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.

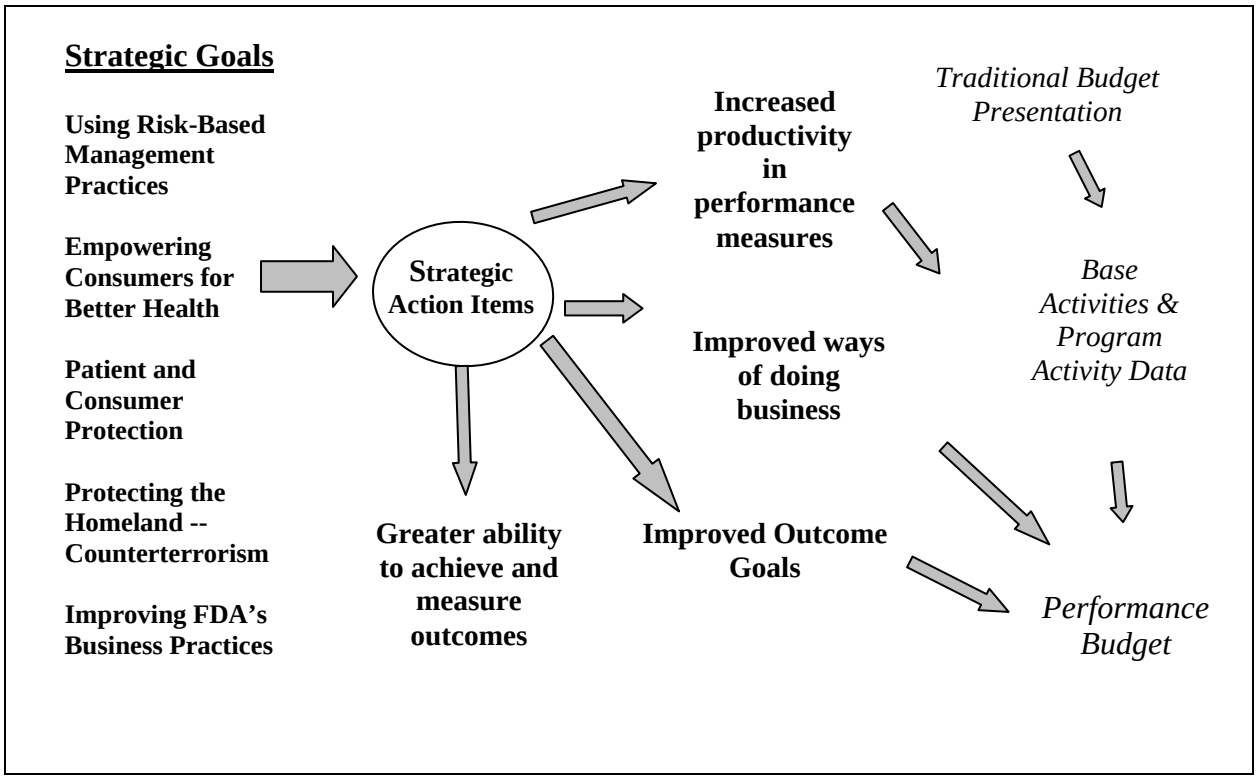
Action items emerging from the Strategic Action Plan will have several beneficial effects on performance planning. First, several of these items constitute improved ways of conducting the FDA's core business. Second, many of the action items enhance FDA's ability to identify, measure, and influence public 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.

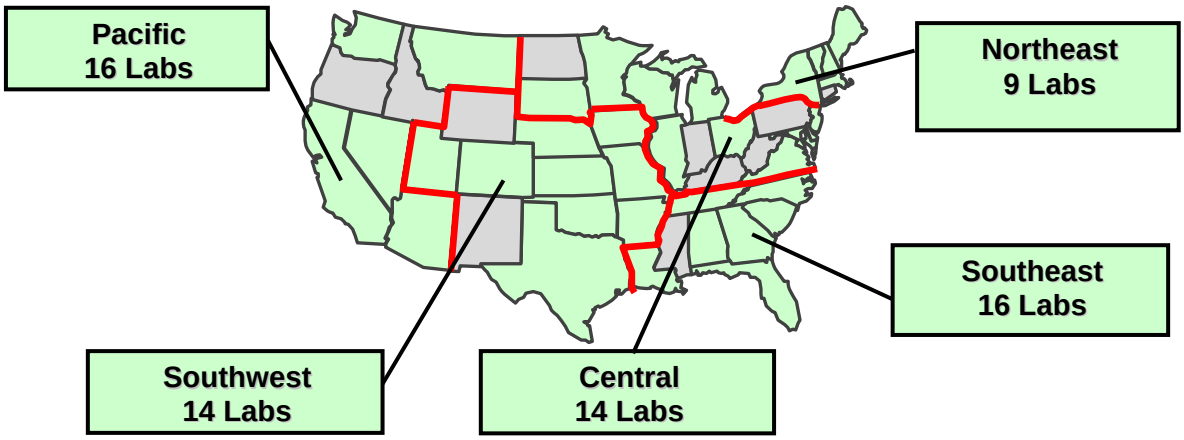
PNC collaborated with CBP in FY 2004 to direct field personnel to hold and examine 20 suspect shipments of imported food. In addition, the PNC responded to 20,430 inquiries and conducted 33,111 intensive reviews of prior notice submissions in order to intercept contaminated products before entering the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

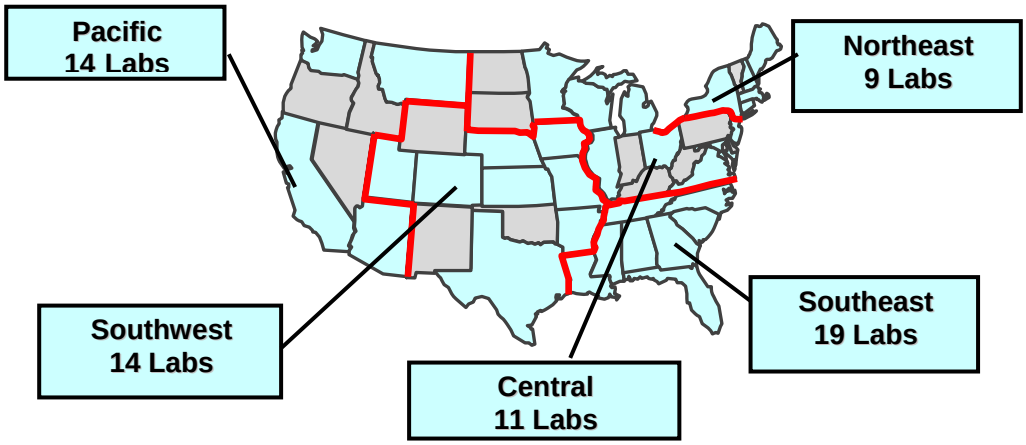
In FY 2006, FDA expects to expend $180,026,000 on Food Defense.

Food Emergency Response Network (FERN)

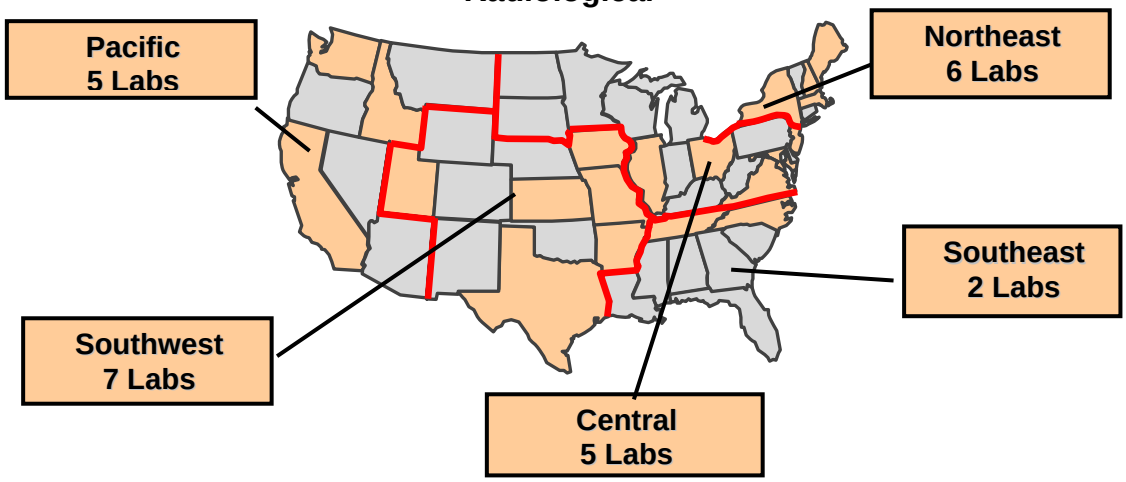
Microbiological



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.

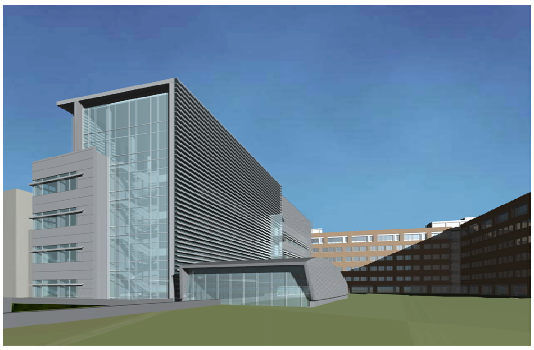
Requested Increase for FY 2006
(Dollars in $000)

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

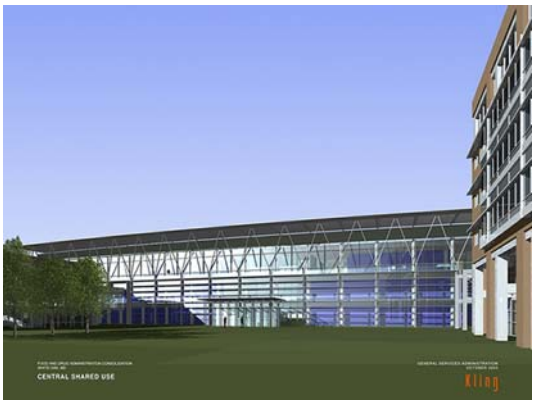
The request will be used for the CDRH Engineering and Physics laboratory and the Shared Data Center move which include:

- 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**

PRESIDENT'S MANAGEMENT AGENDA

The President's Management Agenda (PMA), announced in the summer of 2001, is an aggressive strategy for improving the management of the Federal government. It focuses on five areas of management across the government where improvements and progress can be made to deliver results to the American people. It reflects the Administration's commitment to achieve immediate, concrete, and measurable results in the near term, while focusing on remedies to serious problems, and commits to implement them fully.

The five government-wide goals are Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded E-government, and Budget and Performance Integration. These goals are mutually reinforcing. For example, workforce planning and restructuring undertaken as part of Strategic Management of Human Capital will be defined in terms of each agency's mission, goals, and objectives--a key element of Budget and Performance Integration. Agency restructuring is expected to incorporate organizational and staffing changes resulting from Competitive Sourcing and Expanded E-government. Likewise, efforts toward Budget and Performance Integration will reflect improved program performance and savings achieved from Competitive Sourcing and will benefit from financial and cost accounting and information systems which are part of efforts in Improved Financial Management. This review will give an update of the Agency's progress and achievements made during the past year.

Strategic Management of Human Capital

FDA is moving assertively to meet the goals of the PMA and is firmly committed to the DHHS goals to significantly improving efficiency and controlling FTE growth. The Agency has already taken a series of important steps towards achieving these goals and will continue to do so to meet the PMA and the DHHS initiatives.

Workforce Development Programs -- The FDA has expanded its FAME [Formula for Achieving Managerial Excellence] leadership training created to assist supervisors, managers and team leaders in identifying and developing the critical management and leadership skills necessary to communicate effectively, manage successfully, and create and contribute to motivated high-performance teams. FAME has also been expanded to include a fourth course, Supervisory Potential Program, which was designed to address FDA's succession planning needs and supports the FDA's strategic workforce plan to build a strong FDA by identifying future supervisors early in their careers. FDA widened its audience to include non-supervisory employees seeking the opportunity to explore supervision as a career. A leadership development program was redesigned to internally groom the future leaders of the agency.

Workforce Analysis and Workforce Planning -- A strategic workforce restructuring plan was submitted during the FY 2005 budget process outlining FDA's on-going restructuring initiatives to right-size FDA's workforce

transitioning from a large administrative support staff within each of FDA's components to a smaller, centralized unit providing administrative and support services customized according to component's needs and funded on a reimbursable basis.

FDA is moving toward competency-based business processes that depend on the correct mix of skills and abilities. With improved business processes and realigned support services, FDA should be able to redirect its resources into more mission critical positions whose skills and abilities would enable the Agency to meet its performance commitments.

Workforce Restructuring -- In an effort to improve upon our Human Capital Management Initiative, FDA offered Voluntary Separation Incentives (VSIP) to an estimated 900 employees in various administrative series. The incentives were offered in an effort to reduce administrative FTE and to assist those employees affected by the current competitive sourcing studies. A total of 320 employees accepted this incentive in FY 2004.

In January 2004, FDA began to receive its human resource (HR) services from the Department's Rockville HR Center. FDA retained the strategic workforce planning and several customized programs tailored to Agency operations. These include the administration of the Peer Review System, Commissioned Corp HR liaison, performance management, and award ceremonies.

In early FY 2004, the Office of Shared Services (OSS) was launched to provide administrative services from a single organization. By the end of FY 2004, all of FDA components including the ORA and NCTR were integrated into the OSS framework. The promise of OSS, combined with improved business processes, will allow FDA to maintain administrative service levels with substantially fewer staff.

Special Recruiting -- The Agency has embarked on a strategic recruitment outreach initiative designed to ameliorate the most significant area of under representation in the FDA workforce, namely the Hispanic community. FDA has also participated in the implementation of the Department's Hispanic Outreach Initiative.

Accountability -- In FY 2004, all of FDA's employee performance contracts and plans were linked to Agency and Departmental program goals and management objectives. This requirement will continue in FY 2005.

Improved Financial Performance

Erroneous Payments
FDA participated in the DHHS' Recovery Auditing Work Group, to develop uniform policies and procedures to be used across the Department in complying with the Improper Payment Improvement Act. The final Statement of Work has been submitted for review. FDA also conducted improper payments risk assessments for its Foods, Human Drugs, and Medical Devices programs.

Financial Management Improvement --
At the beginning of FY 2004, FDA transferred its processing of financial transactions (commercial payments,

travel, payroll, etc.) from the Office of Financial Management (OFM) to the OSS, which was created to provide administrative services for all FDA staff in the centers, field, and headquarters using the "shared services" model to achieve savings through management efficiencies and cost effective service delivery. OFM retained the functions related to policy, reporting, systems, application management, budget formulation, and budget execution.

FDA created the User Fees Team to better manage the execution, reporting and accountability of the FDA's user fee programs, in addition to the information provided for the budget formulation process. These programs include the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee and Modernization Act (MDUFMA), Animal Drug User Fee Act (ADUFA), Mammography Quality and Standards Act (MQSA), and Export Certification user fees. The User Fees Team is also responsible for implementing the new user fee system to administer user fee transactions and assist in the development of the financial reports required by Congress for PDUFA, MDUFA, and ADUFA.

FDA received its seventh consecutive unqualified, or clean, audit opinion on its financial statements from the DHHS Office of Inspector General in December 2004.

FDA jointly lead a financial shared services center study for HHS which will be used along with the information obtained from other OPDIVs to formulate DHHS policy on financial services.

Data clean-up and process improvement activities continued in multiple areas, including Open Documents, fund Balance with Treasury, SF-224, Accounts Receivable, Travel Advances, and Grants Reconciliation.

Financial Systems -- In FY 2004, FDA entered the development phase of UFMS. This involves evaluating the software to see if it meets FDA-specific needs, testing the new system and determining training requirements for users. The Agency will also continue data clean-up, collect management reporting requirements, and support the upgrade of the legacy systems.

In FY 2005, FDA will complete implementation of UFMS, replacing its old general ledger accounting system and continue planning for additional modules while continuing to support its current systems. FDA-specific projects are known as the Financial Enterprise Solutions (FES) that is comprised of a set of distinct and separate FDA financial systems that are integrated with HHS' UFMS. The following is a description of the UFMS and FES project activities:

UFMS

- Completed the business process flows that document the FDA approach to processing financial transactions through the system;
- Began the Data Conversion strategy discussions for FDA in preparation for the cutover on October 1, 2004 and April 2005;
- Began validating the FDA accounting transaction codes and associated pairs against the Treasury Standards to identify the gaps;
- Began participation in global interface teams for both global and FDA specific interfaces including: payroll, grants, procurement, travel and property;
- Worked on refining the plan for incorporation of Business Transformation Activities;
- Conducted the FDA Conference Room Pilot with FDA components to demonstrate that Oracle Financial software could meet FDA business needs and that FDA's implementation strategy will meet the UFMS global needs; and,
- Drafted plans for communication, and began reviewing strategies for organizational assessments and Agency-wide end user training.

FDA's share of the FY 2006 UFMS costs is $ 11.595 million, which excludes operations and maintenance costs.

FES

- Modernized financial management infrastructure for the remaining user fee programs (PDUFA, MDUFMA, MQSA, and export certification) based on the successful implementation of the Animal Drug User Fee Act. Accomplishments include:
    - Interfaced to obtain applicant data, track user fee billing and collection, and provide financial reports of user fee activities; and,
    - Modified the Accounts Receivable System by capturing initial user fee program receipts and transitioning these receipts to the Accounts Receivable module of the new financial system.
- Continued the implementation of the Purchase Request Information System (PRISM) by:
    - Working with FDA contracting staff to develop requirements for the contracts implementation of PRISM; and,
    - Begining planning the implementation of i-Procurement software that will automate the process of requisitions and interface with PRISM and UFMS. I-Procurement will begin implementation in April 2005 and continue through FY 2006.

- Travel Manager and 348 Sponsored Travel Module
    - Completed implementation of FDA Travel Manager for the entire Agency;
    - Completed (HHS-348) Sponsored Travel module roll-out;
    - Provided safeguards to insure complete review of documents, compliance with travel regulations and official approvals, including on-line signature capabilities; and,
    - Allowed users to assign and allocate cost differentials among sponsors, handle diverse travel reimbursement categories, certify and print associated documents, and electronically route documents and forms to correct destinations.

Accountability -- FDA has strong internal controls over financial reporting and management practices. Some examples include the following:

- Prepared monthly and quarterly reconciliations as required by the Department to ensure the balances reported in financial reports are accurate;
- Ensured that training, communications, completing critical reconciliations, and holding managers accountable for their assigned areas of responsibility.
- Included financial performance measures in the performance plans of all senior executives at FDA;
- Prepared and submitted FY 2004 Corrective Action Plan to DHHS; and,
- Prepared and released the MDUFMA and PDUFA reports on the management of both user fee funds.

The FY 2004 Conformance Statement determined that FDA's financial management systems were in general conformance to financial system requirements found in OMB Circular A-127. This determination was based on a review of previous audit findings, completed corrective actions, and the design and implementation of new financial management system that is intended to bring all of the Agency's financial systems into substantial compliance to Section 803(a) of the Federal Financial Management Improvement Act (FFMIA).

While the OIG determined in the financial statement audit that FDA's financial management systems do not substantially comply with FFMIA, this noncompliance should be removed once UFMS is fully operational. No instances exist in which FDA's financial management systems do not substantially comply with Federal accounting standards and the U.S Standard General Ledger at the transaction level.

Integrate Financial and Performance Management Systems -- The requirement to support the integration of performance and financial reporting that meet the specifications in OMB Circular A-11, Part 6 has been identified within UFMS. Currently, no method exists for reporting. A custom reporting solution in the Oracle Federal Financial software will be created to comply with this requirement.

In addition, the FDA's Annual Financial Report includes both cost information and performance results. Performance results come from select performance goals and measures chosen by FDA programs, while cost information is derived from the Statement of Net Costs. Combining these elements provides a picture of the program, its accomplishments and costs.

Expanded E-Government

IT Consolidation - FDA continued its progress towards the consolidation of its IT infrastructure by collaborating with DHHS towards achieving its "One HHS" goals and objectives; initiating efforts to accomplish the IT consolidation goals mandated by the reauthorization of PDUFA, and establishing an IT Shared Services organization to manage the FDA's consolidated IT infrastructure. To this end, FDA has:

- Launched the Office of Information Technology Shared Services (OITSS) – The goal of the FDA was to facilitate the goal of IT consolidation, enabling the Agency to deploy IT effectively and efficiently. This was achieved on October 1, 2003. The support of the ORA and NCTR completed by the end of FY 2004. This organization will facilitate management of FDA's IT resources, enabling the Agency to devote more time and effort to its E-Gov. efforts;

- Reorganized the Office of the Chief Information Officer (CIO) to ensure key strategic leadership in IT and improved capability for ensuring that IT strongly supports FDA mission goals and objectives;

- Transitioned all Center, OC and ORA formal IT organizations to directly report to the CIO;

- Awarded the Single Source Infrastructure Service Support Contract in August 2004 that will provide efficiencies and savings through consolidation of services and management of contractors;

- Completed its PDUFA III IT Strategic Plan which outlines long term strategies for meeting PDUFA goals and effecting consolidation;

- Instituted the PDUFA IT Governance process to more closely link PDUFA IT initiatives to satisfying PDUFA III IT goals;

- Made substantial progress in the area of standardization by implementing the Electronic Common Technical Document (eCTD) specification, releasing draft guidance, and deploying the eCTD Viewer system as a tool in reviewing the new application submitted in the eCTD format.

Enterprise Architecture – IT Projects –

- Developed "As Is" baseline architecture and initiated the Agency e-submission strategy by developing requirements and the appropriate target architecture;

- Produced, and initiated implementation of a Corrective Action Plan to effect mature project management practices throughout the Agency including establishment of a project management (PM) training program;

- Developed and implemented the FDA Unified Registration and Listing; in the short term, produced a Food Registration and Account Management Module that met the mandatory requirement for Food Facilities to begin registration on October 12, 2003 and; in the long term, will consolidate other FDA registration systems; and,

- Advanced the Capital Planning and Investment Control process as a result of the establishment of the Project Management Office, which has fostered project management training, and development of policies relating to the systems development life cycle and governance process; and the acquisition and institutionalization of a portfolio investment management tool.

Government E-Projects – FDA has made significant contributions to this effort by providing key IT and technical personnel to actively participate on each DHHS project team. This collaborative effort also extends to the Enterprise Human Resource Planning project and HHS Corporate University. Agency IT staff has also made contributions as part of the development of the HHS 5-Year IT Strategic Plan. The FDA has begun the development of an Enterprise Architecture (EA), having completed an "As Is" baseline. The EA efforts continue to be closely aligned with the DHHS EA Program.

FDA is continuing to contribute key IT and financial technical personnel in support of various Departmental projects. For example, FDA is participating with the Department, who is a managing partner, in the Federal Health Architecture initiative, which is a set of guiding technology and management principles that will impact the health industry by enabling innovation in care, reduced cost, and improved access and enhanced public health threat preparedness.

The Agency is involved in the Business Gateway E-Gov initiative by participating in design and implementation meetings and using the E-Forms Catalog to register FDA forms.

FDA assumed a leadership role in the Department for the Online Rulemaking Initiative – the formal launch of Phase I of www.regulations.gov was successfully held on January 23, 2003. Work has begun on structuring Module 2, and a team has been set up to provide continuing maintenance and web site change control.

The team is now involved in the Phase II requirements process. The team has a representative on the technical and the legal workgroups. The legal workgroup is currently identifying legal issues that will have to be resolved before moving to a central system. The technical

workgroup is working to define the technical blueprint/road map for the construction of the eRulemaking system.

In addition to these activities, FDA supported various Departmental initiatives such as:

Secure One HHS – The goal of Secure One is "to create an enterprise-wide secure and trusted IT environment in support of the overall HHS mission". FDA has supported this goal by establishing a comprehensive security program that:

- Contains security performance measures and metrics, regularly monitored by the FDA Chief Information Systems Security Officer;

- Characterizes and categorizes systems and resources to identify what is most critical and vulnerable, in order to develop reliable and appropriate security plans;

- Institutionalizes an Agency-wide training program impacting both system managers and the general user; and,

- Makes use of a well-coordinated communications effort to highlight security as the highest priority of the FDA CIO and inform all levels of the FDA workforce.

In FY 2004, FDA documented in formal reports (Privacy Impact Assessments, Plan of Actions and Milestones, and Certification and Accreditation) outcomes demonstrating FDA successfully and fully met the goals of the Secure One HHS Program.

Grants Consolidation – FDA is working with NIH staff regarding details of the migration to the eRA/IMPAC II Grants Management System. FDA has also participated in two DHHS subcommittees established to achieve efficiencies and uniform processes across the Department.

HHS enterprise-wide initiatives – Consolidation of like-services has been a linchpin of the "One HHS" strategy. FDA has provided expertise and resources, with special emphasis on the following projects:

- HHSnet – HHSnet is a department wide initiative to architect a comprehensive network design that encompasses all aspects of the HHS Enterprise Network including the build-out of the HHSnet Network Operation Center (HHS/NOC), while maintaining a strong security posture. The goals of the network redesign are to support intra-operational division communications, to ensure high performance and reliability of strategic systems. FDA assumed a leadership role in the effort, working closely with OPDIV and HHS counterparts, and meeting regularly with senior HHS leadership to discuss progress. FDA was the first OPDIV to transition to the new network, and then coordinated the deployment of other segments throughout HHS. FDA will relinquish control in October when the network is operational; and,

- Unified E-mail – Another consolidation strategy has been unifying e-mail systems across HHS

in order to take advantage of economies of scale and common standards. FDA has been a strong participant, having appointed a team responsible for managing FDA's responsibilities from design to rollout. The team is currently working to define FDA requirements and incorporating them into the final design.

Competitive Sourcing

FAIR Act Inventory --
In accordance with the Federal Activities Inventory Reform (FAIR) Act of 1998, FDA submitted its 2004 FAIR Act inventory, which identified 1,516 FTE as commercial and 9,044 FTE as inherently governmental. The development of the FY 2004 FAIR Act inventory began in March 2004.

Competition Schedule – In FY 2003, FDA completed all six scheduled studies involving 230 FTE in an average of 12 months or less meeting both the competitive sourcing standards for success.

Full cost comparison studies of graphic arts/visual information services, medical/scientific library services, and a television studio were done in FY 2003. The decision was to retain the functions in-house, with Most Efficient Organizations (MEOs) implemented in December 2003. Full cost comparison studies on General Accounting, Facilities, and Biological Physical Science Technicians were completed in FY 2003. These MEOs were implemented in March 2004.

FDA estimated total expected savings over a five year performance period for the six MEOs at $16.4 million with no involuntary separations. Coupled with the other administrative restructuring taken in FY 2003 and FY 2004, FDA met the Secretary's goal of administrative staff reduction set in FY 2005 and achieved significant savings that were redirected into mission critical activities. FDA formally began its study for clerical support services on February 26, 2004. This study encompasses 350 FTE and is currently in the source selection phase of the competition with a target completion date of February 25, 2005.

Participates in Department-wide Initiatives -- FDA is also renegotiating its Memorandum of Agreement with the National Treasury Employee's Union to reflect changes to OMB Circular A-76. FDA has also been instrumental in helping HHS formulate its competitive sourcing and green plans. In addition, FDA is working with HHS to develop criteria to define a high performing organization**.**

Budget and Performance Integration

The Office of Management and Budget specified criteria that DHHS had to show progress in order to achieve a passing score. Progress is shown in four areas: performance information in the DHHS FY 2006 budget request, development of the FY 2006 HHS Annual Performance Plan, use of PART information in Agency decision-making, and using reports integrating financial and performance information for agency deliberations.

FDA's FY 2005 Congressional Justification (CJ) integrated performance information throughout the budget

narrative and aligns program sections by FDA strategic goals. The CJ contained an efficiency goal and several outcome performance goals that were recommended in the first PART assessment, and explained how OMB's PART evaluation was used to guide resource and performance decision-making in creating the FY 2005 budget and performance request. The CJ also included full cost information for each performance goal.

Development of Annual Performance Plan / Report -- FDA has worked with the HHS Office of Budget staff to complete the final FY 2006 HHS Annual Performance Plan. Two of the 19 representative programs are from FDA. FDA provided accurate and timely performance and budget information on both of its represented programs. FDA has decreased the overall number of goals in the performance plan from 71 to 44 and also included new long-term outcome goals. In addition, the mix of goals has been refocused toward high-risk goals, particularly to guard against the terrorist threat.

In the FY 2006 budget period, the FDA budget request and performance plan are combined into one performance budget document. This document adds performance plan information along with the FY 2006 performance goals and its full cost information to the traditional budget program chapter. The remaining items contained in the former plan are part of the performance budget's appendices.

Use of Information From PART in the Integration Process -- Since FDA was fully assessed in FY 2005, the Agency did not have any programs to propose for FY 2006-2008.

FDA has responded to the OMB PART with a concerted effort led by our Commissioner and his leadership team. The result of that effort yielded FDA a moderately effective rating. OMB requested FDA to provide yearly updates to show progress on the development of new long-term outcome goals.

Accordingly, FDA developed eight new long-term outcome goals for the FY 2005 PART. In order 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 building the capacity and capability for meeting these commitments.

To monitor the Strategic Action Plan's objectives and GPRA performance commitments, FDA leadership established the Strategic Planning Council to ensure timely progress.

In January 2004, this council agreed to establish a performance framework that systematically linked an array of program activities, outputs, and outcomes to support and demonstrate progress in meeting the long-term outcome goals. This council has also charged that the Agency should prepare for the FY 2006 PART process with DHHS and OMB in order to improve the Agency's PART score and make performance and resource decisions for the upcoming budget cycle.

In addition, the budget and performance integration efforts of the past several years have more consciously linked resources with results. Under this new methodology, the traditional budget presentation is now coupled with performance information presenting a complete resource and performance picture. The presentation order in the FY 2006 performance budget is: base activities (justification), 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 the achievement of long-term public health outcomes and strategic goals.

Examination of Reports Integrating Financial and Performance Information - Through two of its senior Agency level decision-making bodies, the bi-weekly Strategic Planning Council and the Management Council, FDA uses integrated performance and resource information to review the progress of implementing long-term outcome performance goals, to prepare for the PART meetings with DHHS and OMB, and to make performance and resource decisions for the upcoming budget cycle.

FDA also developed a marginal cost methodology that will enable program managers to determine performance and cost impacts on various budget scenarios. This methodology was presented at the Strategic Planning Council for review and concurrence. The Animal, Drugs and Feeds Program is being used as the pilot to test this methodology.

Program Assessment Rating Tool (PART) Summary

Food and Drug Administration

FY 2004–2006

(Dollars in Millions)

FY 2004 PARTs**	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating
FDA's Five Centers were evaluated: -- Center for Biologic Evaluation & Research -- Center for Devices & Radiological Health -- Center for Drug Evaluation & Research -- Center for Food Safety & Applied Nutrition -- Center for Veterinary Medicine				All received Results not Demonstrated

**No resources are shown because OMB decided in the FY 2005 PART process to evaluate FDA as a whole entity and not as separate components as in the FY 2004 PART.

FY 2005 PARTs	FY 2004 Enacted	FY 2005 Appropriation	FY 2006 Request	Narrative Rating
Food and Drug Administration	$1,800,541,000	$1,881,489,000	+$80,948,000	moderately effective
FY 2006 PARTs				
No PART was performed in FDA during the FY 2006 budget cycle.				

Narrative

For the FY 2005 PART, OMB decided to evaluate FDA as a single entity and not five programs. FDA senior leadership made a concerted effort to improve the PART score by developing outcome and efficiency goals, reducing the number of performance goals, and implementing management improvements. Based on these actions, OMB gave FDA a rating of moderately effective. Specifically, the FY 2005 PART assessment found:

- FDA has a clear mission and a unique Federal role in protecting public health;
- FDA is well managed, and a has strong and comprehensive strategic planning process;
- FDA's annual performance goals allow for measurement of performance results;
- FDA generally meets most annual performance goals;
- Financial management at FDA is sound; FDA has received a clean audit free of internal material control weaknesses for five consecutive years; and
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

FDA's senior leadership used integrated performance and financial reports to deliberate and decide on the Agency's approach to preparing FDA's Performance Budget submission. These reports enabled senior managers to understand the FY 2004 funding environment, the projected budget environment in FY 2005, and the cumulative impact of these conditions on the FY 2006 performance budget submission. This information also enabled FDA senior leadership to examine the performance impact under various budget scenarios. The FY 2006 Performance Budget reflects the deliberations of this group, based in large part on the information contained in integrated financial and performance reports.

NOTE: The OMB PART Summary Rating, which follows this summary narrative, contains a correction in the "Actual" column of the Long-term efficiency measure. This number, 2,766, is the correct number. In the FY 2006 President's Budget, this document contains the error.

Program: *Food and Drug Administration*

Agency: *Department of Health and Human Services*

Bureau: *Food and Drug Administration*

Rating: *Moderately Effective*

Program Type: *Regulatory Based*

Last Assessed: *1 year ago*

Key Performance Measures from Latest PART	*Year*	*Target*	*Actual*
Long-term Efficiency Measure: Reduce administrative staff	2004	2,855	2,766
	2005	2,623	
	2008	2,623	
Annual Measure: Percentage of new drugs and biologic product reviews completed within 10 months.	2004	90%	
	2005	90%	
	2006	90%	
Long-term Measure: Percentage of medical device submissions that will receive final decisions within 320 review days.	2001		72%
	2005	70%	
	2006	80%	
	2007	90%	

Recommended Follow-up Actions	*Status*
Is requesting additional food defense resources to support the achievement of FDA's lab surge capacity targets.	Action taken, but not completed
Will track FDA performance on new long-term outcome goals.	Action taken, but not completed

Update on Follow-up Actions:

FDA has started efforts to measure performance on long-term outcome goals developed for the FY 2005 PART. For some of these long-term outcome goals, the agency is developing baseline data needed to measure performance improvements. For others, the agency is focusing efforts on improvements in performance and management practices.

Program Funding Level (in millions of dollars)

2004 Actual	2005 Estimate	2006 Estimate
1,695	1,801	1,881

APPROPRIATIONS LANGUAGE

TITLE VI
RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; and notwithstanding section 521 of Public Law 107–188; [$1,820,849,000] *$1,881,489,000, of which $7,000,000 shall remain available until expended for plans, construction, extension, alteration, and purchase of fixed equipment or facilities*: Provided, That of the amount provided under this heading, [$284,394,000] *$305,332,000* shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, [and] shall be credited to this account and remain available until expended, Provided, That this amount shall not include any fees pursuant to 21 U.S.C. 379h(a)(2) and (a)(3) assessed for fiscal year [2006] *2007* but collected in fiscal year [2005] *2006*; [$33,938,000] *$40,300,000* shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; and [$8,000,000] *$11,318,000* shall be derived from animal drug user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, and animal drug assessments received during fiscal year [2005] *2006*, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year [2005] *2006* limitation: Provided further, That none of these shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701 [*Provided further,* That of the total amount appropriated: (1) $439,038,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $498,647,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $172,714,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $98,964,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $235,078,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $40,530,000 shall be for the National Center for Toxicological Research; (7) $57,722,000 shall be for Rent and Related activities, other than the amounts paid to the General Services Administration for rent; (8) $129,815,000 shall be for payments to the General Services Administration for rent; and (9) $115,970,000 shall be for other activities, including the Office of the Commissioner; the Office of Management; the Office of External Relations; the Office of Policy and Planning; and central services for these offices:]

In addition, mammography user fees authorized by 42 U.S.C. 263b may be credited to this account, to remain available until expended.

In addition, export certification user fees authorized by 21 U.S.C. 381 may be credited to this account, to remain available until expended.

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, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The budget provides a [$108.78] *$49,628,000* increase in budget authority over the FY [2004 Omnibus Appropriation Act] *2005 Enacted Budget*. In addition, the Budget includes an increase of [$39.85] *$31,320,000* in current law user fees over FY [2004] *2005*, which will be used to cover *non pay related* inflationary increases [as well as increases in workload for the PDUFA, MDUFMA, and ADUFA programs]. In total, the budget includes [$1.821] *$1,881,489,000* at the program level, which includes funding for counter terrorism activities that specifically relate to the protection of products or therapies regulated by the FDA (such as drugs, vaccines, foods, and animal feed), and the availability of medical products for public health preparedness in the event of an attack. Specifically, the budget requests increased funding for food defense, *medical device review, the Office of Drug Safety, GSA Rent payments, moving expenses the CDRH Engineering and Physics lab and the shared data facility at the White Oak campus, and maintenance of building and facilities.*[medical counter measures related to terrorism or other related threats to pubic health, medical device reviews, protecting the safety of the U.S. food and feed supply from Bovine Spongiform Encephalopathy (BSE), inflationary pay increases], and moving expenses for a new Human Drugs facility in White Oak, Maryland].

Salaries and Expenses - Explanatory Notes

1/ Language is retained which provides FDA with the authority to credit to this account fees that may have been collected in excess of amounts appropriated in a previous year, if any such excess collections occurred. This is the intent of section 736(g)(4) of the Food Drug and Cosmetic Act, and it exempts FDA from making small individual refunds of unanticipated excess collections. Excess fees from previous years, if any, would be used to reduce the amount of fees FDA would collect in a subsequent year--in effect lowering the fees that FDA would otherwise assess and collect. This is intended to make appropriation language consistent with authorizing language.
2/ Important language is added that enables FDA to collect user fees for drug establishments and products, as set forth in the Prescription Drug User Fee Act (PDUFA), but that such fees collected during fiscal year [2005] *2006* year and assessed for fiscal year [2006] *2007*, not count against the FY [2005] 2006 collection ceiling established in the FY [2005] *2006* appropriation law.

Food and Drug Administration
Fact Sheet – Alabama

FDA Presence: 7 employees in Alabama
Resident Posts: Birmingham, Mobile, and Montgomery
- report to: New Orleans District who
- reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State
There are 1,531 FDA-regulated establishments in the State of Alabama
- Food establishments (includes cosmetics) – 38 percent
- Medical Device and radiological establishments – 31 percent
- Human Drug establishments – 20 percent
- Animal drug and feed establishments – 6 percent
- Biological establishments (includes blood banks) – 5 percent

Industry Highlights
- Three ports of entry – Mobile, Huntsville, Birmingham. Mobile is a large port for exportation of grain products and moderate importation of various food and seafood products.
- Along the Gulf Coast - concentration of the seafood industry.
- Catfish aquaculture
- Medicated feed mills for the poultry industry.
- There is considerable medical device presence, as well as a wide range of clinical research activity through medical university settings.
- Biologics presence is in the form of regional blood testing facilities.

Contracts & Partnerships
State Contracts
Alabama Department of Public Health
- Conduct inspections of food manufacturers for sanitation.

Alabama Department of Public Health
- Conduct inspections of mammography facilities.

Alabama Department of Agriculture and Industries
- Conduct BSE inspections

State Partnerships
Alabama Department of Public Health
- Establish a partnership for the regulation of new x-ray assemblies or reassemblies

Special Programs
Functioning Food Safety Task Force which includes AL Department of Public Health, AL Department of Agriculture, Auburn Cooperative Extension Service, AL Restaurant Association, Winn Dixie (grocer representative).

Food and Drug Administration
Fact Sheet – Alaska

FDA Presence: 2 FDA employees in Alaska
Resident Post: Anchorage
reports to: Seattle District: Bothell, Washington, Charles Breen, DD
reports to: Pacific Region: Oakland, California, Brenda Holman, RFDD

Industry Presence in State
There are 477 FDA-regulated establishments in the State of Alaska
Food establishments (includes cosmetics) –80 percent
Medical device and Radiological establishments – 12 percent
Human drug establishments – 3 percent
Biologic establishments (includes blood banks) – 3 percent
Animal drug and feed establishments – 2 percent

Industry Highlights
- Alaska supplies most of America's salmon, crab, halibut, and herring. Alaska is the number one producer of wild salmon in the world and has the only salmon industry certified as "sustainable".
- Alaska ranks as one of the top ten seafood producers worldwide. More than 6 million pounds of seafood are harvested off Alaska each year, making up approximately 60% of all U.S. production. The total value of Alaska seafood production has topped $2.5 billion annually for several years.
- Dutch Harbor and Kodiak consistently rank as two of the top three ports in the U.S. for tonnage of seafood brought in. Alaska has over 33,000 miles of shoreline -- more than the rest of the U. S. combined.

Contracts, Partnerships & Local Activities
State contracts
Alaska Department Environment and Conservation
- Conduct food safety inspections.

Alaska Department of Health
- Conduct inspections of mammography facilities.

State Partnerships
Alaska Department of Environmental Conservation
- Conduct inspections of the fish and fishery products processing industry for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations.
- Conduct mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms in the State of Alaska.

Food and Drug Administration
Fact Sheet – Arizona

FDA Presence: 27 employees in Arizona
Resident Posts: Phoenix, Tucson, and Douglas
report to: Los Angeles District, Irvine, California, who
reports to: Pacific Region, Oakland, California
Resident Posts (imports): Nogales and San Luis report to:
Southwest Import District, Dallas, Texas, who
reports to Southwest Region, Dallas, Texas

Industry Presence in State

There are 1,816 FDA-regulated establishments in the State of Arizona
Food establishments (includes cosmetics) – 37 percent
Medical Device and Radiological establishments – 36 percent
Human Drug establishments – 17 percent
Biological establishments (includes blood banks) – 4 percent
Animal drug and feed establishments – 6 percent

Industry Highlights

- The Arizona Department of Agriculture and FDA are in the process of formalizing a cooperative agreement on training and technical assistance between the two agencies and Mexico with regard to Good Manufacturing Practices and Good Agricultural Practices.
- There are 5 firms in Arizona that produce human biological products including 6 plasmapheresis centers and 4 American Red Cross facilities.
- There are more than 10 manufacturers of vitamin and mineral Over-the-Counter products.
- Steris, a drug manufacturer in Arizona, is under an injunction.
- Imports into Arizona: The Southwest Import District receives approximately **363,535** line entries per year. The primary products are: Fresh Produce, Frozen Shrimp, and Medical Devices.

Contracts and Partnerships

State Contracts

Arizona Radiation Regulatory Agency
- Conduct inspections of mammography facilities.

Arizona Department of Agriculture
- Conduct inspections of feed mills for medicated feeds and BSE.

State Partnerships

Arizona Department of Agriculture
- Agree to establish working arrangements concerning their mutual planning and share reports of inspection, investigations, and analytical findings relating to raw agricultural products

Arizona Department of Health Services
- Coordinate retail food protection efforts & promote Hazard Analysis and Critical Control Points (HACCP) principles to control food safety hazards at the retail level.

Food and Drug Administration
Fact Sheet - Arkansas

FDA Presence: 71 field and 249 research center employees in Arkansas
Resident Post in Arkansas: Little Rock (2 investigators)
reports to: Dallas District, Dallas, Texas, who
reports to: Southwest Region, Dallas, Texas
Arkansas Regional Laboratory: Jefferson (69)
reports to: Southwest Region, Dallas, Texas
National Center for Toxicological Research (NCTR), Jefferson (249)
Import entries are handled out of the Dallas Southwest Import District Office and through the Dallas District Staff located in Arkansas

Industry Presence in State
There are 1,371 FDA-regulated establishments in the State of Arkansas.
Food establishments (includes cosmetics) - 60 percent
Animal drug and feed establishments - 16 percent
Medical device and Radiological establishments - 13 percent
Human drug establishments -10 percent
Biologic establishments (includes blood banks) -2 percent

Industry Highlights
- Eggs - Arkansas is a major egg production state.
- Poultry - Arkansas is the home of Tyson poultry productions
- Canning - Arkansas is the home of Allen's, Gerber and Bush canning manufacturers
- Grains - Arkansas includes a significant rice, wheat, and soybean production.
- Farming - Arkansas includes productive animal feed production and catfish farming.

The Southwest Import District receives approximately 1,365 line entries per year.

Contracts, Partnerships & Local Activities
State Contracts
Arkansas Department of Health
- Conduct food sanitation inspections.
- Conduct inspections of mammography facilities.

Arkansas State Plant Board
- Conduct feed mill inspections; determines compliance with BSE Rule.

State Partnerships
Arkansas Department of Health
- Establish a partnership with the Arkansas Department of Health to share oversight & authority of regulated dairy manufacturing facilities.
- Has an agreement with the Jefferson Labs (NCTR) for emergency space and also shares in an informal reciprocal agreement with ARL for the FERN.

Local Activities FERN
NCTR, a FDA research center, employs 249 government scientists and approx. 300 contract support personnel who conduct fundamental, translational research that results in developing, modifying or validating FDA regulatory standards. Current work includes studies to assess the phototoxicity of cosmetic ingredients; studies to develop methods/standards for food safety, antibiotic resistance and counter-terrorism agents, and evaluating and incorporating new technologies to aid in understanding the risk associated with FDA regulated products.

Dallas District Public Affairs Specialists respond to consumers and media inquires and conduct consumer education outreach to diverse constituents.

Food and Drug Administration
Fact Sheet – California

FDA Presence: 484 FDA employees in California
Resident Posts: Fresno, Sacramento, San Jose, and Stockton.
report to: San Francisco District, Alameda, who
reports to: Pacific Region, Oakland
Resident Posts: San Diego, Santa Barbara, San Pedro, LAX, Ontario and Canoga Park
report to: Los Angeles District, Irvine, who
reports to: Pacific Region, Oakland
Pacific Region Laboratory Southwest, Irvine, who
reports to: Pacific Region, Oakland
Southwest Import District Resident Posts: Otay Mesa, Calexico, San Diego Seaport/Airport, and Tecate
report to: Southwest Import District, Dallas, Texas who
reports to: Southwest Region, Dallas, Texas

Industry Presence in State
There are 15,969 FDA-regulated establishments in the State of California
Food establishments (includes cosmetics) - 45 percent
Medical device and Radiological establishments - 38 percent
Human drug establishments - 10 percent
Animal drug and feed establishments - 5 percent
Biologic establishments (includes blood banks) - 2 percent

Industry Highlights
- California has the greatest number of medical device and biotechnology firms of any area in the United States. They are concentrated in the San Francisco Bay Area, Orange County and San Diego areas.
- California is a major producer of tree nuts and the only state that produces almonds.
- California receives an estimated 25% - 30% of all FDA regulated commodities imported into the United States, and contains the largest harbor complex in the country. Additionally, with the international cargo from Los Angeles International Airport, courier hubs at regional airports, and the International mail processing facility for all of Southern California the district serves as the "Gateway to the Orient" for imports and exports and with the import operations along the U.S. Mexico border, a significant "Gateway to Mexico." A total of 70% of all incoming cargo is believed to stay within the state boundaries.

Contracts & Partnerships
<u>State contracts</u>
California Department of Food & Agriculture (DFA)

- Conduct follow up investigations of reported tissue residues of food animals detected at the time of slaughter.
- Conduct inspections of feed mills and BSE.

California Department of Health Services (DHS)

- Conduct inspections of mammography facilities and x-ray testing

State Partnerships

California Department of Food & Agriculture (DFA)

- Coordinate efforts to prevent unsafe imported dairy products from entering commerce.
- Coordinate inspections of medicated feed mills and residue investigations.
- Coordinate regulatory activities involving pesticide residues on raw agricultural commodities.

California Department of Health Services (DHS)

- Coordinate retail food protection efforts to promote HACCP principles for food safety
- Conduct inspections of all Acidified & Low Acid Canned Food processors.
- Conduct inspections of seafood processing facilities.
- Continue partnership with the laboratory in Los Angeles to co-locating employees and sharing equipment.
- Establish partnership to co-locate employees in Sacramento.
- Conduct inspections of new x-ray assemblies or re-assemblies.
- Share inspectional and other information to ensure unified food safety programs.

DHS & DFA

- Coordinate cooperative agreement to support the California Egg Quality Assurance Plan.

Other Partnerships in California

- Coordinate with American Council for Food Safety & Quality to maintain sanitation and compliance with regulations for dried fruit and tree nut products.
- Information sharing with the University of California, Irvine, through an electronic communication system that transmits current health information regarding toxic substances throughout the California County Health Departments.

Food and Drug Administration
Fact Sheet - Colorado

FDA Presence: 109 FDA employees in Colorado
Denver District, Denver who
reports to: Southwest Region, Dallas, Texas

Industry Presence in State
There are 1,948 FDA-regulated establishments in the State of Colorado
Food establishments (includes cosmetics) - 40 percent
Medical device and Radiological establishments - 30 percent
Human drug establishments – 17 percent
Animal drug and feed establishments - 10 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights
- Colorado is a major cattle producer and also raises large numbers of hogs and sheep. Weld, Morgan, Larimer, and Boulder counties are the national center for the production of cattle fattened in feedlots rather than on the open range.
- Colorado ranks high among the U.S. states in the amount of land under irrigation. Corn (maize), wheat, and hay are the major crops.
- Colorado has a major food and food product industry.

Contracts & Partnerships
State Contracts
Colorado Department of Health
- Conduct food sanitation inspections.
- Conduct inspections of mammography facilities
- Conduct inspections of medical device manufacturers.

Colorado Department of Agriculture
- Conduct inspections of feed mills for medicated feed and BSE Rule Compliance

State Partnerships
Colorado Department of Health & Environment
- Conduct inspections of artificial tanning facilities
- Conduct federal compliance testing of new assemblies or re-assemblies of x-ray equipment

Food and Drug Administration
Fact Sheet – Connecticut

FDA Presence: 14 FDA employees in Connecticut
Resident Posts: Hartford and Bridgeport
report to: New England District, Stoneham, Massachusetts who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State

There are 1,702 FDA-regulated establishments in the State of Connecticut.
Medical Device and Radiological establishments - 46 percent
Food establishments (includes cosmetics) - 33 percent
Human Drug establishments - 17 percent
Biological establishments (includes blood banks) - 3 percent
Animal Drug and Feed establishments - 1 percent

Industry Highlights

- Connecticut has 20% of the District's Official Establishment Inventory of regulated firms with an emphasis on food and medical devices. New England District includes Maine, Massachusetts, Rhode Island, Vermont, New Hampshire, and Connecticut.
- Several major pharmaceutical manufacturers are located in the state.

Contracts, Partnerships & Local Activities

State Contracts
Connecticut Department of Consumer Protection
- Conduct food sanitation inspections
- Conduct seafood Hazard Analysis and Critical Control Point (HACCP) inspections

Connecticut Department of Environmental Protection
- Conduct inspections of mammography facilities

Local Activities
Connecticut has a Food Safety Task Force in which FDA is a participant.

Food and Drug Administration
Fact Sheet – Delaware

FDA Presence: 9 FDA employees in Delaware
Resident Post: Wilmington
reports to: Philadelphia District, Pennsylvania, who
reports to: Central Region: Philadelphia, Pennsylvania

Industry Presence in State
There are approximately 233 FDA-regulated establishments in the State of Delaware

Food establishments (includes cosmetics) - 35 percent
Medical device and radiological establishments – 32 percent
Human drug establishments - 20 percent
Animal drug and feed establishments - 9 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights
- Active seafood industry

Contracts, Partnerships & Local Activities
State contracts
Delaware Department of Health
- Conduct inspections of mammography facilities.

Partnerships
- Participate in the Delaware Food Safety Council (DFSC), a partnership with the state and local government, academia, industry and USDA to address food safety issues.
- DFSC has a yearly seminar for the retail food industry supported, in part, by a Food Safety Grant from FDA. In 2003 the seminar was held in Dover, DE and approximately 125 persons, mainly from food service establishments throughout the state attended. The focus of 2003 meeting was on food security issues and in communicating proper food handling techniques. While no meeting was held in 2004, the 2005 meeting is currently being planned.

Food and Drug Administration
Fact Sheet – Florida

FDA Presence: 109 employees in Florida
Resident Posts: Boca Raton, Ft. Myers, Jacksonville, Miami Import Operations, Miami Domestic Operations, Tallahassee, Tampa
Major Import ports: Miami, Jacksonville, and Tampa
report to: Florida District Office, Maitland, FL
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in Florida

There are 7,709 FDA-regulated establishments in the State of Florida
Food establishments (includes cosmetics) – 40 percent
Medical devices and Radiological establishments – 37 percent
Human drug establishments – 18 percent
Biologics establishments – 3 percent
Animal drug and feed establishments – 2 percent

Industry Highlights

- 370 high risk food firms of which 219 are high risk seafood firms
- Miami is second largest port in US for importation of fresh seafood
- Miami is fifth largest port in US for importation of FDA regulated commodities
- Over 350 class II & III medical device firms

Contracts, Partnerships & Local Activities

State Contracts/Memoranda of Understanding:

Florida Department of Agriculture and Consumer Services

- Conduct feed mills/BSE, food sanitation and seafood HAACP inspections.

Florida Department of Health

- Conduct inspection of mammography facilities

State Partnerships:

Florida Department of Agriculture & Consumer Services:

- Coordinate efforts to collect and analyze imported and domestic food for pesticide residues.
- Coordinate the regulation of imported and domestic fish and fishery products

Florida Department of Health:

- Conduct inspections of new x-ray assemblies and re-assemblies

Local Activities

- Food safety education initiatives with various target audiences including low-income, limited English, elderly, academia, health professionals and industry
- Seminole County Healthy Kids Partnership promotes positive opportunities for school aged children in Seminole County to learn healthy nutrition and the value of increased daily physical activity.
- Close alliance with U.S. Customs making Florida District's highly successful import operation a trendsetter in the areas of enforcement and customer service

Food and Drug Administration
Fact Sheet – Georgia

FDA Presence: 243 FDA employees in Georgia
Resident Posts in Georgia: Middle Georgia, Savannah, and Tifton
report to: Atlanta District, Atlanta, who
reports to: Southeast Region, Atlanta
Southeast Regional Laboratory, Atlanta
reports to: Southeast Region, Atlanta

Industry Presence in State
There are 2,899 FDA-regulated establishments in the State of Georgia
Food establishments (includes cosmetics) – 47 percent
Medical Device and Radiological establishments – 31 percent
Human Drug establishments – 15 percent
Animal Drug and Feed establishments – 4 percent
Biologic establishments (includes blood banks) – 3 percent

Industry Highlights
- American Red Cross Regional Blood Bank.
- Serologicals Corporation HQ (major plasmapheresis center).
- Cryolife (largest/major tissue bank processor).
- Atlanta Hartsfield-Jackson International Airport landport—60,000+ import entries per annum (condoms, gloves, seafood, produce, and medical devices). Savannah seaport—15,000+ import entries per annum (canned foods, medical devices, bulk grains, agricultural products, and juices). Brunswick seaport—less than 25 entries per annum (90% seafood).

Contracts, Partnerships & Local Activities
State Contracts
Georgia Department of Agriculture
- Conduct inspections for food sanitation, feed mills, and BSE

Georgia Department of Natural Resources
- Conduct inspections of mammography facilities.

State Partnerships
Georgia Department of Agriculture
- Conduct inspections of fish and fishery product processors under HACCP.

Other Partnerships
- Plan training activities to promote health and scientific education with Morris Brown College.
- Conduct educational activities to promote health and dispense information on disease prevention with Spelman College.

Local Activities
- Assist state laboratories with analytical issues.
- FDA ACNA Lab (National nutrition analysis/labeling service lab)
- Microbiology and Chemistry labs for foods, drugs, and cosmetics.
- Georgia Food Safety Task Force

Food and Drug Administration
Fact Sheet – Hawaii

FDA Presence: 9 FDA employees in Hawaii
Resident Post: Honolulu
reports to: San Francisco District, Alameda, California, who
reports to: Pacific Region, Oakland, California

Industry Presence in State
There are 528 FDA-regulated establishments in the State of Hawaii
Food establishments (includes cosmetics) - 64 percent
Medical device and radiological establishments - 27 percent
Human drug establishments - 6 percent
Biologic establishments (includes blood banks) - 2 percent
Animal drug and feed establishments -1 percent

Industry Highlights
- Seafood, domestic and imports, is the largest industry on the Islands
- Importation of goods to Hawaii and through Hawaii to the mainland accounts for 1/3 of FDA resources covering the review, inspection and sampling of products primarily from Asia.

Contracts, Partnerships & Local Activities
State contracts
Hawaii Department of Health
- Conduct inspections of mammography facilities.
- Conduct diagnostic x-ray field tests.

State Partnerships
Hawaii Department of Health
- Conduct inspections of new x-ray assemblies or re-assemblies.
- .Support for a Food Safety Task Force for food safety.

Hawaii Department of Agriculture & Department of Health
- Support the Egg Quality Assurance Plan as an integrated voluntary animal production food safety program designed to ensure the highest quality and safety of eggs (with USDA, University of Hawaii and industry).

Local Activities
Ongoing public affairs cooperation with the
- University of Hawaii,
- Hawaii Cooperative Extension Service,
- Hawaii Dietetic Association,
- Hawaii Section/Institute of Food Technologists, and
- Hawaii Department of Health.

Food and Drug Administration
Fact Sheet - Idaho

FDA Presence: 6 FDA employees in Idaho
Resident Post: Boise, Eastport
report to: Seattle District, Bothell, Washington, Charles Breen, DD
reports to: Pacific Region, Oakland, California, Brenda Holman, RFDD

Industry Presence in State
There are 842 FDA-regulated establishments in the State of Idaho
Food establishments -(includes cosmetics) - 64 percent
Medical device and Radiological establishments -14 percent
Animal drug and feed establishments - 11 percent
Human drug establishments - 10 percent
Biologic establishments (includes blood banks) - 1 percent

Industry Highlights
- Idaho is number one in the nation in the production of potatoes, trout and winter peas. Produces 30% of U.S. potatoes, 50% of processed potatoes and 76 % of food size trout. The state ranks in the top 10 in 22 other agricultural products.
- Out of 144 commodities, Idaho is in the top 10 in more than 30
- Food processing is the second largest industry, next to high tech. Idaho's high-tech industry is one of the state's largest employers
- The dairy industry is the largest single agricultural industry

Contracts, Partnerships & Local Activities
State Contracts
Idaho Department of Health and Welfare
- Conduct food safety inspections.
- Conduct inspections of mammography facilities.

Idaho Department of Agriculture
- Conduct BSE inspections.

State Partnerships
Idaho Department of Health and Welfare
- Establish working arrangements for food safety and sanitation inspections of food firms
- Inspect new x-ray assemblies or re-assemblies.

Idaho Department of Agriculture
- Establish a cooperative program for animal feed with respect to safety & control of BSE

Local Activities
- Regular interaction with the Idaho Department of Agriculture Marketing Division to conduct workshops on food labeling for small start-up food companies.
- Close working relationship with Idaho Gift Institute, to educate small food producers about regulatory requirements.

Food and Drug Administration
Fact Sheet – Illinois

FDA Presence: 67 FDA employees in Illinois
Resident Posts: Mt. Vernon, Gurnee, Peoria, Hinsdale, Springfield, and O'Hare
report to: Chicago District, Chicago, Illinois
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State
There are 5,668 FDA-regulated establishments in the State of Illinois
Food establishments (includes cosmetics) - 44 percent
Medical device and Radiological establishments - 36 percent
Human drug establishments - 12 percent
Animal drug and feed establishments - 5 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights
- Pharmaceuticals – Home to several multi-national manufacturers
- In-vitro diagnostics – Largest manufacturer in the world
- Pumpkins – Nation's only pumpkin cannery
- Candy – Concentration of large manufacturers.
- Significant import operations with a cross-section of FDA regulated commodities.

Contracts, Partnerships & Local Activities
State Contracts
Illinois Department of Agriculture
- Conduct inspections of feed mills to ensure safety and BSE control

Illinois Department of Public Health
- Conduct food safety inspections.

State Partnerships
Illinois Department of Public Health
- Conduct inspections of low acid canned food and acidified food establishments and seafood under the Hazard Analysis and Critical Control Point (HACCP) requirements.
- Collect samples to test foods for contaminants including microbiology and pesticides.
- Conduct joint Seafood HACCP training

Local Activities
- Cooperative program with the City of Chicago Department of Health, the Illinois Department of Public Health, and USDA to test foods supplied to the Chicago Public School lunch program.
- Cooperative program with the City of Chicago Department of Health regarding testing for lead in imported foods.

Food and Drug Administration
Fact Sheet – Indiana

FDA Presence: 20 employees in Indiana

Resident Posts: Indianapolis, Evansville, Fort Wayne, and South Bend
who report to: Detroit District, Detroit, MI
who report to: Central Region, Philadelphia, PA

Industry Presence in State

There are 2,211 active FDA-regulated establishments in the State of Indiana

- Food establishments (includes cosmetics) – 42 percent
- Medical Device and Radiological establishments – 28 percent
- Animal drug and feed establishments – 13 percent
- Human Drug establishments (includes Medical Gas) – 13 percent
- Biological establishments (includes blood banks) – 4 percent

Industry Highlights

- Major drug manufacturers include Eli Lilly, Bristol Myers Squibb, Pfizer.
- Home to three of the world's largest orthopedic implant makers (Zimmer, Biomet, and DePuy), and major diagnostics manufacturer, Roche Diagnostics.
- Very active Medical Device Industry Association known as the Indiana Medical Device Manufacturers Council (IMDMC). Played a major role in implementation of FDA Modernization Act (FDAMA) and medical device inspection initiatives.
- Infant formula manufacturer Bristol Myers Squibb
- Federal Express Hub in Indianapolis

Contracts and Partnerships

Contracts

Indiana Board of Health:

- Conduct inspections of mammography facilities.

Purdue University

- Conduct medicated feed mill and BSE inspections.

Partnerships

Indiana Department of Health:

- Coordinate inspection plan to increase consumer safety by coordinating inspectional information of non-retail food establishments.

Indiana State Board of Animal Health

- Share information on tissue residues in food producing animals

Food and Drug Administration
Fact Sheet – Iowa

FDA Presence: 6 FDA employees in Iowa
Resident Posts: Sioux City (1), Davenport (1), and Des Moines (4)
report to: Kansas City District, Lenexa, Kansas
reports to: Southwest Region, Dallas, Texas

Industry Presence in State
There are 1,629 FDA-regulated establishments in the State of Iowa
Food establishments (includes cosmetics) - 45 percent
Animal drug and feed establishments - 30 percent
Medical device and radiological establishments - 16 percent
Human drug establishments - 9 percent
Biologic establishments (includes blood banks) - 1 percent

Industry Highlights
- Diverse, with all major FDA program areas represented.
- In-vitro diagnostic establishments: Iowa has a heavy concentration of these.
- Bio-research: One of the few bio-equivalency-testing facilities in the country.
- State reports 1800 biotech firms and rand 1st in number of acres producing biotech corn and soybeans

Contracts, Partnerships & Local Activities

State Contracts
Iowa Department of Agriculture and Land Stewardship
- Conduct inspections of medicated feed mills to ensure safety and BSE control

Iowa Department of Inspections and Appeals
- Conduct food safety inspections

State Partnerships
Iowa Department of Agriculture and Land Stewardship
- Sample products for presence of aflatoxin or vomitoxin.
- Coordinate oversight of regulated dairy manufacturing facilities.

Iowa Department of Inspections and Appeals
- Food Safety Inspections

Iowa Department of Public Health
- Conduct inspections of new or reassembled x-ray equipment.

Local Activities
- IA, KS, NE, and MO have agreed to participate in a partnership to conduct program evaluations according to FDA's *Recommended National Retail Food Regulatory Program Standard #9*. Iowa is the lead state in this partnership. FDA has provided a grant to fund the program.

Food and Drug Administration
Fact Sheet – Kansas

FDA Presence: 123 FDA employees in Kansas
Resident Posts: Wichita (2)
reports to: Kansas City District, Lenexa, Kansas
report to: Southwest Region, Dallas, Texas
Regional staff: Lenexa (7)
Report to: Southwest Region, Dallas Texas

Industry Presence in State
There are 1,941 FDA-regulated establishments in the State of Kansas
Food establishments (includes cosmetics) - 54 percent
Animal drug and feed establishments - 01 percent
Medical device and radiological establishments - 18 percent
Human drug establishments - 8 percent
Biologic establishments (includes blood banks) - 2 percent

Industry Highlights
- Agriculture-based economy
  - Top producer of wheat, sorghum, corn, and sunflowers
  - Produced 6.6 million head of cattle in the year 2000
  - Significant animal feed industry
- The 2004 Legislature passed the Kansas Economic Growth Act, creating the Kansas Bioscience Authority. The Authority will invest an estimated $500 million in the development of the state's bioscience industry.

Contracts and Partnerships

State contracts (*)
Kansas Department of Agriculture
- Conduct inspections of medicated animal feed mills to ensure safety and BSE control.
- Conduct food safety inspections

Kansas Department of Health and the Environment
- Conduct mammography facility inspections

State Partnerships (*)
Kansas Department of Agriculture
- Share responsibility for regulating dairy manufacturing facilities.

Kansas Department of Health & Environment
- Conduct inspections of x-ray assemblies and reassemblies.

Local Activities
The District is informally partnering with KDA to share results from the state's BSE inspections.

Food and Drug Administration
Fact Sheet – Kentucky

FDA Presence: 5 FDA employees in Kentucky
Resident Post: Louisville
report to: Cincinnati District, Cincinnati, Ohio who
reports to: Central Region: Philadelphia, Pennsylvania

Industry Presence in State
There are 1,384 FDA-regulated establishments in the State of Kentucky
Food establishments (includes cosmetics) - 39 percent
Medical device and Radiological establishments - 26 percent
Animal drug and feed establishments - 17 percent
Human drug establishments - 14 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights
- Agriculture - Kentucky is the home of a significant agricultural base including dairy and food processing plants.
- Medical device - Kentucky includes medical device and in-vitro diagnostic manufacturers.
- Biologic - Kentucky is the home of blood and plasma firms, clinical research and bioresearch facilities.

Contracts, Partnerships & Local Activities
State Contracts
Kentucky Department of Public Health
- Conduct inspections of mammography facilities.
- Conduct food safety inspections.

University of Kentucky
- Conduct inspections of medicated feed mills and BSE.

State Partnerships
Kentucky Cabinet for Health Services of Commonwealth of Kentucky
- Participated in Better Process Control School
- Participated in FDA Risk Assessment Training
- Conducted Raw Agriculture & Raw Fish Sampling & Analysis for pesticide residues.
- Coordinate testing of new and re-assembled x-ray equipment.
- Cincinnati District had a partnership meeting with OH & KY to discuss current and possible future partnerships with the feed and food individuals.

Local Activities
Kentucky Food Safety Task Force – Quarterly Meetings.
- Composed of State, Federal, Academic, and Industry Representatives with an interest in food safety and security.

Food and Drug Administration
Fact Sheet – Louisiana

FDA Presence: 49 FDA employees in Louisiana
Resident Posts in Louisiana: Baton Rouge, Lafayette, Shreveport

- report to: New Orleans District: New Orleans, Louisiana, who
- reports to: Southeast Region: Atlanta, Georgia

Industry Presence in State
There are 2,288 FDA-regulated establishments in the State of Louisiana

- Food establishments – 63 percent
- Medical device and Radiological establishments – 19 percent
- Human drug establishments – 12 percent
- Biologic establishments (includes blood banks) – 4 percent
- Animal drug and feed establishments – 2 percent

Industry Highlights

- Seafood –a primary industry supplying large volumes of shrimp, crawfish, oysters and fish. Fish include both native and farm-raised, marine and fresh water species.
- Imports – New Orleans is a major port, with green coffee the leading commodity.
- Agriculture – major portions of Louisiana are supplying agricultural products, such as rice, soybeans, sugar cane and cattle.
- Exports – Using the Mississippi River for transportation, the mid continent of the United States markets its grain products to the world through port facilities located along the river in the vicinity of New Orleans.

Contracts & Partnerships
<u>State contracts</u>
Department of Health and Hospitals

- Conduct inspections of food for sanitation and seafood for Hazard Analysis and Critical Control Points (HACCP) requirements.

Department of Environmental Quality

- Conduct inspections of mammography facilities.

Department of Agriculture and Forestry

- Conduct follow-up investigations of violative tissue residues in food animals at the time of slaughter.

<u>State Partnerships</u>
Department of Health and Hospitals

- Coordinate public health emergencies in mutual areas of responsibility.
- Conduct inspections of seafood processors.
- Share oversight and authority of regulated dairy manufacturing facilities

Department of Environmental Quality

- Maintain a program for federal compliance testing of new assemblies or re-assemblies of x-ray equipment.

Department of Agriculture & Forestry

- Maintain a program for monitoring pesticide residues in raw agricultural commodities.

Food and Drug Administration
Fact Sheet – Maine

FDA Presence: 19 FDA employees in Maine
Resident Posts: Augusta, Houlton and Calais
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State

There are 1,000 FDA-regulated establishments in the State of Maine
Food establishments (includes cosmetics) - 71 percent
Medical Device and Radiological establishments - 16 percent
Human Drug establishments - 9 percent
Biological establishments (includes blood banks) - 2 percent
Animal Drug and Feed establishments - 2 percent

Industry Highlights

- Maine's inventory of firms makes up 12% of the District's Official Establishment Inventory of FDA-regulated firms, with the majority of those firms involved in the production and distribution of foods, and more than half of those firms involving seafood/shellfish products.
- Maine also has various ports of entry for imported goods, primarily from Canada.

Contracts & Partnerships

State Contracts
Maine Department of Agriculture
- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections

Maine Department of Human Resources
- Conduct inspections of mammography facilities

Food and Drug Administration
Fact Sheet –Maryland

FDA Presence: 52 FDA employees in Maryland
Resident Posts: Salisbury, Dundalk Marine Terminal (imports) who report to: Baltimore District, Baltimore, Maryland who reports to Central Region, Philadelphia, Pennsylvania.

Industry Presence in State
There are 1,942 FDA-regulated establishments in the State of Maryland
Food establishments (includes cosmetics) - 42 percent
Medical device and Radiological establishments - 37 percent
Human drug establishments - 15 percent
Biologic establishments (includes blood banks) - 6 percent
Animal drug and feed establishments - 3 percent

Industry Highlights
The industry in the state is very diverse and representative of the FDA national inventory, including large, medium and small firms active in all FDA regulated industries:

- Federal Food Service facilities
- Seafood
- Spices
- Bioresearch monitoring facilities (clinical investigators)
- Biotech facilities
- Imported products through the Port of Baltimore and BWI Airport

Contracts & Partnerships

State contracts
Maryland Department of Health and Mental Health

- Conduct food sanitation, seafood, and Low Acid Canned Food (LACF) inspections.

Maryland Department of Agriculture

- Conduct follow-up inspections due to reported finding of illegal residues in the tissue of food animals at slaughter.
- Monitor and perform inspections of feed mills, renderers and others to assure compliance with BSE regulations.

Food and Drug Administration
Fact Sheet – Massachusetts

FDA Presence: 162 FDA employees in Massachusetts including State Programs Branch (5) and Regional Computer Center personnel (4)
Resident Posts: Boston (7 employees) and Worcester (5 employees)
reports to: New England District, Stoneham, Massachusetts (85 employees)
reports to: Northeast Region, Jamaica, New York
Laboratory: Winchester Engineering and Analytical Center, Winchester, Massachusetts (65 employees)
reports to: Northeast Region, Jamaica, New York

Industry Presence in State

There are 4,046 FDA-regulated establishments in the State of Massachusetts
Food establishments (includes cosmetics) - 44 percent
Medical Device and Radiological establishments - 38 percent
Human Drug establishments - 13 percent
Biological establishments (includes blood banks) - 4 percent
Animal Drug and Feed establishments - 1 percent

Industry Highlights

- Houses almost one-half of the regulated industry in New England with special emphases in biotechnology and medical devices. Serves as corporate headquarters for many of these firms.
- In addition, as a coastal state, Massachusetts has a large inventory of seafood establishments.

State Contracts and Partnerships

State Contracts
Massachusetts Department of Public Health
- Conduct inspections of mammography facilities.
- Conduct food sanitation inspections.
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections.

Food and Drug Administration
Fact Sheet – Michigan

FDA Presence: 76 employees in Michigan
Resident Posts: Grand Rapids, Ambassador Bridge, Kalamazoo, and Port Huron
who report to: Detroit District Office, Detroit, MI
who reports to: Central Region, Philadelphia, PA

Industry Presence in State

There are 3,051 active FDA-regulated establishments in the State of Michigan
Food establishments (includes cosmetics) – 45 percent
Medical Device and Radiological establishments – 29 percent
Animal drug and feed establishments – 13 percent
Human Drug establishments (includes Medical Gas) – 10 percent
Biological establishments (includes blood banks) – 3 percent

Industry Highlights: Major firms:

- Drugs: Parkedale Pharmaceuticals (Div. of King Pharmaceuticals), Pfizer, Dow Chemical, Perrigo, BASF, DSM Pharma Chemicals, Zeeland Chemical, Caraco Pharmaceutical.
- Foods: Mead Johnson Nutritionals, Ross Laboratories, Gerber Products, Kellogg Co., Post Cereals.
- Devices: Dow Corning, Stryker Instruments, Terumo Cardiovascular Systems Corp., Atek Medical Manufacturing, Amigo Mobility.
- Biologics: Bioport, Inc. (sole source of Anthrax vaccine), American Red Cross National Testing Laboratory.
- Imports: Michigan ports of entry include airports, seaports, and border crossings along the Canadian border and include an international mail facility in Detroit. FDA-regulated commodities entering through these ports include food (68%), medical devices and radiological products (10%) and cosmetics (6%).

Contracts and Partnerships

State Contracts

Michigan Department of Agriculture

- Conduct medicated feed mill and BSE rule inspections
- Conduct follow up investigations of violative drug tissue residues of food animals detected at the time of slaughter.
- Conduct food safety inspections.

Michigan Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Michigan Department of Agriculture

- Implement an inspection plan to assure quality of non-Interstate Milk Shippers dairy products, other foods & drinks produced at dairy plants.
- Collect animal feed samples for pesticide residue analysis by FDA.
- (with Michigan State University) Jointly share information regarding the establishment of a Hazard Analysis & Critical Control Point (HACCP) pilot project with the apple cider industry.

Michigan Department of Public Health

- Educate consumers about the risks and dangers of AIDS health fraud.

Food and Drug Administration
Fact Sheet – Minnesota

FDA Presence: 65 FDA employees in Minnesota
Resident Post: International Falls
reports to: Minneapolis District: Minneapolis
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State

There are 3,059 FDA-regulated establishments in the State of Minnesota
Food establishments (includes cosmetics) - 38 percent
Medical device and Radiological establishments - 29 percent
Animal drug and feed establishments - 20 percent
Human drug establishments - 10 percent
Biologic establishments (includes blood banks) - 3 percent

Imports

- There are 12 ports of entry in the State of Minnesota.
- FDA regulated import entries are predominantly medical devices, some pharmaceuticals, human food, including whole grain and milled products, and non-medicated animal feed.
- Minnesota FDA regulated import entries from the 12 ports are handled by the Minneapolis District Office and two Resident Posts located on the Canadian border at International Falls, MN, and at Pembina, North Dakota.

Industry Highlights

- Leads the nation in production of sugar beets, green peas for processing, sweet corn for processing, and turkeys
- Second in the nation in production of spring wheat, oats, cultivated wild rice, and canola. Other key crops/products include corn, sunflowers, soybeans, all wheat, barley, dry edible beans, all hay, potatoes, flaxseed, total cheese, American cheese, milk, ice cream, honey, milk cows, and hogs.
- Minnesota ranks seventh nationally in agricultural exports
- Minnesota is home to such major firms as Medtronic, General Mills, 3M, Pillsbury, Land 0'Lakes, and Guidant.
- The University of Minnesota and the Mayo Clinic are very active in medical bio-research

Contracts & Partnerships

Minnesota Department of Agriculture (contracts)

- Conduct GMP inspections of licensed medicated feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food safety inspections, HACCP seafood, and elevator inspections.

Minnesota Health Department (contract)

- Conduct MQSA audits of mammography facilities.

Minnesota Department of Agriculture (partnerships)

- Incident Command System Emergency Response Training

Food and Drug Administration
Fact Sheet – Mississippi

FDA Presence: 6 FDA employees in Mississippi
Resident Post: Jackson
- reports to: New Orleans District: New Orleans, Louisiana, who
- reports to: Southeast Region: Atlanta, Georgia

Major Import Port(s): Gulfport

Industry Presence in State
There are 910 FDA-regulated establishments in the State of Mississippi
- Food establishments (includes cosmetics) – 50 percent
- Medical device and Radiological establishments – 26 percent
- Human drug establishments – 12 percent
- Animal drug and feed establishments – 9 percent
- Biologic establishments (includes blood banks) – 3 percent

Industry Highlights
- Seafood – Mississippi's primary food industry includes Gulf shrimp and oysters on the coast and farm-raised catfish in the Delta.
- Imports – Most of the bananas exported into the south central part of the U.S. are entered through the Port of Gulfport.
- Shipbuilding – A sizeable shipbuilding industry is located in the city of Pascagoula.
- Human Drugs and Devices – Baxter operates a large LVP and device manufacturing facility in Cleveland.
- Agriculture – Poultry, timber, cattle, cotton, and soybeans are major agricultural crops.

Contracts & Partnerships
State Contracts
Mississippi Department of Health
- Conduct food sanitation inspections.
- Conduct mammography facility inspections.

State Partnerships
Mississippi Department of Health
- Share oversight and authority of regulated Interstate Milk Shippers Milk Processing Plants and IMS listed Single Service Container Manufacturing Plants in Mississippi.
- Cooperate in the evaluation of Mississippi's efforts to control contributing factors linked to food borne illness outbreaks.
- Conduct inspections of new x-ray assemblies or re-assemblies.

Mississippi Department of Marine Resources and Department of Agriculture
- Establish a cooperative emergency response plan for natural disasters.

Special Programs
Active Food Safety Task Force which includes MS Department of Health, MS Department of Agriculture and Commerce, MS Department of Marine Resources, MS State University Extension Service, MS Chemical Laboratory, MS Restaurant Association, MS Farm Bureau.

Food and Drug Administration
Fact Sheet – Missouri

FDA Presence: 45 FDA employees in Missouri. *(14 assigned to ORA)*
Resident Posts: St. Louis (14), Springfield (2)
report to: Kansas City District, Lenexa, Kansas
reports to: Southwest Region, Dallas, Texas
CDER National Division of Pharmaceutical Analysis *(St. Louis – 29 FDA employees)*

Industry Presence in State
There are 2,521 FDA-regulated establishments in the State of Missouri
Food establishments (includes cosmetics) – 41 percent
Medical device and Radiological establishments - 25 percent
Animal drug and feed establishments - 17 percent
Human drug establishments - 16 percent
Biologic establishments (includes blood banks) - 2 percent

Industry Highlights
- Key Agricultural Products:
  - Major crops include, soybeans, corn and wheat.
  - During the year 2000, the state produced 4.4 million head of cattle and 263 million chickens.
- Bio-technology:
  - Missouri ranks 11th among the top 25 biotechnology industry states in U.S.
- Major Veterinary Pharmaceutical Industry.

Contracts, Partnerships & Local Activities
State contracts
Missouri Department of Health and Senior Services
- Conduct inspections of mammography facilities.
- Conduct food safety inspections

State Partnerships
Missouri Department of Agriculture
- Sample products for presence of aflatoxin or vomitoxin
- Conduct inspections and other activities involving BSE.

Missouri Department of Health and Senior Services
Coordinate the oversight of dairy manufacturing facilities.
- Pharmaceutical Technical Exchange Association (PTEA) organized by FDA to facilitate information exchange among the 200 member firms. PTEA meets semi-annually in various locations throughout the State of Missouri.
- FDA's St Louis office provides oversight for the FDA-funded *Missouri AIDS Fraud Task Force* comprised of consumer organizations and government agencies from throughout the state.

Food and Drug Administration
Fact Sheet – Montana

FDA Presence: 3 FDA employees in Montana
Resident Posts: Helena and Sweetgrass
report to: Seattle District: Bothell, Washington, Charles Breen, DD
reports to: Pacific Region: Oakland, California, Brenda Holman, RFDD

Industry Presence in State
There are 1,000 FDA-regulated establishments in the State of Montana
Food establishments (includes cosmetics) – 73 percent
Medical device and Radiological establishments – 12 percent
Human drug establishments – 7 percent
Animal drug and feed establishments – 7 percent
Biologic establishments (includes blood banks) – 1 percent

Industry Highlights
- Production and processing of high protein grains and cereals is the leading agricultural activity followed by the beef industry.
- The largest General Mills facility is located in Billings, Montana.
- Over 270 grain elevators are subject to FDA inspectional jurisdiction.

Contracts & Partnerships

State contracts
Montana Department of Agriculture
- Conduct BSE inspections.

Montana Department of Public Health and Human Services
- Conducts inspections of mammography facilities and food facilities.

State Partnerships
Montana Department of Agriculture
- Formalize the ongoing cooperative program, which encourages work sharing, data sharing, and educational exchange with respect to safety of animal feed.

Montana Department of Public Health and Human Services
- Establish working arrangements concerning mutual planning and sharing of reports for inspections, investigations, and analytical findings, related to food firms operating in the State of Montana.

Food and Drug Administration
Fact Sheet – Nebraska

FDA Presence: 4 FDA employees in Nebraska
Resident Post: Omaha
Reports to: Kansas City District, Lenexa, Kansas
Reports to: Southwest Region, Dallas, Texas

Industry Presence in State
There are1,073 FDA-regulated establishments in the State of Nebraska
Food establishments (includes cosmetics) - 51 percent
Animal drug and feed establishments - 23 percent
Medical device and radiological establishments -15 percent
Human drug establishments -10 percent
Biologic establishments (includes blood banks) - 1 percent

Industry Highlights
Key Agricultural State
- Major products include cattle, corn, hogs, soybeans, wheat, sorghum
- Major Industry involves food processing of state's farm output
- In 2004, produced 6.7 million cattle; 3 million hogs, 15 million chickens/broilers

Contracts, Partnerships & Local Activities
State Contracts
Nebraska Department of Agriculture
- Conduct inspections of medicated animal feed mills for safety and BSE control.
- Conduct food safety inspections.

State Partnerships
Nebraska Department of Agriculture
- Sampling and analysis of products for mycotoxins.
- Share oversight of dairy manufacturing facilities.
- Share information on rendering facilities (BSE).
- Conduct inspections of interstate transportation carriers.

Nebraska Department of Health and Human Services
- Inspect new and reassembled x-ray equipment, with FDA providing support

Local Activities
- As part of FDA's BSE enforcement program, the District continues to partner with the State Veterinarian to commission Nebraska Department of Agriculture (NDA) employees who routinely inspect all rendering plants under the jurisdiction of USDA, FDA and NDA.

Food and Drug Administration
Fact Sheet - Nevada

FDA Presence: 3 FDA employees in Nevada
Resident Posts: Reno, Las Vegas
report to: San Francisco District, Alameda, California
reports to: Pacific Region, Oakland, California

Industry Presence in State
There are 569 FDA-regulated establishments in the State of Nevada
Medical device and radiological establishments - 45 percent
Food establishments (includes cosmetics) - 24 percent
Human drug establishments - 15 percent
Animal drug and feed establishments -12 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights
- Growth of tourism and entertainment industry is demonstrated by the fact that there are more than 7000 food service establishments in Clark County (including Las Vegas) alone and by expansion of food-related industries in the state

Contracts & Local Activities
State Contracts
Nevada Department of Human Resources
- Conduct inspections of mammography facilities.

Nevada Department of Agriculture
- Conduct inspections of animal feed establishments for BSE

Local Activities
- Ongoing public affairs cooperation with Nevada Cooperative Extension Service, Nevada Dietetic Association, University of Nevada Las Vegas and University of Nevada Reno
- FDA has worked closely with the Nevada State Health Division, Bureau of Health Protection Services, in oversight and training in areas of acidified foods and fluid milk, to provide for better coverage and more uniform application of laws and regulations

Food and Drug Administration
Fact Sheet – New Hampshire

FDA Presence: 5 FDA employees in New Hampshire
Resident Post: Concord
reports to: New England District, Stoneham, Massachusetts who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State

There are 631 FDA-regulated establishments in the State of New Hampshire
Food establishments (includes cosmetics) - 45 percent
Medical Device and Radiological establishments - 37 percent
Human Drug establishments - 14 percent
Biological establishments (includes blood banks) - 3 percent
Animal Drug and Feed establishments - 1 percent

Industry Highlights

- New Hampshire is responsible for overseeing approximately 7% of the New England District's Official Establishment Inventory of regulated firms, with an emphasis on foods and medical devices.

State Contracts, Partnerships & Local Activities

Local Activities
New Hampshire has a Safe Food Alliance in which FDA is a participant.

Food and Drug Administration
Fact Sheet – New Jersey

FDA Presence: 86 employees in New Jersey
Resident Posts: Voorhees, New Brunswick
report to: New Jersey District, Parsippany (Newark), New Jersey
reports to: Central Region, Philadelphia
Industry Presence in State
There are 4,126 FDA-regulated establishments in the State of New Jersey
Food establishments (includes cosmetics) – 46 percent
Medical Device and Radiological establishments – 32 percent
Human Drug establishments – 18 percent
Biological establishments (includes blood banks) – 2 percent
Animal drug and feed establishments – 2 percent

Industry Highlights

- New Jersey is recognized internationally as the center of the global pharmaceutical industry. It is home to some of the largest pharmaceutical companies. Throughout the 1990's, New Jersey-based pharmaceutical companies discovered and developed more than 1/3 of new drugs approved by FDA and are responsible for over 40% of the prescription medicine sales in the U.S.
- The medical device industry is also a major industry in New Jersey, producing approximately 8% of U.S. medical technology sales.
- New Jersey also has a large and thriving seafood industry and is home to several major food-processing companies.

Contracts & Partnerships

State Contracts

New Jersey Department of Health and Senior Services
- Conducts 400 food safety inspections, including seafood HAACP inspections.

New Jersey Department of Environmental Protection
- Conducts inspections of mammography facilities

New Jersey Department of Agriculture
- Conducts follow up investigations of violative tissue residues in food animals found at the time of slaughter.
- Conduct inspections of feed mills for compliance with medicated feed and BSE-related requirements.

State Partnerships

New Jersey Department of Health and Senior Services
- Training and equipment to enhance capabilities of State to conduct food safety inspections.

New Jersey Department of Environmental Protection
- Equipment and supplies to enhance collection and analysis of agricultural food commodities for pesticide levels.

Food and Drug Administration
Fact Sheet – New Mexico

FDA Presence: 6 FDA employees in New Mexico
Resident Posts in New Mexico (Imports, 2 employees):
Santa Teresa and Columbus report to:
Southwest Import District: Dallas, Texas
Resident Post: Albuquerque reports to: Denver District, Denver, Colorado

Industry Presence in State
There are 703 FDA-regulated establishments in the State of New Mexico
Food establishments (includes cosmetics) - 47 percent
Human drug establishments - 22 percent
Medical device and Radiological establishments - 20 percent
Animal drug and feed establishments - 7 percent
Biologic establishments (includes blood banks) - 5 percent
The Southwest Import District (SWID) receives approximately 15,604 line entries per year. The primary products are: Candy, Fresh Peppers, pecans, Fresh/dried corn.

Industry Highlights
- Large Industry making acidified products such as salsa and specialty sauces.
- Higher concentration of PhD's than any other state
- Home to four federal research labs, three strong research and development universities and the new Technology Research Corridor. These institutions alone bring together a total R&D spending of almost $5 billion
- Third in natural gas production, second in onshore proven gas reserves and first in coal bed methane gas production and reserves. Leader in alternative power sources

Contracts and Partnerships
State Contracts
New Mexico Department of Agriculture and Environmental Services
- Conduct inspections of medicated feed mills for safety and BSE control.

New Mexico State University
- Conduct scientific review of rapid test methods for validity and potential use in FDA Laboratories for regulatory screening

State Partnerships
New Mexico Department of Agriculture
- Conduct federal compliance testing of new assemblies or re-assemblies of x-ray equipment.

New Mexico Departments of Health, Agriculture, Environment, Livestock; Albuquerque City Health Department, Bernalillo County Environmental Health Department; NM Food Producers/Processors Association; NM University Cooperative Extension Service; and other industry and consumer groups
- Formalize ongoing cooperative program to educate regulators, industry & consumers on HACCP, food safety principles, & develop/implement statewide HACCP training plan.

Food and Drug Administration
Fact Sheet – New York

FDA Presence: 383 FDA employees in New York State
Resident Posts: Albany, Alexandria Bay, Binghamton, Champlain, Central Islip, Massena, New Windsor, Ogdensburg, Rochester, Syracuse, and White Plains, in addition to an office in Buffalo.

Report to: New York District, Jamaica (New York) who
Reports to: Northeast Region, Jamaica (New York)
Northeast Regional Laboratory, New York who reports to: Northeast Region

Industry Presence in State

There are 8,533 regulated establishments in the State of New York

Food establishments (includes cosmetics) - 39 percent
Medical Device and Radiological establishments - 36 percent
Human drug establishments - 16 percent
Animal drug and feed establishments - 6 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights

- Imports - New York ports of entry include airports, a seaport and numerous border crossings along the Canadian border. Approximately 33% of the FDA regulated commodities enter the country through New York. Cheese, seafood, and active pharmaceutical ingredients are the top three high volume commodities entering New York. International postal facilities at JFK Airport and also at the Buffalo location require New York District surveillance activities overseeing a significant volume of pharmaceutical entries.
- Generic drugs - New York supports a significant generic drug industry.
- Bioresearch – A significant number of clinical investigators and Institutional Review Boards affiliated with the many NYC metropolitan hospitals.
- Dairy - New York is one of the lead dairy states in the country.
- Livestock - New York receives a significant number of reports on violative residues in food animals detected at the time of slaughter from the USDA.
- Food - New York is the home of a highly visible food interstate conveyance sanitation program at the airports, rail and bus transportation locations. Food processors would include smoked fish, seafood, vegetables and cheese.

Contracts & Partnerships

State contracts

New York Department of Agriculture and Markets

- Conduct inspections of food firms including LACF, seafood HACCP, and food sanitation; BSE and medicated feed mills; and tissue residue inspections. NYSDAM audits its state inspectors under FDA contract.

New York State Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

New York Department of Agriculture and Markets

- Coordinate the food protection efforts to reduce consumer risk, eliminate duplication, define regulatory roles, and improve channels of communication.
- Collect samples of domestic foods for pesticide/mycotoxin surveillance analysis.

Other

- Conduct inspections of mammography facilities by New York City inspectors.
- Enhanced collaborative efforts with U.S. Customs resulting in the detection of entries previously circumventing FDA's entry review process.
- NYSDAM and FDA have agreed to work together to halt the entry and distribution of adulterated foods. This collaborative effort will include the sampling of imported foods encountered by NYSDAM in the marketplace for ultimate submission to FDA for analysis. When a violation is confirmed by both Agencies, NYSDAM will initiate the appropriate regulatory action on the market while FDA will initiate an Import Alert to prevent future entries of the violative product.

Food and Drug Administration
Fact Sheet – North Carolina

FDA Presence: 20 FDA employees in North Carolina
Resident Posts: Asheville, Charlotte, Greensboro, Greenville, Raleigh, and Wilmington
report to: Atlanta District, Atlanta, Georgia, who
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State
There are 2,734 FDA-regulated establishments in the State of North Carolina
Food establishments (includes cosmetics) – 44 percent
Medical Device and Radiological establishments – 28 percent
Human Drug establishments – 19 percent
Animal Drug and Feed establishments –7 percent
Biological establishments (includes blood banks) – 3 percent

Industry Highlights
- Major international drug firms located in Research Triangle Park area.
- Significant medical device industries.
- Land ports in Charlotte (10,000 entries per annum), Raleigh (6,000 entries per annum), and Greensboro (4,000 entries per annum)—major products include foods, drugs, and medical devices. Sea ports in Wilmington (2,000 entries per annum)—major products include animal feeds and commodities such as grapes, and Morehead City-Beaufort (less than 25 entries per annum)—major products include dry bulk animal feed and human food.

Contracts, Partnerships & Local Activities

State Contracts
North Carolina Department of Agriculture
- Conduct inspections of feed mills for medicated feed and BSE
- Conduct food sanitation inspections

North Carolina Department of Environment & Natural Resources
- Conduct inspections of mammography facilities.

State Partnerships
North Carolina Department of Agriculture
- Conduct joint statutory inspectional coverage of the medical gas manufacturing and repacking industries.
- Conduct inspection of fish & fisheries products processors for compliance with the Hazard Analysis and Critical Control Points (HACCP) regulations.

North Carolina Department of Environment & Natural Resources
- Conduct inspections of new x-ray assemblies or reassemblies.

Local Activities
North Carolina Food Safety and Security Task Force

Food and Drug Administration
Fact Sheet – North Dakota

FDA Presence: 4 FDA employees in North Dakota
Resident Posts: Dunseith, Fargo, and Pembina
reports to: Minneapolis District, Minneapolis, Minnesota
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State
There are 1,009 FDA-regulated establishments in the State of North Dakota
Food establishments (includes cosmetics) – 63 percent
Animal drug and feed establishments - 29 percent
Medical Device and Radiological establishments - 5 percent
Human drug establishments - 2 percent
Biologic establishments (includes blood banks) – 1 percent

Imports
- There are 20 active ports of entry in the State of North Dakota.
- FDA regulated import entries are predominantly human food, including whole grain and milled products, and non-medicated animal feed.
- North Dakota FDA regulated import entries are predominantly handled out of the 2 ND Northern border ports staffed by FDA in Pembina and Dunseith.

Industry Highlights
- Agriculture – Leads the nation in barley, oats, sunflowers, dry edible beans, dry edible peas, flax, and canola production. Ranks second in wheat, lentils, and honey production. Other key crops include rye, potatoes, and sugarbeets.
- North Dakota ranks eighth nationally in agricultural exports.
- Raising of elk, deer and buffalo for meat is a rapidly expanding part of the state's agri-industry.

Contracts & Partnerships
State Contracts
North Dakota Department of Agriculture:
- Conduct GMP inspections of licensed feed mills, and BSE inspections of licensed and unlicensed feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

North Dakota Department of Health:
- Conduct inspections of mammography facilities.

Partnerships
North Dakota State University Extension
- Improving Food Handling through Education and Outreach.

Food and Drug Administration
Fact Sheet – Ohio

FDA Presence: 125 FDA employees in Ohio

- **Cincinnati District Office** and three Resident Posts: Brunswick (Cleveland area), Columbus, and Toledo
- **Forensic Chemistry Center:** Cincinnati, Ohio, (50 total)

The Cincinnati District Office and the Forensic Chemistry Center are separate organizations, each independently reports to the RFDD in the Central Region Office in Philadelphia, Pennsylvania

Industry Presence in State

There are 4,304 FDA-regulated establishments in the State of Ohio

Medical Device and Radiological establishments – 35 percent
Food establishments (includes cosmetics) - 34 percent
Human drug establishments - 15 percent
Animal drug and feed establishments - 12 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights

- Eggs – Ohio leads the nation in egg production.
- Agriculture – Ohio includes a significant agricultural base including "mega-farms."

Contracts, Partnerships & Local Activities

State Contracts

Department of Agriculture

- Conduct inspections of feed mills for medicated feed and BSE.
- Conduct human food sanitation inspections.
- Conduct follow up investigations of violative drug residues in food animals at the time of slaughter

Department of Health

- Conduct inspections of mammography facilities

State Partnerships

Ohio Department of Agriculture

- Establish training for state employees in analytical procedures & to conduct joint inspections.
- Joint training of the livestock industry on producing and marketing livestock without drug residues.
- Participated in FDA Food Preservation Training.
- Cincinnati District had a partnership meeting with OH & KY to discuss current and possible future partnerships with the feed and food individuals

Ohio Department of Health

- Conduct federal compliance testing of new assemblies or re-assemblies of x-ray equipment.
- Cincinnati District had a partnership meeting with OH & KY to discuss current and possible future partnerships with the feed and food individuals

Local Activities

- Quarterly FORC-G Meetings with State and local officials on food safety issue.

Food and Drug Administration
Fact Sheet – Oklahoma

FDA Presence: 4 FDA employees in Oklahoma
Resident Posts: Oklahoma City and Tulsa
report to: Dallas District, Dallas, Texas who
reports to: Southwest Region, Dallas, Texas
Import Entries are handled from the Dallas Southwest Import District office in Dallas, Texas and with the assistance of the staff located at the Oklahoma Resident Post.

Industry Presence in State
There are approximately 1,312 FDA-regulated establishments in Oklahoma
Food establishments (includes cosmetics) - 59 percent
Medical device and Radiological establishments - 16 percent
Animal drug and feed establishments - 16 percent
Human drug establishments - 8 percent
Biologic establishments (includes blood banks) - 3 percent

Industry Highlights
- Eggs - Oklahoma is a major egg production state.
- Poultry – Oklahoma is home to Tyson poultry productions
- Foods – Oklahoma is the home of Bama pies.
- Grains - Oklahoma produces a significant amount of winter wheat, peanuts, soybeans, and seeds for sprouts.
- Farming - Oklahoma is a major producer of feeder cattle, milk and catfish.
- Medical devices – Oklahoma is home to major device manufacturers including dental implants and kidney dialysis supplies.
- Dietary Supplements – Oklahoma is home to Shaklee manufacturing.
- Bioresearch – the University of Oklahoma, School of Medicine generates work in the bioresearch program area.

The Southwest Import District receives approximately 1,016 line entries per year.

Contracts, Partnerships and Local Activities
State Contracts
Oklahoma Department of Health
- Conduct inspections of mammography facilities.

Oklahoma Department of Agriculture
- Conduct inspections of feed mills to determine compliance with BSE Rule.

State Partnerships
Oklahoma Department of Agriculture
- Share oversight and authority of regulated dairy manufacturing facilities

Dallas District Public Affairs Specialists respond to consumers and media inquires and conduct consumer education outreach to diverse constituents.

Food and Drug Administration
Fact Sheet - Oregon

FDA Presence: 13 FDA employees in Oregon
Resident Posts: Portland and Beaverton who
report to: Seattle District, Bothell, Washington, Charles Breen, DD
reports to: Pacific Region, Oakland, California, Brenda Holman, RFDD

Industry Presence in State
There are 2,576 FDA-regulated establishments in the State of Oregon
Food establishments (includes cosmetics) - 72 percent
Medical device and Radiological establishments - 18 percent
Human drug establishments - 7 percent
Biologic establishments (includes blood banks) - 1 percent
Animal drug and feed establishments - 2 percent

Industry Highlights
- Oregon agriculture, fisheries, and food processing activities are valued to exceed $5.25 Billion in commerce.
- Biotechnology, medical device, and medical research activities are growing industries within the State.

Contracts, Partnerships & Local Activities
State Contracts
Oregon Department of Agriculture
- Conduct food sanitation inspections, including seafood HACCP.
- Conduct follow-up investigations of violative tissue residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Oregon State Department of Human Resources
- Conduct inspections of mammography facilities

State Partnerships
Oregon State Department of Agriculture
- Share information and training to enhance consumer protection in food safety.

Local Activities
FDA representatives participate in:
- Interagency Food Safety Team
- Oregon Alliance Working for Antibiotic Resistance Education
- Oregon Emergency Planning Food Security Core Committee
- Oregon Emergency Planning Food Security Production Committee

Food and Drug Administration
Fact Sheet – Pennsylvania

FDA Presence: Approximately 100 employees in Pennsylvania
Residence Posts: Harrisburg, North Wales, Pittsburgh, and, Scranton
report to: Philadelphia District, Philadelphia
reports to: Central Region, Philadelphia

Industry Presence in State:
There are 4,727 FDA-regulated establishments in the Commonwealth of Pennsylvania.

- Food Establishments (includes cosmetics) - 42 percent
- Medical Device and Radiological establishments -31 percent
- Human Drug establishments- 19 percent
- Animal drug and feed establishments – 4 percent
- Biological establishments (includes blood banks) – 4 percent

Industry Highlights:

- Pennsylvania has a large pharmaceutical industry.
- Pennsylvania is one of the Nation's largest producer of dairy products, mushrooms, poultry and eggs.

Contracts, Partnerships & Local Activities

State Contracts:
Pennsylvania Department of Agriculture

- Conduct inspections of medicated feed mills, including coverage of BSE.

Pennsylvania Department of Environmental Research

- Conduct inspections of mammography facilities

State Partnerships:
Pennsylvania Department of Agriculture:

- Coordinate regulatory activities enforcing the Nutrition Labeling & Education Act.
- Coordinate their regulatory activities relating to inspection of seafood and Low Acid Canned Food Industries
- Coordinate workplanning and inspectional activities to assure all non-medicated feed mills in Pennsylvania are inspected yearly to assure compliance with regulations designed to prevent the introduction of BSE

Pennsylvania Departments of Agriculture & Health:

- Assure consumers that eggs from Pennsylvania are of minimal risk to cause food-borne disease from *Salmonella enteriditis.*

Local Activities
Participate in the Pennsylvania AIDS Health Fraud Task Force

FDA funded Medicated Feed Inspection training for Pennsylvania Dept. of Agriculture employees scheduled for 3/30 to 4/1/04 in Harrisburg, PA

Food and Drug Administration
Fact Sheet – Rhode Island

FDA Presence: 5 FDA employees in Rhode Island
Resident Post: East Providence
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica, New York

Industry Presence in State

There are 744 FDA-regulated establishments in the State of Rhode Island
Food establishments (includes cosmetics) – 58 percent
Medical Device and Radiological establishments – 28 percent
Human Drug establishments – 12 percent
Biological establishments (includes blood banks) – 2 percent
Animal Drug and Feed establishments - <1%

Industry Highlights

- Rhode Island is responsible for 9% of the District's Official Establishment Inventory of FDA-regulated firms with an emphasis on foods and medical devices.

State Contracts and Partnerships

State Contracts
Rhode Island Department of Health
- Conduct food sanitation inspections
- Conduct seafood HACCP (Hazard Analysis and Critical Control Point) inspections
- Conduct inspections of mammography facilities.

Food and Drug Administration
Fact Sheet – South Carolina

FDA Presence: 11 employees in South Carolina
Resident Posts: Charleston, Columbia, and Greenville
report to: Atlanta District, Atlanta, Georgia, who
reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State
There are 1,205 FDA-regulated establishments in the State of South Carolina
Food establishments (includes cosmetics) – 56 percent
Medical Device and Radiological establishments – 27 percent
Human Drug establishments – 14 percent
Biological establishments (includes blood banks) – 3 percent
Animal Drug and feed establishments – 2 percent

Industry Highlights
- Major egg industry
- Major food supplement manufacturer
- Charleston ranks 4th in the nation among the largest container seaports; 45,000 entries annually; 75 custom house brokers; major commodities include canned, fresh, and frozen foods and seafood

Contracts, Partnerships & Local Activities

State Contracts
South Carolina Department of Agriculture
- Conducts inspections of food manufacturers for sanitation.

South Carolina Department of Health & Environmental Controls
- Conduct inspections of mammography and soft drink/bottled water facilities.

State Partnerships
South Carolina Department of Health & Environmental Control & Office of the South Carolina Veterinarian
- Support the South Carolina Egg Quality Assurance Plan in an integrated voluntary animal production food safety program designed to ensure the highest quality and safety of eggs.

Local Activities
- South Carolina Interagency Food Safety Council

Food and Drug Administration
Fact Sheet – South Dakota

FDA Presence: 2 FDA employees in South Dakota
Resident Post: Sioux Falls
reports to: Minneapolis District, Minneapolis, Minnesota
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State
There are 834 FDA-regulated establishments in the State of South Dakota
Food establishments (includes cosmetics) - 39 percent
Animal drug and feed establishments - 44 percent
Medical device and Radiological establishments – 10 percent
Human drug establishments - 5 percent
Biologic establishments (includes blood banks) – 2 percent

Imports
- There is one port of entry in the State of South Dakota.
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The majority of SD FDA regulated import entries are handled out of the Minneapolis District FDA office.

Industry Highlights
- Agriculture: Ranks second in the production of sunflowers.
- Other key crops/products include wheat, oats, rye, all hay, alfalfa hay, corn, sorghum, soybeans, flax, proso millet and honey.
- Cattle and sheep ranching are also a significant parts of the State's economy.

Contracts
South Dakota Department of Agriculture
- Conduct GMP inspections of licensed feed mills, and BSE inspections of licensed and unlicensed feed facilities.
- Conduct follow up investigations of first time violators of tissue residues in food animals.

South Dakota Department of Environment and Health
- Conduct inspections of mammography facilities.

State Partnerships
- Training Video for Food Service Employees.

Food and Drug Administration
Fact Sheet – Tennessee

FDA Presence: 48 FDA employees in Tennessee
Resident Posts: Chattanooga, Knoxville and Memphis, who

- report to: Branch Office, Nashville, Tennessee, who
- reports to: New Orleans District, New Orleans, Louisiana, who
- reports to: Southeast Region, Atlanta, Georgia

Industry Presence in State
There are 2,171 FDA-regulated establishments in the State of Tennessee

- Food establishments (includes cosmetics) – 34 percent
- Medical device and radiological establishments - 37 percent
- Human drug establishments - 19 percent
- Biologic establishments (includes blood banks) - 5 percent
- Animal drug and feed establishments - 5 percent

Industry Highlights

- Memphis import operation works around the clock to review 100,000 entries of regulated products annually for Fed-Ex, the nation's largest overnight courier service
- Major medical research centers at universities and hospitals in Memphis and Nashville
- One national biologics testing laboratory and several regional blood banking operations
- Major oral antibiotic manufacturer
- 2 major implantable device manufacturers
- Rapidly expanding freshwater prawn/shrimp industry
- 10 Paddlefish roe (domestic caviar) processors

Contracts & Partnerships
<u>State contracts</u>
Tennessee Department of Agriculture

- Conduct inspections of food manufacturers for sanitation.
- Conduct feed mill inspections for BSE compliance.

Tennessee Department of Health

- Conduct inspections of mammography facilities

<u>State Partnerships</u>
Tennessee Department of Agriculture and University of Tennessee Agricultural Extension Service

- Assist new and small food manufacturers in meeting appropriate state and federal guidelines for producing safe and honestly labeled food products

Tennessee Department of Agriculture

- Conduct inspections of feed mills for medicated feeds and BSE.

Tennessee Department of Environment and Conservation

- Regulation of new x-ray assemblies or reassemblies.

<u>Special Programs</u>
Active Food Safety Task Force since 2002. The TN Departments of Agriculture, Inspection & Veterinary Services; TN Department of Health Epidemiologist, TN Department of Education, Univ. of TN Agricultural Extension Service and several industry representatives meet quarterly for program planning and information sharing.

Food and Drug Administration
Fact Sheet -- Texas

FDA Presence: 136 FDA employees in Texas
Import Resident Posts: Dallas-Fort Worth International Airport,
Houston Seaport/Airport, Yselta/El Paso, Laredo/Columbia/Lincoln-Juarez, Eagle Pass/
Del Rio, Rio Grande City, Pharr, Los Indios, Brownsville
report to: Southwest Import District (SWID) (52), Dallas
reports to: Southwest Region, Dallas
Domestic Resident Posts: Austin, El Paso, Houston, Ft. Worth, San Antonio
report to: Dallas District (94), Dallas
reports to: Southwest Region (24), Dallas
ORA HQ (4) and Office of Shared Services (14)

Industry Presence in Texas
There are approx. 7,645 FDA-regulated establishments in the State of Texas
Food establishments (includes cosmetics) - 53 percent
Medical devices and Radiological establishments - 24 percent
Human drug establishments – 9 percent
Animal drug and feed establishments - 11 percent
Biologics establishments (includes blood banks) - 3 percent

Industry Highlights
- Seafood - Texas Gulf Coast is the home of numerous seafood firms.
- Imports into Texas - The Southwest Import District (SWID) receives approximately 1,488,717 line entries per year. Primary products are fresh produce, seafood, processed foods, and medical devices.
- Human Drugs and Medical Devices – Texas is the home of Alcon, Allergan, Abbott, Hoechst-Cellanese, Mentor, Hospira and Cyberonics.

Contracts, Partnerships & Local Activities
State Contracts (all with the Texas Department of State Health Services)
- Conduct inspections for food sanitation.
- Conduct inspections for milk safety
- Conduct inspections for reported violative residue in food animals at slaughter.
- Conduct inspections of mammography facilities.
- Conduct medical device inspections

State Partnerships
Texas Department of Health
- Examine, sample & test imported foods, cosmetics, drugs & medical devices and take appropriate action.
- Conduct inspections of medical gas and OTC drug manufacturers and repackers.
- Conduct inspections of new x-ray assemblies and re-assemblies.
- Coordinate inspections of dairy manufacturing facilities.

Office of the Texas State Chemist – Feed and Fertilizer Control Service
- Coordinate inspections of animal feed production and BSE

Dallas District Public Affairs Specialists respond to consumers and media inquires and conduct consumer education outreach to diverse constituents.

Food and Drug Administration
Fact Sheet – Utah

FDA Presence: 7 FDA employees in Utah
Resident Post: Salt Lake City
reports to: Denver District, Denver, Colorado

Industry Presence in State

There are 992 FDA-regulated establishments in the State of Utah
Food establishments (includes cosmetics) - 44 percent
Medical device and radiological establishments - 27 percent
Human drug establishments –19 percent
Animal drug and feed establishments –6 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights

- Agriculture is dependent on irrigation, and more than three-fourths of farm income is from livestock and livestock products. Hay is the most important crop, followed by wheat, barley, and corn (maize).
- Following the national trend, farm employment and the number of farms in Utah have declined since 1960, but productivity has increased. Almost three-fourths of Utah's farm income comes from livestock products, the remainder from field crops, fruit, and canning crops.
- Utah has a thriving biotechnology and medical device manufacturing industry and is home to several of the nation's largest disposable device manufacturers.

Contracts, Partnerships & Local Activities

State contracts

Utah Department of Health
- Conduct inspections of mammography facilities.

Utah Department of Agriculture
- Conduct inspections of feed mills for medicated feed and BSE

State Partnerships

Utah Department of Agriculture & Food, Utah Department of Health and Industry
- Support the Utah Egg Quality Assurance Plan to ensure quality and safety of shell eggs.

Utah Department of Environmental Quality
- Conduct inspections of new x-ray assemblies or re-assemblies.

Food and Drug Administration
Fact Sheet – Vermont

FDA Presence: 4 FDA employees in Vermont
Resident Posts: Essex Junction and Highgate Springs
reports to: New England District, Stoneham, Massachusetts, who
reports to: Northeast Region, Jamaica (New York), New York

Industry Presence in State

There are 545 FDA-regulated establishments in the State of Vermont
Food establishments (includes cosmetics) - 74 percent
Medical Device and Radiological establishments – 12 percent
Human Drug establishments – 8 percent
Animal Drug and Feed establishments – 5 percent
Biological establishments (includes blood banks) – 1 percent

Industry Highlights

- Vermont has 7% of the District's Official Establishment Inventory of FDA-regulated firms with a concentration in the food area.

State Contracts and Partnerships

State Contracts
Vermont Department of Agriculture
- Conduct follow-up inspections/investigations of violative drug tissue residues in food animals at the time of slaughter.

Vermont Department of Health
- Conduct inspections of mammography facilities.
- Conduct food sanitation inspections.

Food and Drug Administration
Fact Sheet – Virginia

FDA Presence: 31 FDA employees in Virginia
Resident Posts: Falls Church, Norfolk, Norfolk Import Terminal, Richmond, and Roanoke who
report to: Baltimore District, Baltimore, Maryland who
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State

There are 2,186 FDA-regulated establishments in the State of Virginia
Food establishments (includes cosmetics) - 50 percent
Medical device and Radiological establishments - 31 percent
Human drug establishments - 10 percent
Animal drug and feed establishments - 5 percent
Biologic establishments (includes blood banks) - 4 percent

Industry Highlights

The industry in the state is very diverse and representative of the FDA national inventory including large, medium and small firms active in all FDA regulated product lines.

- Seafood
- Federal Food Service facilities
- Biotech firms
- HQ of the largest blood supplier in the U.S.
- Imported products via the ports of Norfolk/Newport News and Dulles International Airport

Contracts & Partnerships

State Contracts

Virginia Department of Agriculture and Consumer Services
- Conduct inspections of feed mills, monitor compliance with BSE regulations.
- Conduct food safety inspections.

Virginia Department of Health
- Conduct inspections of mammography facilities.

State Partnerships

Virginia Department of Agriculture and Consumer Services
- Collect and analyze food commodities grown for pesticides and industrial chemicals.

Virginia Department of Health Professions
- Inspect human and veterinary drug manufacturers, repackers and distributors

Virginia Department of Health
- Conduct inspections of the crabmeat processing industry.
- Collect and analyze clam and ocean quahog samples for marine biotoxins.
- Conduct seafood HACCP and human food sanitation inspections

Virginia Bureau of Radiological Health
- Conduct testing of new and re-assembled x-ray equipment.

Food and Drug Administration
Fact Sheet – Washington

FDA Presence: 177 FDA employees in Washington
Resident Posts: Blaine, Seattle, Spokane, Yakima, Oroville, and Tacoma.
report to: Seattle District: Bothell, Charles Breen, DD
reports to: Pacific Region: Oakland, California, Brenda Holman, RFDD
Pacific Northwest Regional Laboratory: Bothell, who reports to Pacific Region

Industry Presence in State

There are 4061 FDA-regulated establishments in the State of Washington
Food establishments (includes cosmetics) –70percent
Medical device and Radiological establishments – 18 percent
Human drug establishments – 6 percent
Animal drug and feed establishments – 4 percent
Biologic establishments (includes blood banks) – 2 percent

Industry Highlights

- Washington leading industries include dairy, fruit, biotechnology, and medical devices. Washington ranks in the top 5 nationwide in production of 29 different agricultural products. One of the largest and most diversified food and agricultural exporters.

Contracts, Partnerships & Local Activities

State Contracts: Washington Department of Agriculture

- Conduct inspections for food sanitation.
- Conduct investigations of reported violative residues in food animals at the time of slaughter.
- Conduct BSE inspections.

Washington Department of Health

- Conduct inspections of mammography facilities. Conduct inspections of new X-ray assemblies or re-assemblies.

State Partnerships

Washington Department of Agriculture

- Coordinate the regulation for food safety by work sharing, data sharing and educational exchange, including all current and future inspectional and sampling contracts.
- Coordinate the regulation of the fish and fishery products processing industry.
- Participate in a cooperative program, which encourages work sharing, data sharing, and educational exchange concerning animal feed safety.

Local Activities

- Active involvement with the Washington Food Safety Forum a coalition of Federal and State agencies and state commodity commissions established to educate and promote accurate food safety information to the media.
- Member of the Food Safety Review Council. The group works in partnership with the Department of Health in developing advisory technical interpretations of the state food service regulations and other matters.

Food and Drug Administration
Fact Sheet – Washington D.C.

FDA Presence

Resident Post: Falls Church Resident Post services Washington D.C, who reports to: Baltimore District, Baltimore, Maryland who reports to Central Region, Philadelphia, Pennsylvania.

Industry Presence in Washington D.C.

There are 262 FDA-regulated establishments in Washington D.C.

- Food establishments (includes cosmetics) - 45 percent
- Medical device and Radiological establishments - 29 percent
- Human drug establishments - 16 percent
- Biologic establishments (includes blood banks) - 10 percent

Food and Drug Administration
Fact Sheet – West Virginia

FDA Presence: 3 FDA employees in West Virginia
Resident Posts: Charleston and Morgantown
report to: Baltimore District, Baltimore, Maryland
reports to: Central Region, Philadelphia, Pennsylvania

Industry Presence in State
There are 629 FDA-regulated establishments in the State of West Virginia
Food establishments (includes cosmetics) - 47 percent
Medical device and Radiological establishments - 26 percent
Human drug establishments - 12 percent
Animal drug and feed establishments - 11 percent
Biologic establishments (includes blood banks) – 4 percent

Industry Highlights
- One of the largest producers of generic drug tablets in the country.
- Aquaculture (seafood)
- Many small acidified food producers (cottage industries)

Contracts & Partnerships

State Contracts
West Virginia Department of Health and Human Services
- Conduct inspections for food safety.
- Conduct inspections of mammography facilities.

West Virginia Department of Agriculture
- Conduct inspections of warehouses and seafood processors for food safety.
- Monitor and perform inspections of feed mills, renderers and others to assure compliance with BSE regulations.

State Partnerships
West Virginia Department of Agriculture
- Conduct inspections of fish farms and processors, collect samples and analyze for pesticide and industrial chemical residues

West Virginia Radiological Health Program
- Conduct inspections new and reassembled x-ray equipment

Food and Drug Administration
Fact Sheet – Wisconsin

FDA Presence: 23 FDA employees in Wisconsin
Resident Posts in Wisconsin: Milwaukee, Madison, Green Bay, and LaCrosse
report to: Minneapolis District, Minneapolis, Minnesota, who
reports to: Central Region: Philadelphia, Pennsylvania

Industry Presence in State
There are 3,838 FDA-regulated establishments in the State of Wisconsin
Food establishments (includes cosmetics) - 57 percent
Medical device and Radiological establishments – 17 percent
Animal drug and feed establishments - 17 percent
Human drug establishments - 8 percent
Biologic establishments (includes blood banks) -2 percent

Imports
- There are 7 ports of entry in the State of Wisconsin.
- FDA regulated import entries are primarily food, food additives, cardiovascular and radiological devices.
- The Wisconsin FDA regulated import entries are handled out of the Minneapolis District Office and the International Falls, MN, Resident Post.

Industry Highlights
- Milk & Dairy - Leads the nation in cheese and dry whey production; second in milk and butter production.
- Cranberries - Wisconsin ranks first in cranberry production.
- Low Acid Canned Foods - Ranks first in snapbeans. Significant processing includes carrots, sweet corn, green peas, cucumbers/pickles, cabbage (kraut), and beets.
- Seafood – Home of more than 90 firms that process or handle seafood.
- Agriculture – Significant production occurs for: maple syrup, mint for oil, potatoes, oats, tart cherries, corn for silage, ginseng, honey, and milk cows.
- Medical Devices – Wisconsin is the home of two major medical device manufacturers -- GE Medical Systems & General Electric Medical Systems Information Technology

Contracts & Partnerships
State Contracts
Department of Agriculture, Trade & Consumer Protection
- Conduct GMP inspections at licensed feed mills and BSE inspections at licensed and unlicensed feed facilities.
- Conduct food sanitation, seafood HACCP, and juice HACCP inspections.
- Conduct follow-up investigations of first time violators of tissue residues in food animals.

Department of Health and Social Services
- Conduct inspections of mammography facilities

State Partnerships
Wisconsin Department of Agriculture
- Food Security Awareness Training
- GMP Training for On-Farm Feed Mixers of Medicated Feed

Food and Drug Administration
Fact Sheet – Wyoming

FDA Presence

Wyoming is covered by the Denver District, Denver, Colorado, who reports to: Southwest Region, Dallas, Texas

Industry Presence in State

There are 235 FDA-regulated establishments in the State of Wyoming

- Food establishments (includes cosmetics) – 51 percent
- Human Drug establishments – 18 percent
- Medical Device and Radiological establishments – 17 percent
- Animal drug and feed establishments – 10 percent
- Biological establishments (includes blood banks) – 4 percent

Industry Highlights

- The mineral extraction industry and the travel and tourism sector are the main drivers behind Wyoming's economy.
- Wyoming's mineral commodities include coal, natural gas, coal bed methane, crude oil, and trona. Wyoming ranks highest in mining employment in the U.S.
- The main agricultural commodities produced in Wyoming include livestock (beef), hay, sugar beets, grain (wheat and barley), and wool. Over 91% of land in Wyoming is classified as rural.

Contracts, Partnerships & Local Activities

State Contracts

Wyoming Department of Agriculture

- Conduct food sanitation inspections

Wyoming Department of Health

- Conduct inspections of mammography facilities.

State Partnerships

Wyoming Department of Agriculture

- Share oversight & authority of regulated dairy manufacturing facilities.

Wyoming State Board of Pharmacy

- Conduct inspections of medical gas manufacturing facilities and share reports with the Denver District Office.

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Food and Drug Administration

Funding Levels for Major Initiatives
(Budget Authority in $000s)

FY 2004-2006

Initiative	FY 2004 Actuals	FY 2005 Enacted	FY 2006 Request
Counterterrorism-Food Defense/Security	115,660	149,952	180,026
Counterterrorism- Medical Countermeasures	52,620	57,159	57,159
White Oak Consolidation	2,361	17,846	21,974
Drug Review /1	204,775	210,221	214,905
BSE	21,479	29,566	29,566
Generic Drug Resources /2	56,422	56,228	56,228
Patient Safety	65,411	64,888	69,888
Non-Add:			
Office of Drug Safety:	*15,800*	*17,900*	*22,900*

1/FY 2005 and FY 2006 are estimates based upon economic assumptions for the FY 2006 budget.

2/Includes CDER and ORA resources. FY 2005 includes the portion of cost of living that pertains to the generic drugs program.

Food and Drug Administration
Summary of Base Resources

Summary of Base Resources for Requested Increases in FY 2005	FY 2004 Actuals[1]	FY 2005 Enacted[2]	FY 2006 Request	Requested Increase
Counterterrorism Food Defense/Security [2/]	115,660,000	149,952,000	180,026,000	30,074,000
Medical Device and Radiological Health Program [3/]	191,143,000	214,965,000	220,961,000	5,996,000
Office of Drug Safety	15,800,000	17,900,000	22,900,000	5,000,000
GSA Rent	114,354,000	113,479,000	117,579,000	4,100,000
White Oak Consolidation (also in FY 2004 and 2005 PDUFA User Fees)	2,361,000	17,846,000	21,974,000	4,128,000
Buildings and Facilities	22,504,000	-	7,000,000	7,000,000
TOTAL BA INCREASES	461,822,000	514,142,000	570,440,000	56,298,000
User Fees:				
PDUFA	232,082,000	284,394,000	305,332,000	20,938,000
White Oak Consolidation (PDUFA) (Non-Add)	*3,770,000*	*3,000,000*	-	*(3,000,000)*
MDUFMA	23,875,000	33,938,000	40,300,000	6,362,000
ADUFA	1,083,000	8,354,000	11,318,000	2,964,000
MQSA	12,716,000	16,919,000	17,173,000	254,000
Export Certification	1,806,000	1,615,000	1,639,000	24,000
Color Certification	6,128,000	5,223,000	6,001,000	778,000
TOTAL USER FEE INCREASES	277,690,000	350,443,000	381,763,000	31,320,000
TOTAL FDA INCREASES	739,512,000	864,585,000	952,203,000	87,618,000

[1/] Includes 0.59 percent rescission from FY 2004 Omnibus Appropriations.
[2/] Includes 0.80 percent rescission from FY 2005 Omnibus Appropriations.
[3/] The Medical Device and Radiological Health Program is the total for CDRH and the field estimate for the Device and Radiological Health Program. This amount is needed to meet one of the triggers for the MDUFMA program.

FOOD AND DRUG ADMINISTRATION
Summary of Changes
FY 2006 Congressional Justification Submission

	Budget Authority	User Fees	Program Level	Program Level FTE
FY 2005 Appropriated	**$1,461,792,000**	**$350,443,000**	**1,812,235,000**	**10,357**
FY 2005 Rescission	**($11,694,000)**	**$0**	**($11,694,000)**	**0**
FY 2005 Enacted [1/]	**$1,450,098,000**	**$350,443,000**	**$1,800,541,000**	**10,357**
FY 2006 Built in Changes:				
Cost of Living Increases	$36,509,000		$36,509,000	
Pay Absorptions	($36,509,000)		($36,509,000)	(251)
Subtotal: Cost of Living Changes	***$0***		***$0***	**(251)**
FY 2006 Program Changes:				
Budget Authority				
Food Defense	$30,074,000		$30,074,000	17
Medical Device Review	$5,996,000		$5,996,000	16
Office of Drug Safety	$5,000,000		$5,000,000	20
GSA Rent	$4,100,000		$4,100,000	-
FDA White Oak Consolidation	$4,128,000		$4,128,000	-
Buildings and Facilities	$7,000,000		$7,000,000	-
Administrative Efficiencies	($1,554,000)		($1,554,000)	(14)
Information Technology Reduction	($5,116,000)		($5,116,000)	(15)
Subtotal: Budget Authority Program Changes	***$49,628,000***		***$49,628,000***	***24***
Total Budget Authority Changes from FY 2005 Enacted to FY 2006 Estimate	**$49,628,000**	**$0**	**$49,628,000**	**(227)**
FY 2006 User Fee Changes:				
PDUFA ($12,700,000 for GSA rent)		$20,938,000	$20,938,000	24
MDUFMA ($3,203,000 for GSA Rent and $783,000 for Other Rent)		$6,362,000	$6,362,000	7
ADUFA ($1,371,000 for GSA Rent)		$2,964,000	$2,964,000	22
MQSA		$254,000	$254,000	(6)
Color Certification		$778,000	$778,000	-
Export Certification		$24,000	$24,000	-
Total User Fee Changes from FY 2005 Enacted to FY 2006 Estimate		**$31,320,000**	**$31,320,000**	**47**
Net Program Level Change from FY 2005 Enacted to FY 2006 Estimate	**$49,628,000**	**$31,320,000**	**$80,948,000**	**(180)**
TOTAL FDA REQUEST FOR FY 2006	**$1,499,726,000**	**$381,763,000**	**$1,881,489,000**	**10,177**

[1/] Includes a 0.80 percent rescission.

Food and Drug Administration
FY 2006 Crosswalk to Summary of Change - Budget Authority

Program	Food Defense		Medical Device Review		Office of Drug Safety		GSA Rent and Other rent and Rent Related	FDA White Oak Consolidation	Buildings and Facilities	Attrition	Administrative Efficiencies		Information Technology Reduction		Total Budget Authority Change	
	FTE	$000	FTE	$000	FTE	$000	$000	$000	$000	FTE	FTE	$000	FTE	$000	FTE	$000
Center for Food Safety and Applied Nutrition	**7**	**$4,822**	**0**	**$0**	**0**	**$0**	**$428**	**$0**	**$0**	**(16)**	**(2)**	**($232)**	**(2)**	**($773)**	**(13)**	**$4,245**
Center	*7*	*4,822*								*(16)*	*(2)*	*(232)*	*(2)*	*(773)*	*(13)*	*3,817*
GSA and Other Rent Related Activities							*428*			*0*					*-*	*428*
Center for Drug Evaluation and Research	**0**	**$0**	**0**	**$0**	**20**	**$5,000**	**$459**	**$0**	**$0**	**(11)**	**(3)**	**($301)**	**(6)**	**($1,865)**	**0**	**$3,293**
Center					*20*	*5,000*				*(11)*	*(3)*	*(301)*	*(6)*	*(1,865)*	*-*	*2,834*
GSA and Other Rent Related Activities							*459*			*0*					*-*	*459*
Center for Biologics Evaluation and Research	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$60**	**$0**	**$0**	**(14)**	**(1)**	**($132)**	**(2)**	**($665)**	**(17)**	**($737)**
Center										*(14)*	*(1)*	*(132)*	*(2)*	*(665)*	*(17)*	*(797)*
GSA and Other Rent Related Activities							*60*			*0*					*-*	*60*
Center for Vetrinary Medicine	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$218**	**$0**	**$0**	**(6)**	**0**	**$0**	**0**	**$0**	**(6)**	**$218**
Center										*(6)*					*(6)*	*-*
GSA and Other Rent Related Activities							*218*			*0*					*-*	*218*
Center for Devices and Radiological Health	**0**	**$0**	**3**	**$1,796**	**0**	**$0**	**$310**	**$0**	**$0**	**(20)**	**0**	**$0**	**0**	**$0**	**(17)**	**$2,106**
Center			*3*	*1,796*						*(20)*					*(17)*	*1,796*
GSA and Other Rent Related Activities			*0*	*-*			*310*			*0*					*-*	*310*
National Center for Toxicological Research	**0**	**$1,000**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**$0**	**(4)**	**(1)**	**($54)**	**0**	**$0**	**(5)**	**$946**
Center	*0*	*$1,000*								*(4)*	*(1)*	*(54)*			*(5)*	*946*
GSA and Other Rent Related Activities															*-*	*-*
Other Activities	**2**	**$1,500**	**0**	**$0**	**0**	**$0**	**150**	**0**	**0**	**(13)**	**0**	**($120)**	**(3)**	**($1,350)**	**(14)**	**$180**
Office of the Commissioner	*2*	*1,500*								*(6)*	*0*	*(72)*	*(1)*	*(125)*	*(5)*	*1,303*
Office of Management										*(7)*	*0*	*(48)*	*(2)*	*(1,225)*	*(9)*	*(1,273)*
GSA and Other Rent Related Activities							*150*								*-*	*150*
Office of Regulatory Affairs	**8**	**$22,752**	**13**	**$4,200**	**0**	**-**	**$2,475**	**$0**	**$0**	**(167)**	**(7)**	**(715)**	**(2)**	**(463)**	**(155)**	**28,249**
Foods Program Estimate	*8*	*22,752*								*(91)*	*(5)*	*(532)*	*(2)*	*(336)*	*(90)*	*21,884*
GSA and Other Rent for the Foods Program							*1,400*								*-*	*1,400*
Human Drugs Program Estimate										*(33)*	*(2)*	*(137)*		*(96)*	*(35)*	*(233)*
GSA and Other Rent for the Human Drugs Program							*349*								*-*	*349*
Biologics Program Estimate										*(10)*		*(46)*		*(31)*	*(10)*	*(77)*
GSA and Other Rent for the Biologics Program							137								*-*	*137*
Animal Drugs and Feeds Program Estimate										*(12)*					*(12)*	*-*
GSA and Other Rent for the Animal Drugs and Feeds Program							136								*-*	*136*
Devices and Radiological Health Program Estimate			*13*	*4,200*						*(21)*					*(8)*	*4,200*
GSA and Other Rent for the Devices and Radiological Health Program							453								*-*	*453*
GSA and Other Rent and Rent Related (non-add)		-		-		-	*4,100*	-	-	*0*		-		-	-	*$4,100*
FDA White Oak Consolidation		**$0**		**$0**		**$0**	**$0**	**$4,128**	**$0**	**0**		**$0**		**$0**	-	**$4,128**
Buildings and Facilities		**$0**		**$0**		**$0**	**$0**	**$0**	**$7,000**			**$0**		**$0**	-	**$7,000**
Total	**17**	**$30,074**	**16**	**$5,996**	**20**	**$5,000**	**$4,100**	**$4,128**	**$7,000**	**(251)**	**(14)**	**($1,554)**	**(15)**	**($5,116)**	**(227)**	**$49,628**

Food and Drug Administration
FY 2006 Crosswalk to Summary of Change - User Fee

Program	PDUFA		MDUFMA		ADUFA		MQSA		Export Certification		Color Certification Fund		Total User Fee Passback	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Center for Food Safety and Applied Nutrition	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Center													-	-
GSA and Other Rent Related Activities													-	-
Center for Drug Evaluation and Research	**17**	**14,356**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**17**	**$14,356**
Center	*17*	*14,146*											*17*	*14,146*
GSA and Other Rent Related Activities		*210*											-	*210*
Center for Biologics Evaluation and Research	**2**	**6,624**	**1**	**673**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**3**	**$7,297**
Center	*2*	*6,580*	*1*	*562*									*3*	*7,142*
GSA and Other Rent Related Activities	-	*44*	-	*111*									-	*155*
Center for Vetrinary Medicine	**-**	**-**	**-**	**-**	**18**	**2,462**	**-**	**-**	**-**	**-**	**-**	**-**	**18**	**$2,462**
Center					*18*	*1,553*							*18*	*1,553*
GSA and Other Rent Related Activities					-	*909*							-	*909*
Center for Devices and Radiological Health	**-**	**-**	**6**	**4,886**	**-**	**-**	**(6)**	**163**	**-**	**-**	**-**	**-**	**-**	**$5,049**
Center			*6*	*4,387*			*(6)*	*163*					-	*4,550*
GSA and Other Rent Related Activities			-	*499*									-	*499*
National Center for Toxicological Research	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**$0**
Center													-	-
GSA and Other Rent Related Activities													-	-
Other Activities	**4**	**$1,408**	**-**	**$495**	**4**	**$502**	**-**	**$10**	**-**	**$0**	**-**	**$0**	**8**	**$2,415**
Office of the Commissioner	-	*990*	-	*80*	*1*	*123*							*1*	*1,193*
Office of Management	*4*	*388*	-	*394*	*3*	*288*	-	*10*					*7*	*1,080*
GSA and Other Rent Related Activities	-	*30*		*21*	-	*91*							-	*142*
Office of Regulatory Affairs	**1**	**$1,550**	**-**	**$308**	**-**	**$0**	**-**	**$81**	**-**	**$0**	**-**	**$0**	**1**	**$1,939**
Foods Program Estimate													-	-
GSA and Other Rent for the Foods Program													-	-
Human Drugs Program Estimate	*1*	*887*											*1*	*887*
GSA and Other Rent for the Human Drugs Program		*9*											-	*9*
Biologics Program Estimate	-	654	-	70									-	*724*
GSA and Other Rent for the Biologics Program		-		5									-	*5*
Animal Drugs and Feeds Program Estimate													-	-
GSA and Other Rent for the Animal Drugs and Feeds Program													-	-
Devices and Radiological Health Program Estimate			-	212			-	81					-	*293*
GSA and Other Rent for the Devices and Radiological Health Program				21									-	*21*
													-	-
GSA and Other Rent and Rent Related (non add)		*293*		*657*		*1,000*		-		-		-	-	*1,950*
FDA White Oak Consolidation		**($3,000)**											**-**	**($3,000)**
Export Certification									**-**	**$24**			**-**	**24**
Color Certification											**-**	**$778**	**-**	**778**
Total	**24**	**$20,938**	**7**	**$6,362**	**22**	**$2,964**	**(6)**	**$254**	**0**	**$24**	**0**	**$778**	**47**	**$31,320**

Food and Drug Administration
FY 2006 Crosswalk to Summary of Change - Program Level
Dollars in Thousands

FY 2006 Program Level Changes	Budget Authority																User Fees													
	Food Defense		Medical Device Review		Office of Drug Safety		GSA Rent	FDA White Oak Consolidation	Buildings and Facilities	Attrition	Administrative Efficiencies		Information Technology Reduction		TOTAL BUDGET AUTHORITY REQUEST		PDUFA[1]		MDUFMA		ADUFA[2]		MQSA		Color and Export Cert. Fund	Total Current User Fees		TOTAL PROGRAM LEVEL REQUEST	
	FTE	$000	FTE	$000	FTE	$000	$000	$000	$000	FTE	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000
Center for Food Safety and Applied Nutrition	**7**	**$4,822**					**$428**			***(16)***	***(2)***	**($232)**	***(2)***	**($773)**	***(13)***	**$4,245**										0	**$0**	**(13)**	**$4,245**
Center	*7*	*4,822*								*(16)*	*(2)*	*(232)*	*(2)*	*(773)*	*(13)*	*$3,817*										*0*	*$0*	*(13)*	*$3,817*
GSA and Other Rent Related Activities							*428*			*0*						*$428*										*0*	*$0*	-	*$428*
Center for Drug Evaluation and Research					**20**	**$5,000**	**$459**			***(11)***	***(3)***	**($301)**	***(6)***	**($1,865)**	***0***	**$3,293**	***17***	**$14,356**								17	**$14,356**	**17**	**$17,649**
Center					*20*	*5,000*				*(11)*	*(3)*	*(301)*	*(6)*	*(1,865)*	*0*	*$2,834*	*17*	*14,146*								*17*	*$14,146*	*17*	*$16,980*
GSA and Other Rent Related Activities							*459*			*0*						*$459*	*0*	*210*									*$210*	-	*$669*
Center for Biologics Evaluation and Research							**$60**			***(14)***	***(1)***	**($132)**	***(2)***	**($665)**	***(17)***	**($737)**	***2***	**$6,624**	***1***	**$673**						3	**$7,297**	**(14)**	**$6,560**
Center										*(14)*	*(1)*	*(132)*	*(2)*	*(665)*	*(17)*	*($797)*	*2*	*6,580*	*1*	*562*						*3*	*$7,142*	*(14)*	*$6,345*
GSA and Other Rent Related Activities							*60*			*0*						*$60*	*0*	*44*	*0*	*111*						*0*	*$155*	-	*$215*
Center for Vetrinary Medicine							**$218**			***(6)***	***0***	**$0**	***0***	**$0**	***(6)***	**$218**					***18***	**$2,462**				18	**$2,462**	**12**	**$2,680**
Center										*(6)*	*0*	*0*			*(6)*	*$0*					*18*	*1,553*				*18*	*$1,553*	*12*	*$1,553*
GSA and Other Rent Related Activities							*218*			*0*						*$218*					*0*	*909*				*0*	*909*	-	*$1,127*
Center for Devices and Radiological Health			**3**	**$1,796**			**$310**			***(20)***	***0***	**$0**	***0***	**$0**	***(17)***	**$2,106**			***6***	**$4,886**			***(6)***	**$163**		0	**$5,049**	**(17)**	**$7,155**
Center			*3*	*1,796*						*(20)*	*0*	*0*			*(17)*	*$1,796*			*6*	*4,387*			*(6)*	*163*		*0*	*$4,550*	*(17)*	*$6,346*
GSA and Other Rent Related Activities							*310*			*0*						*$310*			*0*	*499*			*0*	*0*		*0*	*499*	-	*$809*
National Center for Toxicological Research	**0**	**$1,000**					**$0**			***(4)***	***(1)***	**($54)**	***0***	**$0**	***(5)***	**$946**										0	**$0**	**(5)**	**$946**
Center	*0*	*1,000*								*(4)*	*(1)*	*(54)*			*(5)*	*$946*										*0*	*-*	*(5)*	*$946*
GSA and Other Rent Related Activities							*0*			*0*						*$0*										*0*	*$0*	-	*$0*
Other Activities	**2**	**$1,500**					**$150**			***(13)***	***0***	**($120)**	***(3)***	**($1,350)**	***(14)***	**$180**	***4***	**$1,408**	***0***	**$495**	***4***	**$502**	***0***	**$10**		8	**$2,415**	**(6)**	**$2,595**
Office of the Commissioner	*2*	*1,500*								*(6)*	*0*	*(72)*	*(1)*	*(125)*	*(5)*	*$1,303*	*0*	*990*	*0*	*80*	*1*	*123*				*1*	*$1,193*	*(4)*	*$2,496*
Office of Management										*(7)*	*0*	*(48)*	*(2)*	*(1,225)*	*(9)*	*($1,273)*	*4*	*388*	*0*	*394*	*3*	*288*	*0*	*10*		*7*	*$1,080*	*(2)*	*($193)*
GSA and Other Rent Related Activities							*150*									*$150*	*0*	*30*	*0*	*21*	*0*	*91*				*0*	*$142*	-	*$292*
Office of Regulatory Affairs	**8**	**$22,752**	**13**	**$4,200**			**$2,475**			***(167)***	***(7)***	**($715)**	***(2)***	**($463)**	***(155)***	**$28,249**	***1***	**$1,550**	***0***	**$308**			***0***	**$81**		1	**$1,939**	**(154)**	**$30,188**
Foods Program Estimate	*8*	*22,752*								*(91)*	*(5)*	*(532)*	*(2)*	*(336)*	*(90)*	*$21,884*										*0*	*$0*	*(90)*	*$21,884*
GSA and Other Rent for the Foods Program							*1,400*								*0*	*$1,400*										*0*	*$0*	-	*$1,400*
Human Drugs Program Estimate										*(33)*	*(2)*	*(137)*	*0*	*(96)*	*(35)*	*($233)*	*1*	*887*								*1*	*$887*	*(34)*	*$654*
GSA and Other Rent for the Human Drugs Program							*349*								*0*	*$349*		*9*								*0*	*$9*	-	*$358*
Biologics Program Estimate										*(10)*	*0*	*(46)*	*0*	*(31)*	*(10)*	*($77)*		*654*	*0*	*70*						*0*	*$724*	*(10)*	*$647*
GSA and Other Rent for the Biologics Program							*137*								*0*	*$137*				*5*						*0*	*$5*	-	*$142*
Animal Drugs and Feeds Program Estimate										*(12)*					*(12)*	*$0*										*0*	*$0*	*(12)*	*$0*
GSA and Other Rent for the Animal Drugs and Feeds Program							*136*								*0*	*$136*										*0*	*$0*	-	*$136*
Devices and Radiological Health Program Estimate			*13*	*4,200*						*(21)*					*(8)*	*$4,200*				*212*			*0*	*81*		*0*	*293*	*(8)*	*$4,493*
GSA and Other Rent for the Devices and Radiological Health Program							*453*								*0*	*$453*				*21*						*0*	*21*	-	*$474*
GSA and Other Rent and Rent Related (non add)							*4,100*											*293*				*1,000*				*0*	*$1,293*	-	*$1,293*
FDA White Oak Consolidation								*4,128*								**$4,128**		*(3,000)*								0	**($3,000)**	**-**	**$1,128**
Export Certification																									**$24**	0	**$24**	**-**	**$24**
Color Certification																									**$778**	0	**$778**	**-**	**$778**
Buildings and Facilities									**$7,000**							**$7,000**										0	**$0**	**-**	**$7,000**
Total	**17**	**$30,074**	**16**	**$5,996**	**20**	**$5,000**	**$4,100**	**$4,128**	**$7,000**	**(251)**	**(14)**	**($1,554)**	**(15)**	**($5,116)**	**(227)**	**$49,628**	**24**	**$20,938**	**7**	**$6,362**	**22**	**$2,964**	**(6)**	**$254**	**$24**	**47**	**$31,320**	**(180)**	**$80,948**

Food and Drug Administration
ALL PURPOSE TABLE - Budget Authority
(Dollars in Thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Center for Food Safety & Applied Nutrition	**910**	**$167,534**	**901**	**$167,332**	**894**	**$175,189**	**881**	**$179,434**
Center for Food Safety & Applied Nutrition	*910*	*144,366*	*901*	*143,958*	*894*	*152,002*	*881*	*155,819*
GSA Rent and Rent Related Activities		*23,168*		*23,374*		*23,187*	*0*	*23,615*
Center for Drug Evaluation and Research	**1,218**	**$229,372**	**1,445**	**$230,882**	**1,380**	**$230,588**	**1,380**	**$233,881**
Center for Drug Evaluation and Research	*1,218*	*210,828*	*1,445*	*210,661*	*1,380*	*210,529*	*1,380*	*213,363*
GSA Rent and Rent Related Activities		*18,544*		*20,221*		*20,059*	0	*20,518*
Center for Biologics Evaluation and Research	**559**	**$103,537**	**575**	**$102,392**	**565**	**$102,869**	**548**	**$102,132**
Center for Biologics Evaluation and Research	*559*	*96,265*	*575*	*96,365*	*565*	*96,890*	*548*	*96,093*
GSA Rent and Rent Related Activities		*7,272*	-	*6,027*		*5,979*	0	*6,039*
Center for Veterinary Medicine	**346**	**$66,573**	**315**	**$66,960**	**315**	**$67,551**	**309**	**$67,769**
Center for Veterinary Medicine	*346*	*54,530*	*315*	*54,602*	*315*	*55,292*	*309*	*55,292*
GSA Rent and Rent Related Activities		*12,043*	-	*12,358*		*12,259*	0	*12,477*
Center for Devices and Radiological Health	**935**	**$156,961**	**971**	**$158,904**	**1,003**	**$180,948**	**986**	**$183,054**
Center for Devices and Radiological Health	*935*	*140,646*	*971*	*141,059*	*1,003*	*163,246*	*986*	*165,042*
GSA Rent and Rent Related Activities		*16,315*	-	*17,845*		*17,702*	0	*18,012*
National Center for Toxicological Research	**207**	**$39,869**	**233**	**$39,883**	**225**	**$40,435**	**220**	**$41,381**
National Center for Toxicological Research	*207*	*39,652*	*233*	*39,652*	*225*	*$40,206*	220	41,152
Rent Related Activities		*217*	-	*231*		*229*	0	*229*
Office of Regulatory Affairs	**3,817**	**$513,906**	**3,769**	**$512,520**	**3,582**	**$540,144**	**3,427**	**$568,393**
Foods Program Estimate	*2,172*	*262,686*	*2,063*	*263,099*	*2,056*	*283,524*	*1,966*	*305,408*
GSA and Other Rent for the Foods Program	-	*36,655*	-	*34,500*	-	*35,890*	*0*	*37,290*
Human Drugs Program Estimate	*725*	*81,290*	*757*	*81,459*	*670*	*80,959*	*635*	*80,726*
GSA and Other Rent for the Human Drugs Program	-	*12,235*	-	*12,660*	-	*11,695*	*0*	*12,044*
Biologics Program Estimate	*233*	*26,089*	*229*	*25,991*	*216*	*26,222*	*206*	*26,145*
GSA and Other Rent for the Biologics Program	-	*3,932*	-	*3,830*	-	*3,770*	*0*	*3,907*
Animal Drugs and Feeds Program Estimate	*246*	*28,928*	*263*	*28,856*	*240*	*35,194*	*228*	*35,194*
GSA and Other Rent for the Animal Drugs and Feeds Program	-	*4,152*	-	*4,397*	-	*4,189*	*0*	*4,325*
Devices and Radiological Health Program Estimate	*441*	*50,497*	*457*	*50,085*	*400*	*51,719*	*392*	*55,919*
GSA and Other Rent for the Devices and Radiological Health Program	-	*7,442*	-	*7,643*	-	*6,982*	*0*	*7,435*
Other Activities	**575**	**$98,597**	**644**	**$97,545**	**597**	**$94,528**	**583**	**94,708**
Office of the Commissioner	*344*	*42,932*	*332*	*42,460*	*311*	*41,894*	*306*	*43,197*
Office of Management	*231*	*40,371*	*312*	*40,852*	*286*	*38,515*	*277*	*37,242*
Central Services		*6,872*	-	*6,878*	-	*6,823*	*0*	*6,823*
GSA Rent and Rent Related Activities		*8,422*	-	*7,355*		*7,296*	*0*	*7,446*
FDA Consolidation at White Oak		**$2,361**		**$2,361**		**$17,846**		**21,974**
Other Rent and Rent Related Activities (non add)		*$36,043*	-	*$36,047*		*$35,758*		*$35,758*
GSA Rental Payments (non add)		*$114,354*	-	*$114,394*		*$113,479*	*0*	*$117,579*
TOTAL, Salaries & Expenses	**8,567**	**$1,378,710**	**8,853**	**$1,378,779**	**8,561**	**$1,450,098**	**8,334**	**$1,492,726**
Buildings and Facilities		**$22,504**	**-**	**$6,959**	**-**	**-**	**0**	**7,000**
TOTAL Budget Authority	**8,567**	**$1,401,214**	**8,853**	**$1,385,738**	**8,561**	**$1,450,098**	**8,334**	**$1,499,726**

Food and Drug Administration
ALL PURPOSE TABLE - User Fees
(Dollars in thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses, Definite Appropriations:								
Prescription Drug User Fee Act (PDUFA):								
Center for Drug Evaluation and Research	**972**	**$167,119**	**904**	**$179,156**	**1015**	**$208,696**	**1,032**	**$223,052**
Center for Drug Evaluation and Research	*972*	*162,653*	*904*	*172,954*	*1,015*	*199,762*	*1,032*	*213,908*
GSA Rent and Rent Related Activities		*4,466*	**-**	*6,202*	**-**	*8,934*	*0*	*9,144*
Center for Biologics Evaluation and Research	**217**	**$41,181**	**214**	**$38,357**	**214**	**$40,214**	**216**	**$46,838**
Center for Biologics Evaluation and Research	*217*	*40,170*	*214*	*37,049*	*214*	*38,353*	*216*	*44,933*
GSA Rent and Rent Related Activities		*1,011*	**-**	*1,308*	**-**	*1,861*	*0*	*1,905*
Office of Regulatory Affairs	**41**	**$5,808**	**69**	**$10,572**	**40**	**$7,506**	**41**	**$9,056**
Human Drugs Program Estimate	*34*	*4,821*	*64*	*9,106*	*28*	*5,046*	*29*	*5,933*
GSA and Other Rent for the Human Drugs Program	**-**	**-**	**-**	*226*	**-**	*260*	**-**	*269*
Biologics Program Estimate	*7*	*987*	*5*	*1,222*	*12*	*2,088*	*12*	*2,742*
GSA and Other Rent for the Biologics Program	**-**	**-**	**-**	*18*	**-**	*112*	**-**	*112*
Other Activities (PDUFA)	**122**	**$14,204**	**145**	**$21,740**	**146**	**$24,978**	**150**	**$26,386**
Office of the Commissioner	*63*	*7,658*	*75*	*12,338*	*75*	*14,021*	*75*	*15,011*
Office of Management	*59*	*5,877*	*70*	*8,510*	*71*	*9,717*	*75*	*10,105*
GSA Rent and Rent Related Activities		*669*	**-**	*892*	**-**	*1,240*	*0*	*1,270*
FDA Consolidation at White Oak		**3,770**	**-**	**-**	**-**	**3,000**		
GSA Rent (PDUFA) (non-add)	*-*	*$6,146*	*-*	*$8,646*	*-*	*$12,407*	*0*	*$12,700*
Subtotal PDUFA	**1,352**	**$232,082**	**1,332**	**$249,825**	**1,415**	**$284,394**	**1,439**	**$305,332**
Medical Device User Fee and Modernization Act (MDUFMA):								
Center for Biologics Evaluation and Research	**21**	**$3,673**	**33**	**$7,835**	**36**	**$8,395**	**37**	**$9,068**
Center for Biologics Evaluation and Research	*21*	*3,437*	*33*	*7,322*	*36*	*7,850*	*37*	*8,412*
GSA Rent and Rent Related Activities		*236*	*0*	*513*	*0*	*545*	*0*	*656*
Center for Devices and Radiological Health	**100**	**$18,245**	**136**	**$18,755**	**152**	**$20,086**	**158**	**$24,972**
Center for Devices and Radiological Health	*100*	*17,253*	*136*	*16,590*	*152*	*17,786*	*158*	*22,173*
GSA Rent and Rent Related Activities		*992*	*0*	*2,165*	*0*	*2,300*	*0*	*2,799*
Office of Regulatory Affairs	**6**	**$676**	**8**	**$991**	**10**	**$1,063**	**10**	**$1,371**
Biologics Program Estimate	*1*	*68*	*1*	*297*	*2*	*319*	*2*	*389*
GSA and Other Rent for the Biologics Program	*-*	*-*	*-*	*18*	*-*	*30*	*-*	*35*
Devices and Rad. Health Program Estimate	*5*	*608*	*7*	*552*	*8*	*593*	*8*	*805*
GSA and Other Rent for the Devices and Radiological Health Program	*-*	*-*	*-*	*124*	*-*	*121*	*-*	*142*
Other Activities (MDUFMA)	**10**	**1,281**	**20**	**$4,073**	**22**	**$4,394**	**22**	**$4,889**
Office of the Commissioner	*3*	*384*	*5*	*1,076*	*6*	*1,153*	*6*	*1,233*
Office of Management	*7*	*758*	*15*	*2,712*	*16*	*2,908*	*16*	*3,302*
GSA Rent and Rent Related Activities		*139*		*285*		*333*	*0*	*354*
Other Rent and Rent Related Activities (MDUFMA) (non-add)		*$287*	*-*	*$640*	*-*	*$686*	*0*	*$783*
GSA Rental Payments (MDUFMA) (non-add)		*$1,080*	*-*	*$2,465*	*-*	*$2,643*	*0*	*$3,203*
Subtotal (MDUFMA)	**137**	**$23,875**	**197**	**$31,654**	**220**	**$33,938**	**227**	**$40,300**
Animal Drug User Fee Act (ADUFA):				**$31,654**				
Center for Veterinary Medicine	**3**	**$1,083**	**40**	**$5,000**	**58**	**$8,107**	**76**	**$10,569**
Center for Veterinary Medicine	*3*	*$983*	*40*	*$4,750*	*58*	*7,748*	*76*	*9,301*
GSA Rent and Rent Related Activities		*100*		*250*		*359*	*0*	*1,268*
Other Activities (ADUFA)			**-**	**-**	**2**	**$247**	**6**	**$749**
Office of the Commissioner							*1*	*123*
Office of Management			**-**	**-**	*2*	*235*	*5*	*523*
GSA Rent and Rent Related Activities			*0*	*-*		*12*	*0*	*103*
GSA Rental Payments (ADUFA) (non-add)		**$100**	**-**	**$250**	*-*	**$371**	*0*	*$1,371*
Subtotal (ADUFA)	**3**	**$1,083**	**40**	**$5,000**	**60**	**$8,354**	**82**	**$11,318**
Total Definite Appropriations	**1,492**	**$257,040**	**1,569**	**$286,479**	**1,695**	**$326,686**	**1,748**	**$356,950**
Indefinite Appropriations:								
Mammography Quality and Standards Act (MQSA):								
Center for Devices and Radiological Health	**$26**	**$4,039**	**32**	**$5,069**	**32**	**$5,174**	**26**	**$5,337**
Center for Devices and Radiological Health	*26*	*4,039*	*32*	*5,069*	*32*	*5,174*	*26*	*5,337*
Office of Regulatory Affairs	**8**	**$8,463**	**16**	**$11,309**	**16**	**$11,543**	**16**	**$11,624**
Devices and Rad. Health Program Estimate	*8*	*8,463*	*16*	*11,309*	*16*	*11,543*	*16*	*11,624*
Other Activities - Office of Management and Systems (MQSA)	**2**	**$214**	**2**	**$198**	**2**	**$202**	**2**	**$212**
Office of Management and Systems	*2*	*214*	*2*	*198*	*2*	*202*	*2*	*212*
Subtotal (MQSA)	**36**	**$12,716**	**50**	**$16,576**	**50**	**$16,919**	**44**	**$17,173**
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**$1,639**
Color Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
Total Indefinite Appropriations	**82**	**$20,650**	**101**	**$23,225**	**101**	**$23,757**	**95**	**$24,813**
Total User Fees	**1,574**	**$277,690**	**1,670**	**$309,704**	**1,796**	**$350,443**	**1,843**	**$381,763**

Note: Does not contain Reimbursable resources. In FY 2004 actuals the reimbursable FTE level was 69, and FY 2005 and FY 2006 is estimated at 65.

Food and Drug Administration
ALL PURPOSE TABLE - Total Program Level
(Dollars in Thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Center for Food Safety & Applied Nutrition	**910**	**$167,534**	**901**	**$167,332**	**894**	**$175,189**	**881**	**$179,434**
Center for Food Safety & Applied Nutrition	*910*	*$144,366*	*901*	*$143,958*	*894*	*$152,002*	*881*	*155,819*
GSA Rent and Rent Related Activities	-	*23,168*	-	*23,374*	-	*23,187*	*0*	*23,615*
Center for Drug Evaluation and Research	**2,190**	**$396,491**	**2,349**	**$410,038**	**2,395**	**$439,284**	**2,412**	**$456,933**
Center for Drug Evaluation and Research	*2,190*	*$373,481*	*2,349*	*$383,615*	*2,395*	*$410,291*	*2,412*	*427,271*
GSA Rent and Rent Related Activities	-	*23,010*	-	*26,423*	-	*28,993*	*0*	*29,662*
Center for Biologics Evaluation and Research	**797**	**$148,391**	**822**	**$148,584**	**815**	**$151,478**	**801**	**$158,038**
Center for Biologics Evaluation and Research	*797*	*$139,872*	*822*	*$140,736*	*815*	*$143,093*	*801*	*149,438*
GSA Rent and Rent Related Activities	-	*8,519*	-	*7,848*	-	*8,385*	*0*	*8,600*
Center for Veterinary Medicine	**349**	**$67,656**	**355**	**$71,960**	**373**	**$75,658**	**385**	**$78,338**
Center for Veterinary Medicine	*349*	*$55,513*	*355*	*$59,352*	*373*	*$63,040*	*385*	*64,593*
GSA Rent and Rent Related Activities		*$12,143*		*$12,608*		*$12,618*	*0*	*13,745*
Center for Devices and Radiological Health	**1,061**	**$179,245**	**1,139**	**$182,728**	**1,187**	**$206,208**	**1,170**	**$213,363**
Center for Devices and Radiological Health	*1,061*	*$161,938*	*1,139*	*$162,718*	*1,187*	*$186,206*	*1,170*	*192,552*
GSA Rent and Rent Related Activities	-	*17,307*	-	*20,010*	-	*20,002*	*0*	*20,811*
National Center for Toxicological Research	**207**	**$39,869**	**233**	**$39,883**	**225**	**$40,435**	**220**	**41,381**
National Center for Toxicological Research	*207*	*39,652*	*233*	*39,652*	*225*	*40,206*	220	41,152
Rent Related Activities		*217*		*231*		*229*	0	229
Field Activities Total	**3,872**	**$528,853**	**3,862**	**$535,392**	**3,648**	**$560,256**	**3,494**	**$590,444**
Foods Program Estimate	*2,172*	*$262,686*	*2,063*	*$263,099*	*2,056*	*$283,524*	*1,966*	*305,408*
GSA and Other Rent for the Foods Program	-	*$36,655*	-	*$34,500*	-	*$35,890*	-	*$37,290*
Human Drugs Program Estimate	*759*	*$86,111*	*821*	*$90,565*	*698*	*$86,005*	*664*	*86,659*
GSA and Other Rent for the Human Drugs Program	-	*$12,235*	-	*$12,886*	-	*$11,955*	-	*$12,313*
Biologics Program Estimate	*241*	*27,144*	*235*	*27,510*	*230*	*28,629*	*220*	*29,276*
GSA and Other Rent for the Biologics Program	-	*3,932*	-	*3,866*	-	*3,912*	-	*4,054*
Animal Drugs and Feeds Program Estimate	*246*	*$28,928*	*263*	*$28,856*	*240*	*$35,194*	*228*	*35,194*
GSA and Other Rent for the Animal Drugs and Feeds Program	-	*$4,152*	-	*$4,397*	-	*$4,189*	-	*$4,325*
Devices and Radiological Health Program Estimate	*454*	*$59,568*	*480*	*$61,946*	*424*	*$63,855*	*416*	*68,348*
GSA and Other Rent for the Devices and Radiological Health Program	-	*$7,442*	-	*$7,767*	-	*7,103*	-	*7,577*
Other Activities	**709**	**$114,296**	**811**	**$123,556**	**769**	**$124,349**	**763**	**126,944**
Office of the Commissioner	*410*	*$50,974*	*412*	*$55,874*	*392*	*$57,068*	*388*	*59,564*
Office of Management	*299*	*47,220*	*399*	*52,272*	*377*	*51,577*	*375*	*51,384*
Central Services	-	*6,872*	-	*6,878*	-	*6,823*	-	*$6,823*
GSA Rent and Rent Related Activities	-	9,230	-	8,532	-	*8,881*	-	9,173
FDA Consolidation at White Oak	**-**	**$6,131**	**-**	**$2,361**	**-**	**$20,846**	**-**	**$21,974**
GSA and Other Rent and Rent Related Activities (non-add)	**-**	**$158,010**	**-**	**$162,442**	**-**	**$165,344**	**-**	**$171,394**
GSA Rent (non-add)		*121,680*		*125,755*		*128,900*		*134,853*
Other Rent and Rent Related Activities (non-add)		*36,330*		*36,687*		*36,444*		*36,541*
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**$1,639**
Color Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
TOTAL, Salaries & Expenses	**10,141**	**$1,656,400**	**10,523**	**$1,688,483**	**10,357**	**$1,800,541**	**10,177**	**$1,874,489**
Buildings and Facilities	**-**	**$22,504**	**-**	**$6,959**	**-**	**-**	**-**	**$7,000**
Total Program Level	**10,141**	**$1,678,904**	**10,523**	**$1,695,442**	**10,357**	**$1,800,541**	**10,177**	**$1,881,489**
Less User Fees:								
Current Law:								
Prescription Drug User Fee Act (PDUFA)	**1,352**	**232,082**	**1,332**	**249,825**	**1,415**	**284,394**	**1,439**	**305,332**
Medical Devices (MDUFMA)	**137**	**$23,875**	**197**	**$31,654**	**220**	**$33,938**	**227**	**$40,300**
Animal Drugs (ADUFA)	**3**	**$1,083**	**40**	**$5,000**	**60**	**$8,354**	**82**	**$11,318**
Mammography Quality Standards Act (MQSA)	**36**	**$12,716**	**50**	**$16,576**	**50**	**$16,919**	**44**	**$17,173**
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**$1,639**
Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
SUBTOTAL User Fees	**1,574**	**$277,690**	**1,670**	**$309,704**	**1,796**	**$350,443**	**1,843**	**$381,763**
Total Budget Authority	**8,567**	**$1,401,214**	**8,853**	**$1,385,738**	**8,561**	**$1,450,098**	**8,334**	**$1,499,726**

Note: Does not contain Reimbursable resources. In FY 2004 actuals the reimbursable FTE level was 69, and FY 2005 and FY 2006 is estimated at 65

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Food and Drug Administration
Comparable: FY 2006 Crosswalk to Summary of Change - Budget Authority

Program	Food Defense		Medical Device Review		Office of Drug Safety		GSA Rent and Other Rent and Rent Related	FDA White Oak Consolidation	Buildings and Facilities	Attrition	Administrative Efficiencies		Information Technology Reduction		Total Budget Authority Change	
	FTE	$000	FTE	$000	FTE	$000	$000	$000	$000	FTE	FTE	$000	FTE	$000	FTE	$000
Foods	**15**	**$27,574**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**$0**	**(107)**	**(7)**	**($764)**	**(4)**	**($1,109)**	**(103)**	**$25,701**
Center	*7*	*4,822*								*(16)*	*(2)*	*(232)*	*(2)*	*(773)*	*(13)*	*3,817*
Field Activities	*8*	*22,752*								*(91)*	*(5)*	*(532)*	*(2)*	*(336)*	*(90)*	*21,884*
Human Drugs	**0**	**$0**	**0**	**$0**	**20**	**$5,000**	**$0**	**$0**	**$0**	**(44)**	**(5)**	**($438)**	**(6)**	**($1,961)**	**(35)**	**$2,601**
Center					*20*	*5,000*				*(11)*	*(3)*	*(301)*	*(6)*	*(1,865)*	*-*	*2,834*
Field Activities										*(33)*	*(2)*	*(137)*	*0*	*(96)*	*(35)*	*(233)*
Biologics	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**$0**	**(24)**	**(1)**	**($178)**	**(2)**	**($696)**	**(27)**	**($874)**
Center										*(14)*	*(1)*	*(132)*	*(2)*	*(665)*	*(17)*	*(797)*
Field Activities										*(10)*		*(46)*	*0*	*(31)*	*(10)*	*(77)*
Animal Drugs and Feeds	**0**	**$0**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**$0**	**(18)**	**0**	**$0**	**0**	**$0**	**(18)**	**$0**
Center										*(6)*			*0*	*-*	*(6)*	*-*
Field Activities										*(12)*			*0*	*-*	*(12)*	*-*
Devices and Radiological Health	**0**	**$0**	**16**	**$5,996**	**0**	**$0**	**$0**	**$0**	**$0**	**(41)**	**0**	**$0**	**0**	**$0**	**(25)**	**$5,996**
Center			*3*	*1,796*						*(20)*			*0*	*-*	*(17)*	*1,796*
Field Activities			*13*	*4,200*						*(21)*			*0*	*-*	*(8)*	*4,200*
NCTR	**0**	**$1,000**	**0**	**$0**	**0**	**$0**	**$0**	**$0**	**$0**	**(4)**	**(1)**	**($54)**	**0**	**$0**	*(5)*	*946*
Other Activities	**2**	**$1,500**	**0**	**$0**	**0**	**$0**	**0**	**0**	**0**	**(13)**	**0**	**($120)**	**(3)**	**($1,350)**	**(14)**	**30**
Office of the Commissioner	*2*	*1,500*								*(6)*	*-*	*(72)*	*(1)*	*(125)*	*(5)*	*1,303*
Office of Management										*(7)*	*-*	*(48)*	*(2)*	*(1,225)*	*(9)*	*(1,273)*
GSA and Other Rent and Rent Related		**-**				**-**	**4,100**	**-**	**-**						*-*	*4,100*
FDA White Oak Consolidation		**$0**		**$0**		**$0**	**$0**	**$4,128**	**$0**					**$0**	*-*	*4,128*
Buildings and Facilities		**$0**		**$0**		**$0**	**$0**	**$0**	**$7,000**					**$0**	*-*	*7,000*
Salaries & Expenses Increases	**17**	**$ 30,074**	**16**	**$ 5,996**	**20**	**$ 5,000**	**$ 4,100**	**$ 4,128**	**$ 7,000**	**(251)**	**(14)**	**(1,554)**	**(15)**	**(5,116)**	**(227)**	**49,628**
Non-Field	*9*	*7,322*	*3*	*1,796*	*20*	*5,000*	*-*	*-*	*-*	*(84)*	*(7)*	*(839)*	*(13)*	*(4,653)*	*(72)*	*8,626*
Field	*8*	*22,752*	*13*	*4,200*	*0*	*-*	*-*	*-*	*-*	*(167)*	*(7)*	*(715)*	*(2)*	*(463)*	*(155)*	*25,774*
Rent/Buildings and Facilities	*0*	*0*	*0*	*-*	*-*	*-*	*4,100*	*4,128*	*7,000*	*0*	*-*	*-*	*-*	*-*	*-*	*15,228*
Total	**17**	**$30,074**	**16**	**$5,996**	**20**	**$5,000**	**$ 4,100**	**$4,128**	**$7,000**	**(251)**	**(14)**	**($1,554)**	**(15)**	**($5,116)**	**(227)**	**$49,628**

Food and Drug Administration
Comparable: FY 2006 Crosswalk to Summary of Change - User Fee

Program	PDUFA		MDUFMA		ADUFA		MQSA		Export Certification		Color Certification Fund		Total User Fee Passback	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	-	$0	-	$0	-	$0	-	$0	-	$0	-	$0	0	$0
Center													*0*	*-*
Field Activites													*0*	*-*
Human Drugs	18	$15,033	-	$0	-	$0	-	$0	-	$0	-	$0	18	$15,033
Center	*17*	*14,146*											*17*	*14,146*
Field Activities	*1*	*887*											*1*	*887*
Biologics	2	$7,234	1	$632	-	$0	-	$0	-	$0	-	$0	3	$7,866
Center	*2*	*6,580*	*1*	*562*									*3*	*7,142*
Field Activities	*-*	*654*	*-*	*70*									*0*	*724*
Animal Drugs and Feeds	-	$0	-	$0	18	$1,553	-	$0	-	$0	-	$0	18	$1,553
Center					*18*	*1,553*							*18*	*1,553*
Field Activities					*-*	*-*							*0*	*-*
Devices and Radiological Health	-	$0	6	$4,599	-	$0	(6)	$244	-	$0	-	$0	0	$4,843
Center			*6*	*4,387*			*(6)*	*163*					*0*	*4,550*
Field Activities			*-*	*212*			*-*	*81*					*0*	*293*
NCTR	-	$0	-	$0	-	$0	-	$0	-	$0	-	$0	0	$0
Other Activities	4	$1,378	-	$474	4	$411	-	$10	-	$0	-	$0	8	$2,273
Office of the Commissioner	*-*	*990*	*-*	*80*	*1*	*123*	*-*	*-*					*1*	*1,193*
Office of Management	*4*	*388*	*-*	*394*	*3*	*288*	*-*	*10*					*7*	*1,080*
GSA and Other Rent and Rent Related (non add)		$293		657		$1,000							0	1,950
FDA White Oak Consolidation		($3,000)											0	(3,000)
Export Certification									-	$24			0	24
Color Certification											-	$778	0	778
TOTAL	24	$20,938	7	$6,362	22	$2,964	(6)	$254	-	$24	-	$778	47	31,320
Non-Field	***23***	***22,104***	***7***	***5,423***	***22***	***1,964***	***(6)***	***173***	***-***	***24***	***-***	***778***	***46***	***30,466***
Field	***1***	***1,541***	***-***	***282***	***-***	***-***	***-***	***81***	***-***	***-***	***-***	***-***	***1***	***1,904***
Rent/B&F	***-***	***(2,707)***	***-***	***657***	***-***	***1,000***	***-***	***-***	***-***	***-***	***-***	***-***	***0***	***(1,050)***
Total	24	$20,938	7	$6,362	22	$2,964	(6)	$254	0	$24	0	$778	47	$31,320

Food and Drug Administration
Comparable: FY 2006 Crosswalk to Summary of Change - Program Level
Dollars in Thousands

FY 2006 Program Level Changes	Budget Authority																User Fees													
	Food Defense		Medical Device Review		Office of Drug Safety		GSA Rent	FDA White Oak Consolidation	Buildings and Facilities	Attrition	Administrative Efficiencies		Information Technology Reduction		TOTAL BUDGET AUTHORITY REQUEST		PDUFA[1]		MDUFMA		ADUFA[2]		MQSA		Color and Export Cert. Fund	Total Current User Fees		TOTAL PROGRAM LEVEL REQUEST	
	FTE	$000	FTE	$000	FTE	$000	$000	$000	$000	FTE	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	$000	FTE	$000	FTE	$000
Foods	**15**	**$27,574**					**$0**			***(107)***	***(7)***	***($764)***	***(4)***	***($1,109)***	***(103)***	***$25,701***										0	**$0**	**(103)**	**$25,701**
Center	*7*	*4,822*								*(16)*	*(2)*	*(232)*	*(2)*	*(773)*	*(13)*	*$3,817*										*0*	*$0*	*(13)*	*$3,817*
Field Activities	*8*	*22,752*								*(91)*	*(5)*	*(532)*	*(2)*	*(336)*	*(90)*	*$21,884*										*0*	*$0*	*(90)*	*$21,884*
Human Drugs					**20**	**$5,000**	**$0**			***(44)***	***(5)***	***($438)***	***(6)***	***($1,961)***	***(35)***	***$2,601***	***18***	**$15,033**								18	**$15,033**	**(17)**	**$17,634**
Center					*20*	*5,000*				*(11)*	*(3)*	*(301)*	*(6)*	*(1,865)*	*0*	*$2,834*	*17*	*14,146*								*17*	*$14,146*	*17*	*$16,980*
Field Activities										*(33)*	*(2)*	*(137)*	*0*	*(96)*	*(35)*	*($233)*	*1*	*887*								*1*	*$887*	*(34)*	*$654*
Biologics							**$0**			***(24)***	***(1)***	***($178)***	***(2)***	***($696)***	***(27)***	***($874)***	***2***	**$7,234**	***1***	**$632**						3	**$7,866**	**(24)**	**$6,992**
Center										*(14)*	*(1)*	*(132)*	*(2)*	*(665)*	*(17)*	*($797)*	*2*	*6,580*	*1*	*562*						*3*	*$7,142*	*(14)*	*$6,345*
Field Activities										*(10)*	*0*	*(46)*	*0*	*(31)*	*(10)*	*($77)*	*0*	*654*	*0*	*70*						*0*	*$724*	*(10)*	*$647*
Animal Drugs and Feeds							**$0**			***(18)***	***0***	***$0***	***0***	***$0***	***(18)***	***$0***					***18***	**$1,553**				18	**$1,553**	**-**	**$1,553**
Center										*(6)*	*0*	*0*	*0*	*0*	*(6)*	*$0*					*18*	*1,553*				*18*	*$1,553*	*12*	*$1,553*
Field Activities										*(12)*	*0*	*0*	*0*	*0*	*(12)*	*$0*					*0*	*0*				*0*	*$0*	*(12)*	*$0*
Devices and Radiological Health			**16**	**$5,996**			**$0**			***(41)***	***0***	***$0***	***0***	***$0***	***(25)***	***$5,996***			***6***	**$4,599**			***(6)***	**$244**		0	**$4,843**	**(25)**	**$10,839**
Center			*3*	*1,796*						*(20)*	*0*	*0*	*0*	*0*	*(17)*	*$1,796*			*6*	*4,387*			*(6)*	*163*		*0*	*$4,550*	*(17)*	*$6,346*
Field Activities			*13*	*4,200*						*(21)*	*0*	*0*	*0*	*0*	*(8)*	*$4,200*			*0*	*212*			*0*	*81*		*0*	*$293*	*(8)*	*$4,493*
NCTR	**0**	**$1,000**					**$0**			***(4)***	***(1)***	***($54)***	***0***	***$0***	**(5)**	**$946**										**0**	**$0**	**(5)**	**$946**
Other Activities	**2**	**$1,500**					**$0**			***(13)***	***0***	***($120)***	***(3)***	***($1,350)***	***(14)***	***$30***	***4***	**$1,378**	***0***	**$474**	***4***	**$411**	***0***	**$10**		8	**$2,273**	**(6)**	**$2,303**
Office of the Commissioner	*2*	*1,500*								*(6)*	*0*	*(72)*	*(1)*	*(125)*	*(5)*	*$1,303*	*0*	*990*	*0*	*80*	*1*	*123*	*0*	*0*		*1*	*$1,193*	*(4)*	*$2,496*
Office of Management										*(7)*	*0*	*(48)*	*(2)*	*(1,225)*	*(9)*	*($1,273)*	*4*	*388*	*0*	*394*	*3*	*288*	*0*	*10*		*7*	*$1,080*	*(2)*	*($193)*
GSA and Other Rent and Rent Related							*4,100*									**4,100**		*293*		*657*		*1,000*				**0**	**$1,950**	**-**	**$6,050**
FDA White Oak Consolidation								*4,128*								**$4,128**		*(3,000)*								0	**($3,000)**	**-**	**$1,128**
Export Certification																									**$24**	0	**$24**	**-**	**$24**
Color Certification																									**$778**	0	**$778**	**-**	**$778**
Buildings and Facilities									**$7,000**							**$7,000**										0	**$0**	**-**	**$7,000**
Total	**17**	**$30,074**	**16**	**$5,996**	**20**	**$5,000**	**$4,100**	**$4,128**	**$7,000**	**(251)**	**(14)**	**($1,554)**	**(15)**	**($5,116)**	**(227)**	**$49,628**	**24**	**$20,938**	**7**	**$6,362**	**22**	**$2,964**	**(6)**	**$254**	**$24**	**47**	**$31,320**	**(180)**	**$80,948**

Food and Drug Administration
Comparable: ALL PURPOSE TABLE - Budget Authority
(Dollars in Thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**3082**	**$407,052**	**2,964**	**$407,057**	**2,950**	**$435,526**	**2,847**	**$461,227**
Center	*910*	*144,366*	*901*	*143,958*	*894*	*152,002*	*881*	*155,819*
Field Activities	*2,172*	*262,686*	*2,063*	*263,099*	*2,056*	*283,524*	*1,966*	*305,408*
Human Drugs	**1,943**	**$292,118**	**2,202**	**$292,120**	**2,050**	**$291,488**	**2,015**	**$294,089**
Center	*1,218*	*210,828*	*1,445*	*210,661*	*1,380*	*210,529*	*1,380*	*213,363*
Field Activities	*725*	*81,290*	*757*	*81,459*	*670*	*80,959*	*635*	*80,726*
Biologics	**792**	**$122,354**	**804**	**$122,356**	**781**	**$123,112**	**754**	**$122,238**
Center	*559*	*96,265*	*575*	*96,365*	*565*	*96,890*	*548*	*96,093*
Field Activities	*233*	*26,089*	*229*	*25,991*	*216*	*26,222*	*206*	*26,145*
Animal Drugs and Feeds	**592**	**$83,458**	**578**	**$83,458**	**555**	**$90,486**	**537**	**$90,486**
Center	*346*	*54,530*	*315*	*54,602*	*315*	*55,292*	*309*	*55,292*
Field Activities	*246*	*28,928*	*263*	*28,856*	*240*	*35,194*	*228*	*35,194*
Devices and Radiological Health	**1376**	**$191,143**	**1,428**	**$191,144**	**1,403**	**$214,965**	**1,378**	**$220,961**
Center	*935*	*140,646*	*971*	*141,059*	*1,003*	*163,246*	*986*	*165,042*
Field Activities	*441*	*50,497*	*457*	*50,085*	*400*	*51,719*	*392*	*55,919*
National Center for Toxicological Research	**207**	**$39,652**	**233**	**$39,652**	**225**	**$40,206**	**220**	**$41,152**
Other Activities	**575**	**$90,175**	**644**	**$90,190**	**597**	**$87,232**	**583**	**87,262**
Office of the Commissioner	*344*	*42,932*	*332*	*42,460*	*311*	*41,894*	*306*	*43,197*
Office of Management	*231*	*40,371*	*312*	*40,852*	*286*	*38,515*	*277*	*37,242*
Central Services		*6,872*	*-*	*6,878*	*-*	*6,823*	*0*	*6,823*
FDA Consolidation at White Oak		**$2,361**		**$2,361**		**$17,846**		**21,974**
Other Rent and Rent Related Activities		**$36,043**	**-**	**$36,047**		**$35,758**		**$35,758**
GSA Rental Payments		**$114,354**	**-**	**$114,394**		**$113,479**	**0**	**$117,579**
TOTAL, Salaries & Expenses	**8,567**	**$1,378,710**	**8,853**	**$1,378,779**	**8,561**	**$1,450,098**	**8,334**	**$1,492,726**
Non-Field Activities	*4,750*	*776,462*	*5,084*	*776,487*	*4,979*	*805,397*	*4,907*	*814,023*
Field Activities	*3,817*	*449,490*	*3,769*	*449,490*	*3,582*	*477,618*	*3,427*	*503,392*
Rent Activities	*0*	*152,758*	*0*	*152,802*	*0*	*167,083*	*0*	*175,311*
Buildings and Facilities		**$22,504**	**-**	**$6,959**	**-**	**-**	**0**	**7,000**
TOTAL Budget Authority	**8,567**	**$1,401,214**	**8,853**	**$1,385,738**	**8,561**	**$1,450,098**	**8,334**	**$1,499,726**

Food and Drug Administration
Comparable: ALL PURPOSE TABLE - User Fees
(Dollars in thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses, Definite Appropriations:								
Prescription Drug User Fee Act (PDUFA):								
Human Drugs (PDUFA)	**1006**	**$167,474**	**968**	**$182,060**	**1043**	**$204,808**	**1,061**	**$219,841**
Center	*972*	*162,653*	*904*	*172,954*	*1,015*	*199,762*	*1,032*	*213,908*
Field Activities	*34*	*4,821*	*64*	*9,106*	*28*	*5,046*	*29*	*5,933*
Biologics (PDUFA)	**224**	**$41,157**	**219**	**$38,271**	**226**	**$40,441**	**228**	**$47,675**
Center	*217*	*40,170*	*214*	*37,049*	*214*	*38,353*	*216*	*44,933*
Field Activities	*7*	*987*	*5*	*1,222*	*12*	*2,088*	*12*	*2,742*
Other Activities (PDUFA)	**122**	**$13,535**	**145**	**$20,848**	**146**	**$23,738**	**150**	**$25,116**
Office of the Commissioner	*63*	*7,658*	*75*	*12,338*	*75*	*14,021*	*75*	*15,011*
Office of Management	*59*	*5,877*	*70*	*8,510*	*71*	*9,717*	*75*	*10,105*
FDA Consolidation at White Oak		**3,770**	**-**	**-**	**-**	**3,000**	**0**	**-**
GSA Rental Payments (PDUFA)	-	**6,146**	-	**$8,646**	-	**$12,407**	**0**	**12,700**
Subtotal PDUFA	**1,352**	**$232,082**	**1,332**	**$249,825**	**1,415**	**$284,394**	**1,439**	**$305,332**
Medical Device User Fee and Modernization Act (MDUFMA):								
Biologics (MDUFMA)	**22**	**$3,505**	**34**	**$7,619**	**38**	**$8,169**	**39**	**$8,801**
Center	*21*	*3,437*	*33*	*7,322*	*36*	*7,850*	*37*	*8,412*
Field Activities	*1*	*68*	*1*	*297*	*2*	*319*	*2*	*389*
Devices and Radiological Health (MDUFMA)	**105**	**$17,861**	**143**	**$17,142**	**160**	**$18,379**	**166**	**$22,978**
Center	*100*	*17,253*	*136*	*16,590*	*152*	*17,786*	*158*	*22,173*
Field Activities	*5*	*608*	*7*	*552*	*8*	*593*	*8*	*805*
Other Activities (MDUFMA)	**10**	**1,142**	**20**	**$3,788**	**22**	**$4,061**	**22**	**$4,535**
Office of the Commissioner	*3*	*384*	*5*	*1,076*	*6*	*1,153*	*6*	*1,233*
Office of Management	*7*	*758*	*15*	*2,712*	*16*	*2,908*	*16*	*3,302*
Other Rent and Rent Related Activities (MDUFMA)		*$287*	*-*	*$640*	*-*	*$686*	*0*	*$783*
GSA Rental Payments (MDUFMA)		*$1,080*	*-*	*$2,465*	*-*	*$2,643*	*0*	*$3,203*
Subtotal (MDUFMA)	**137**	**$23,875**	**197**	**$31,654**	**220**	**$33,938**	**227**	**$40,300**
Animal Drug User Fee Act (ADUFA):								
Center for Veterinary Medicine	**3**	**$983**	**40**	**$4,750**	**58**	**$7,748**	**76**	**$9,301**
Other Activities (ADUFA)			**-**	**-**	**2**	**$235**	**6**	**$646**
Office of the Commissioner							*1*	*123*
Office of Management			**-**	**-**	*2*	*235*	*5*	*523*
GSA Rental Payments (ADUFA)		**$100**	**-**	**$250**	-	**$371**	**0**	**$1,371**
Subtotal (ADUFA)	**3**	**$1,083**	**40**	**$5,000**	**60**	**$8,354**	**82**	**$11,318**
Total Definite Appropriations	**1,492**	**$257,040**	**1,569**	**$286,479**	**1,695**	**$326,686**	**1,748**	**$356,950**
Indefinite Appropriations:								
Mammography Quality and Standards Act (MQSA):								
Devices and Radiological Health (MQSA)	**26**	**$4,039**	**32**	**$5,069**	**32**	**$5,174**	**26**	**$5,337**
Center	*26*	*4,039*	*32*	*5,069*	*32*	*5,174*	*26*	*5,337*
Field Activities	*8*	*8,463*	*16*	*11,309*	*16*	*11,543*	*16*	*11,624*
Other Activities - Office of Management and Systems (MQSA)	**2**	**$214**	**2**	**$198**	**2**	**$202**	**2**	**$212**
Office of Management and Systems	*2*	*214*	*2*	*198*	*2*	*202*	*2*	*212*
Subtotal (MQSA)	**36**	**$12,716**	**50**	**$16,576**	**50**	**$16,919**	**44**	**$17,173**
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**1,639**
Color Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
Total Indefinite Appropriations	**82**	**$20,650**	**101**	**$23,225**	**101**	**$23,757**	**95**	**$24,813**
Total User Fees	**1,574**	**$277,690**	**1,670**	**$309,704**	**1,796**	**$350,443**	**1,843**	**$381,763**

Food and Drug Administration
Comparable: ALL PURPOSE TABLE - Total Program Level
(Dollars in Thousands)

PROGRAM	FY 2004 Actuals		FY 2004 Current Estimate		FY 2005 Enacted		FY 2006 Request	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**3,082**	**$407,052**	**2,964**	**$407,057**	**2,950**	**$435,526**	**2,847**	**$461,227**
Center	*910*	*$144,366*	*901*	*$143,958*	*894*	*$152,002*	*881*	*$155,819*
Field Activities	*2,172*	*262,686*	*2,063*	*263,099*	*2,056*	*283,524*	*1,966*	*305,408*
Human Drugs	**2,949**	**$459,592**	**3,170**	**$474,180**	**3,093**	**$496,296**	**3,076**	**$513,930**
Center	*2,190*	*$373,481*	*2,349*	*$383,615*	*2,395*	*$410,291*	*2,412*	*$427,271*
Field Activities	*759*	*86,111*	*821*	*90,565*	*698*	*86,005*	*664*	*$86,659*
Biologics	**1,038**	**$167,016**	**1,057**	**$168,246**	**1,045**	**$171,722**	**1,021**	**$178,714**
Center	*797*	*$139,872*	*822*	*$140,736*	*815*	*$143,093*	*801*	*$149,438*
Field Activities	*241*	*27,144*	*235*	*27,510*	*230*	*28,629*	*220*	*$29,276*
Animal Drugs and Feeds	**595**	**$84,441**	**618**	**$88,208**	**613**	**$98,234**	**613**	**$99,787**
Center	*349*	*$55,513*	*355*	*$59,352*	*373*	*$63,040*	*385*	*$64,593*
Field Activities	*246*	*$28,928*	*263*	*$28,856*	*240*	*$35,194*	*228*	*$35,194*
Devices and Radiological Health	**1,515**	**$221,506**	**1,619**	**$224,664**	**1,611**	**$250,061**	**1,586**	**$260,900**
Center	*1,061*	*$161,938*	*1,139*	*$162,718*	*1,187*	*$186,206*	*1,170*	*$192,552*
Field Activities	*454*	*59,568*	*480*	*61,946*	*424*	*63,855*	*416*	*$68,348*
National Center for Toxicological Research	**207**	**$39,652**	**233**	**$39,652**	**225**	**$40,206**	**220**	**$41,152**
Other Activities	**709**	**$105,066**	**811**	**$115,024**	**769**	**$115,468**	**763**	**$117,771**
Office of the Commissioner	*410*	*$50,974*	*412*	*$55,874*	*392*	*$57,068*	*388*	*$59,564*
Office of Management	*299*	*47,220*	*399*	*52,272*	*377*	*51,577*	*375*	*$51,384*
Central Services	*-*	*6,872*	*-*	*6,878*	*-*	*6,823*	*-*	*$6,823*
FDA Consolidation at White Oak	**-**	**$6,131**	**-**	**$2,361**	**-**	**$20,846**	**-**	**$21,974**
GSA and Other Rent and Rent Related Activities	***-***	***158,010***	***-***	***162,442***	***-***	***165,344***	***-***	***171,394***
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**$1,639**
Color Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
TOTAL, Salaries & Expenses	**10,141**	**$1,656,400**	**10,523**	**$1,688,483**	**10,357**	**$1,800,541**	**10,177**	**$1,874,489**
Buildings and Facilities	**-**	**22,504**	**-**	**6,959**	**-**	**-**	**-**	**7,000**
Total Program Level	**10,141**	**$1,678,904**	**10,523**	**$1,695,442**	**10,357**	**$1,800,541**	**10,177**	**$1,881,489**
Less User Fees:								
Current Law:								
Prescription Drug User Fee Act (PDUFA)	**1,352**	**232,082**	**1,332**	**249,825**	**1,415**	**284,394**	**1,439**	**305,332**
Medical Devices (MDUFMA)	**137**	**$23,875**	**197**	**$31,654**	**220**	**$33,938**	**227**	**$40,300**
Animal Drugs (ADUFA)	**3**	**$1,083**	**40**	**$5,000**	**60**	**$8,354**	**82**	**$11,318**
Mammography Quality Standards Act (MQSA)	**36**	**$12,716**	**50**	**$16,576**	**50**	**$16,919**	**44**	**$17,173**
Export Certification	**11**	**$1,806**	**13**	**$1,570**	**13**	**$1,615**	**13**	**$1,639**
Certification Fund	**35**	**$6,128**	**38**	**$5,079**	**38**	**$5,223**	**38**	**$6,001**
SUBTOTAL User Fees	**1,574**	**$277,690**	**1,670**	**$309,704**	**1,796**	**$350,443**	**1,843**	**$381,763**
Total Budget Authority	**8,567**	**$1,401,214**	**8,853**	**$1,385,738**	**8,561**	**$1,450,098**	**8,334**	**$1,499,726**