public health and reduce suffering by providing quicker access to important lifesaving, safe, and effective drugs and devices; and,

- Prevent unnecessary injury and death caused by adverse drug reactions, injuries, medication errors, and product problems.

User Fee Increases for FY 2006
(Dollars in $000)

Program	
PDUFA Total	**$20,938**
MDUFMA	**$6,362**
ADUFA	**$2,964**
MQSA	**$254**
Export Certification	**$24**
Color Certification	**$778**
Total	**$31,320**

PDUFA: + $20,938,000

The Bioterrorism Act of 2002 reauthorized the collection of PDUFA user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. This authority is effective for five years and directs FDA to strengthen and improve the review and monitoring of drug safety, consider greater interaction with sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases, and develop principles for improving first-cycle reviews.

For FY 2006, FDA requests an increase of $20,938,000 for a total of $305,332,000 in PDUFA user fees. This increase is based on inflation and workload factors for the FDA drug review program.

PDUFA Increase for FY 2006
(Dollars in $000)

Program	
Human Drugs	$14,356
Biologics	$6,624
Field Activities	$1,550
Other Activities	$1,408
White Oak	($3,000)
Total	**$20,938**

Fees collected support the following FDA performance goals:

- Improve the efficiency and effectiveness of the new drug review program to ensure a safe and effective drug supply is available;

- Review and approve 90 percent of standard original PDUFA NDA/BLA submissions within ten months; and review and act on 90 percent of priority original PDUFA NDA/BLA submissions within six months of receipt; and,

- Review and approve 90 percent of standard PDUFA efficacy supplements within ten months; and review and act on 90 percent of priority PDUFA efficacy supplements within six months of receipt.

MDUFMA: + $6,362,000

The Medical Device User Fee and Modernization Act (MDUFMA) of 2002 is patterned after the successful Prescription Drug User Fee Act that has enabled FDA to add over 1,000 employees to the drug review process over the last decade.

This multi-year effort is designed to improve the quality and timeliness of the medical device review process. It authorizes the collection of user fees to supplement the appropriated portion of the medical device review program for the review of medical device applications. The fee is collected from device manufacturers that submit premarket applications, certain supplements to those applications, and premarket notifications.

Implementation of MDUFMA makes available new revenue for completing more timely and complete device reviews, by reducing the cumulative approval time, reducing the number of review cycles, encouraging and supporting high quality applications, and providing a more efficient resolution of outstanding issues.

For FY 2006, FDA is requesting an increase of $6,362,000 for a total of $40,300,000 in MDUFMA fees. This increase is based on inflation for the medical device review program.

MDUFMA Increase for FY 2006
(Dollars in $000)

Program	
Biologics	$673
Devices	$4,886
Field Activities	$308
Other Activities	$495
Total	**$6,362**

Fees collected support the following FDA performance goals:

- Complete review and decision on 80 percent of expedited PMAs within 300 days;

- Complete review and decision on 80 percent of 180 day PMA supplements within 180 days; and,

- Complete review and decision on 75 percent of 510(k)s (Premarket notifications) within 90 days.

ADUFA: + $2,964,000

The Animal Drug User Fee Act (ADUFA) was enacted on November 18, 2003 through the Consolidated Appropriations Act of 2004. This legislation provides a cost-efficient, high quality animal drug review process that is predictable and performance driven, to ensure the safe and effective animal drugs are available on the market The program requires new animal drug

applicants, sponsors, and establishments to incur a fee to expedite their respective applications.

The availability of safe and effective animal drugs allows food animal producers to maintain healthy animals with the assurance that resulting food products will be safe, wholesome, and free of drug residue. A safe and effective drug supply also ensures companion, service animals that assist the disabled, and other animals such as zoo animals will live healthier and longer lives.

ADUFA Increase for FY 2006
(Dollars in $000)

Program	
ADUFA	
Veterinary Medicine	$2,462
Other Activities	$502
Total	**$2,964**

The fees collected support the following FDA performance goal:

- Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. This goal is dependent upon a sustained level of base and user fee resources.

MQSA: + $254,000

Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight American women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which was reauthorized in October 2004, addresses the public health need for safe and reliable mammography. The Act required that mammography facilities be certified by October 1994, and inspected annually to ensure compliance with national quality and safety standards.

The reauthorization codified existing certification practices for mammography facilities and laid the groundwork for further study of key issues that include ways to improve physicians' ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms.

FDA is authorized to collect fees to pay for the costs of the annual inspections. In FY 2006, FDA is requesting a $254,000 increase for a total of $17,173,000 in MQSA fees. This increase is based on inflation and workload factors for the medical device review program.

MQSA Increase for FY 2006
(Dollars in $000)

Program	
MQSA	
Medical Devices	$163
Field Activities	$81
Other Activities	$10
Total	**$254**

This program supports FDA's strategic goal of reducing the risk of medical devices and radiation emitting products on the market by assuring product quality and correcting problems associated with their production and use.

Export Certification (Drugs/Devices):

+ $24,000

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device, that the product to be exported meets certain requirement of the law. This applies to products approved for sale in the U.S., as well as unapproved products. The purpose of these certificates is to promote the export of products made in the U.S. The $24,000 increase will cover the programs' inflationary costs.

Color Certification: + $778,000

The Federal Food, Drug and Cosmetic Act (FFD&C) requires the certification of color additives. This function, which is administered by FDA's Center for Food Safety and Applied Nutrition, involves assessing the quality and safety of color additives used in foods, drugs and cosmetics. Employee salaries and expenses are funded directly by FDA's Revolving Fund for Certification and Other Services which is financed entirely by fees paid by commercial organizations. The FY 2005 increase of $778,000 will cover the programs inflationary costs and covers a anticipated fee increase with industry.

Requested Certification Increases for FY 2006
(Dollars in $000)

Program	Center	Field	Total
Export Cert.	$24	$0	$24
Color Cert.	$778	$0	$778
Total	**$802**	**$0**	**$802**