PERFORMANCE BUDGET OVERVIEW

Introduction

As we prepare to celebrate the centennial of the 1906 Pure Food and Drugs Act, the Food and Drug Administration (FDA) faces important challenges and opportunities for the 21st century. Innovations in science and technology, shifting market trends in regulated industries throughout the global economy, and emerging diseases and other public health threats have magnified the importance of FDA's role in protecting and advancing the public health. At the same time, budget realities challenge us to formulate new approaches to meet the expanding scope and complexity of our public health mission. These challenges serve as catalysts for change. FDA recognizes the need to modernize and transform our operations to address the emerging needs of the 21st century. FDA will meet these challenges while maintaining its century-old commitment to principles that have made us the world's "gold standard" for regulating food and medical products. These principles reflect our:

- Dedication to the safety of the products that we regulate.
- Dedication to protecting Americans against persistent and emerging public health threats.
- Commitment to advancing the public health by empowering consumers to make healthy nutrition choices.
- Commitment to accelerating the development and availability of promising new medical therapies and technologies that will extend and improve lives.

FDA has designed a budget request for FY 2007 that responds to 21st century challenges and meets the opportunities that lie ahead, including the following high-priority areas:

- **Pandemic Preparedness –** To prepare our nation against the threat of pandemic flu, FDA proposes a suite of activities to safeguard the public health. These include collaborating with the U.S. and international health community to recognize and respond to emerging threats, accelerating manufacturing capability to quickly produce and deliver sufficient quantities of safe and effective vaccines, and addressing pandemic-related impacts on the animal and food sectors that FDA regulates.

- **Critical Path –** FDA proposes funding for its Critical Path Initiative to accelerate the field of personalized medicine and to translate discoveries in medical science into safe and effective new medical treatments. The Critical Path Initiative will focus on bottlenecks in the medical product development pipeline that impede the ability to transform investments in basic medical research into products that improve patient health.

- **Food Defense –** We will expand the network of laboratories that analyze samples in the event of a terrorist attack on our nation's food supply. This is a cooperative effort involving States and other federal agencies, where FDA will enhance the capacity of our laboratory surveillance network to rapidly detect and respond to threats to the food

supply. FDA will also protect our nation from the threat of bioterrorism by proposing a program of targeted food defense research.

- **Medical Product Safety –** To improve patient safety, FDA proposes significant new investments in our human drug and transplantable human tissue safety programs. To increase our capacity to recognize and act on emerging drug safety issues, FDA will modernize its adverse drug event information systems and broaden the sources of data that we analyze for drug safety signals. To manage the risks of human tissue transplants, which have grown to over a million procedures a year, FDA is implementing new risk-based program to detect, analyze, and respond to actual or potential disease transmission involving human tissues.

As we explain in detail below, FDA conducted a deliberate, strategically focused process to formulate our FY 2007 budget request, in consultation with the Department of Health and Human Services (DHHS) and the Office of Management and Budget (OMB). We set priorities that align with the Secretary's 500-Day Plan, DHHS goals, the President's Management Agenda, and FDA's vision for how we need to perform our public health mission in the 21st Century. We are seeking ways to leverage our resources responsibly through collaboration with other public health agencies and stakeholders. For the tax dollars that we spend, we are targeting high-yield investments that will significantly reduce health risks or improve the ability of the product innovators to translate medical discoveries into important new products. We view these strategies as essential to maintaining our position as the world's premier regulatory agency, and protecting the FDA "brand" that has served as a symbol of trust for the American public during the past hundred years.

In the remaining sections of this Performance Budget Overview, we present the statement of FDA's mission, a discussion of FDA's strategic plan, a summary of FDA's performance, and an overview of FDA's FY 2007 budget request, including justifications for proposed initiatives.

Statement of FDA Mission

As a scientific regulatory agency and an operating division of the DHHS that is responsible for protecting and advancing the public health in the United States, FDA's responsibilities cover a wide range of regulatory activities. FDA decisions affect 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.

FDA's mission derives from a variety of statutes, beginning with the Pure Food and Drugs Act of 1906, which prohibited interstate commerce in misbranded and adulterated foods, drinks, and drugs. The Food, Drug, and Cosmetics Act (FD&CA) of 1938 extended FDA's responsibilities to cover cosmetics and therapeutic devices, and granted FDA important new authorities, including the requirement that manufacturers demonstrate the safety of drugs before they can be marketed. Over the years, amendments to the FD&CA have expanded or clarified FDA responsibilities. They are the basis for our current programs for foods, human drugs, biologics, medical devices and radiological health, animal drugs and feeds, supporting toxicological research, and crosscutting programs such as combination products, international programs, pediatrics, and women's health. More recently, FDA's mission expanded in the area of counter-terrorism and homeland security, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Project BioShield Act of 2004, and Homeland Security Presidential Directives.

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, our nation's 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.

Finally, FDA plays a significant role in addressing the Nation's counterterrorism capability and ensuring the security of the food supply.

FDA Strategic Plan

FDA advances its broad public health mission by managing efforts to achieve a comprehensive set of long-term strategic goals and linking budget resources to program performance.

2003 Strategic Action Plan

In 2003, FDA developed a Strategic Action Plan that identified five broad strategic goals:

- Efficient risk management.
- Improving health through better information.
- Improving patient and consumer safety.
- Protecting America from terrorism.
- More effective regulation through a stronger workforce.

Within each strategic goal area, FDA identified high-level objectives and specific action items that the Agency could accomplish within approximately two years. We internally track progress on these action items. In 2004, FDA reported on its accomplishments toward achieving the objectives and action items in the document, *FDA Progress and Priorities 2004: Protecting and Advancing America's Health.* By the end of FY 2005, FDA had accomplished nearly all of the action items that the agency established for itself.

2005 Review of FDA's Operating Strategy

In early 2005, FDA recognized that some emerging external trends, coupled with changes in the federal budget environment, called for a reexamination of FDA's operating strategy. During a

series of strategic planning meetings, agency leadership developed a draft vision for FDA operations in the 21st Century that reflects many of the principles embodied in the President's Management Agenda and the e-Government initiative. FDA leaders also recognized that to achieve this vision in an era of budget austerity, we would need to achieve break-through improvements in productivity. This led us to adopt a theme of transforming FDA operations.

One of the first steps FDA is taking to achieve this transformation is to revise FDA's strategic goal framework. Our intention is to better align the strategic goals with FDA's business process model, while simultaneously streamlining FDA's performance management system so that there is a single, coherent hierarchy of strategic goals, long-term goals and objectives, annual performance goals and measures, and short-term action items. Figure 1 represents the elements of the strategic goal framework, through the concept of a pyramid. Table 1 (see below) shows how the revised strategic goals align with FDA's three core business processes. This alignment and streamlining will help make the performance management system easier to understand across all of FDA's operating units. As the alignment of the framework matures, the annual performance measures will cover a greater portion of FDA's day-to-day activities. This will increase the relevance and usefulness of the performance information to FDA managers. With the realignment of lower-level goals to strategic goals, FDA can more effectively show how its activities and outputs contribute to accomplishing Departmental initiatives and strategic goals, which ultimately support seven Presidential Initiatives (healthcare reform, health information technology, healthier living, protecting the homeland, Project Bio-Shield, the President's Emergency Plan for HIV/AIDS relief, and President's Management Agenda). FDA is currently engaged in a long-term planning effort to complete this revised strategic goal framework and improve our performance management system so that we will more fully satisfy the intent of OMB Circular A-11 and the PART evaluation process.

Figure 1. FDA's Revised Goal Framework

The transition to the new strategic goal framework and performance management system will ensure that we develop well-formulated goals and measures, establish appropriate baseline data and targets, and complete existing goal tracking and reporting commitments. FDA is developing a transition plan that we will synchronize with the PART review cycle, so that the PART review process remains a valuable catalyst and feedback mechanism for performance improvement at FDA. This will help ensure that we effectively allocate resources through priority setting in our budget formulation process. FDA is developing a revised strategic plan in FY 2006, which will include the revised goal framework.

Table 1 – FDA's Revised Strategic Goals Align with the Agency's Core Business Processes

FDA Core Business Processes	Revised Strategic Goals
Pre-Market Review: Fostering innovative technologies to improve health, and assessing the safety and effectiveness of new medical products and the safety of new food ingredients.	Increasing access to innovative products and technologies to improve health
Product Safety and Compliance: Setting standards for manufacturing quality and safety and inspecting manufacturing facilities and products to assure safety, quality and compliance with FDA regulations.	Improving product quality, safety, and availability through better manufacturing and product oversight
Consumer and Patient Safety: Conducting post-marketing surveillance and informing the public to ensure the safety for consumers and patients who use FDA-regulated products.	Enhancing patient and consumer protection and empowering them with better information about regulated products
[cross-cutting support functions]	Transforming FDA business operations, systems and infrastructure to support FDA's mission in the 21st Century

Developing FY2007 Budget Priorities

Agency leadership made a deliberate choice about the criteria it used to evaluate the FY 2007 budget priorities. These criteria focused on supporting high-yield returns, advancing the Secretary's 500-Day priorities and DHHS strategic goals, and meeting agency-wide public health priorities. FDA developed the following table to illustrate how these various priorities were aligned and support our priority setting for FY 2007.

Table 2. FDA Strategic and Outcome Goals Aligned By HHS Strategic Goals & Secretarial "500 Day" Priorities
(*We have used the numbering sequence found in the HHS Strategic Plan*)

HHS STRATEGIC GOALS AND OBJECTIVES		SECRETARY'S 500-DAY PRIORITIES	FDA STRATEGIC GOALS	FDA LONG-TERM GOALS
2. Enhance the ability of the Nation's health care system to effectively respond to bioterrorism and other public health challenges.	Build the capacity of the health care system to respond to public health threats in a more timely and effective manner, especially bioterrorism threats	-- Transform Health Care System; -- Advance Medical Research -- Secure the Homeland; and,	1. Increasing access to innovative products and technologies to improve health	1.1. Increase the number of safe and effective new products by increasing the predictability, efficiency and effectiveness of product development, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism; 1.2. Sustain access to safe and effective new products by improving rapid, transparent and predictable science-based review of marking applications; and, 1.3. Increase access to safe and effective veterinary products, and to safe and nutritious food products, including products for unmet animal and human health needs.
	Improve the safety of food, drugs, biological products, and medical devices		3. Improving product quality, safety, and availability through better manufacturing and product oversight	3.1. Maximize the quality of medical products and dietary supplements and the safety of tissues and foods, as well as ensure their availability, by stimulating use of improved manufacturing technologies and product characterization techniques and by modernizing regulatory standards; and, 3.2. Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products.
4. Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	Accelerate private sector new drug development	-- Advance Medical Research -- Improve the Human Condition Around the World	*[FDA's applied research programs directly support all three of the above core mission-oriented strategic goals.]*	*[FDA's outcome goals 1.1 and 1.3 above directly support acceleration of private sector development of new drugs.]*
	Improve coordination, communication, and application of health research results			*[FDA's outcome goals 2.1, 2.2, 2.3, and 3.1 directly support improved coordination, communication, and application of health research results.]*
	Strengthen mechanisms for ensuring protection of human subjects & the integrity of the research process			*[FDA's research policies, peer review practices, Good Clinical Practices regulations and guidelines, and training programs directly ensure the protection of human subjects and integrity of the research process.]*
5. Improve the Quality of Health Care Services	Reduce medical errors	-- Transform Health Care System -- Advance Medical Research -- Secure the Homeland -- Improve the Human Condition Around the World	2. Enhancing patient and consumer protection and empowering them with better information about regulated products	2.1. Increase ability of consumers to make food choices and to use food handling practices associated with health benefits and reduced risk of food-borne and chronic diseases; 2.2. Improve safe and effective use of medical products with better information technology and effective risk/benefit communication; and, 2.3. Improve problem detection and take timely and effective risk management actions with all FDA-regulated products.
	Increase consumer/ patient use of health care quality information			
	Improve consumer and patient protections			
8. Achieve Excellence in Management Practices		-- Transform Health Care System	4. Transforming FDA business operations, systems and infrastructure to support FDA's mission in the 21st Century	4.1. Improve the efficiency and effectiveness of program management through focused performance budget and financial management strategies, aligned with FDA and HHS business strategies; 4.2. Increase the quality, effectiveness, and adaptability of the FDA workforce by implementing a human capital management strategy that is responsive, proactive, and continually improving; 4.3. Increase capability to efficiently and cost effectively maintain an information technology (IT) environment to support FDA business goals; and, 4.4. Coordinate and integrate operations to enhance consistency and quality of resource management, and to achieve economies of scale.

Overview of FDA Performance

Over the past year, FDA has worked hard to address key challenges in fulfilling our public health mission. Our goal is to maximize the benefits and minimize the risks from the products we regulate by providing high quality and consistent oversight in an environment of changing public health risks, new technologies, and changing market dynamics. We do this by continuously applying the best science and most effective management to get the greatest public health gains for taxpayer dollars. We take our charge as guardians of the public health very seriously. FDA met or exceeded performance targets for all but one FY 2005 performance goal in cases where final results have been reported.

The public health environment is continually evolving due to the rapid growth in scientific advances. At the same time, we are called upon to carry out our public health responsibilities in an atmosphere of budget austerity. To do this well, we have persistently examined our strategic direction and performance measures. In the past year, FDA's senior leadership has refined the agency's long-term goals and objectives, resulting in four strategic goals and 12 long-term goals, all designed to fulfill our commitment to public health, contribute to the success of Secretary Leavitt's 500-day plan, and contribute toward achievement of key Presidential Initiatives to advance public health and homeland security. We continued the process of aligning our annual performance goals to these strategic and long-term goals. Over the next year, we plan to continue to develop better risk-based, outcome-oriented goals and measures.

In 2003, OMB conducted its FY 2005 Program Assessment Rating Tool (PART) review of FDA and issued the following findings:

- FDA has a clear mission and unique Federal role in protecting public health.
- FDA is well managed, and has a strong and comprehensive strategic planning process.
- FDA 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 [started in FY 2003].
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

FDA's PART Summary Table (see next page) summarizes the latest progress with PART. FDA will continue to improve our performance management system by reviewing and revising our annual performance goals and long-term outcome goals so that they align well with our revised strategic goal framework. Moreover, FDA will continue to improve how we used performance information to support resource allocation and other management decisions.

Program Assessment Rating Tool (PART) Summary

Food and Drug Administration

FY 2005 - 2007

(Dollars in Millions)

Program	FY 2006 Enacted	FY 2007 Request	FY 2006 +/- FY 2007	Narrative Rating
FY 2005 PART				
Food and Drug Administration	$1,876	$1,947	$71	Moderately Effective
FY 2006 PART				
No PART was performed in FDA during the FY 2006 budget cycle.				
FY 2007 PART				
No PART was performed in FDA during the FY 2007 budget cycle.				

Narrative

FDA's funding request for FY 2007 supports the Department's strategic goals and Secretary's priorities, and will enable continued progress toward Long-Term Outcome Goals that FDA developed after the FY 2004 PART. During FY 2005 and continuing into FY 2006, FDA has engaged in a reinvigorated strategic planning process that is designed to ensure that annual performance goals align with a coherent framework of strategic and long-term outcome goals, as envisioned in the PART process and OMB Circular A-11. Of its eight outcome goals, FDA has completed the efficiency goal and is achieving significant progress toward the other seven goals, as reported annually to OMB. FDA has developed a new efficiency measure related to human drug safety surveillance for the FY 2007 performance budget. Further information on FDA's PART summary may be found at www.expectmore.gov.

[1] Includes the 1 percent rescission in the FY 2006 column.

Overview of FDA's Budget Request

The Food and Drug Administration (FDA) performance budget request for FY 2007 is $1,947,282,000, which is $70,798,000 higher than the President's FY 2006 enacted level. This request is funded through new budget authority, a strategic redeployment of base program resources, and current law and proposed new user fees. It supports the President's public health and bioterrorism initiatives and Secretary Leavitt's 500-Day priorities.

Recognizing competing national priorities – from deficit-reduction to the war on terror – FDA leadership conducted a deliberate, comprehensive review of programs needs, performance commitments, and agency, departmental, and administration public health goals and priorities. Our Agency leadership established criteria to evaluate FY 2007 budget priorities based on whether they generated high-yield returns and advanced these priorities. After conducting this exercise and identifying priority initiatives, FDA leaders employed marginal cost principles to determine appropriate funding levels.

The FY 2007 program level increase of $70,798,000 will enable the agency to fund six critical initiatives: pandemic preparedness, food defense, drug safety, critical path to personalized medicine, human tissues, and additional budget authority to meet statutory obligations under the animal drug and medical devices user fee programs. To fund these priorities and other important activities, FDA is proposing a strategic redeployment of resources from base programs to achieve program reductions and redirection. Under this budget, FDA would reduce or eliminate lower priority work while redirecting staff and resources to higher priority activities.

FY 2007 Summary of Budget Changes

Table 3 shows the FY 2007 summary of budget changes at the program level and demonstrates the willingness of Agency leadership to make difficult programmatic choices. FDA will use program offsets to fund initiatives that advance these priorities.

The FY 2007 budget submission is reflects the Administration's strong support for meeting our human capital and infrastructure needs while allowing us to advance targeted initiatives that will yield high public health impact. Ever conscious of the need for budget restraint, FDA is proposing a pragmatic approach based on program offsets to achieve the funding necessary to advance our specific public health initiatives.

Table 3 – Summary of Change – Program Level

Program Resource Change*	Total
Budget Authority	
Pandemic Preparedness	+$30,490,000**
Food Defense	+$19,873,000
Critical Path to Personalized Medicine	+$5,940,000
Drug Safety	+$3,960,000
Tissues	+$2,475,000
Statutory Trigger Needs for ADUFA and MDUFMA	+$7,425,000
Cost of Living	+$20,267,000
Unified Financial Management System (UFMS)	+$1,180,000
Infrastructure	+$14,265,000
Buildings and Facilities	(2,970,000)
Budget Authority Offsets	($52,277,000)
User Fees	
Prescription Drug User Fee Act	+$15,268,000
Medical Device User Fee and Modernization Act	+$3,426,000
Animal Drug User Fee Act	+$286,000
Indefinite User Fees	+$1,190,000
Total Program Level	**+$70,798,000**
Proposed User Fees (Non-Add Reclassified as Mandatory)	
Reinspection User Fee	$22,000,000
Food and Animal Fee Export Certification User Fee	$3,536,000

* This table uses the same order as the FY 2007 Crosswalk to Summary of Change – Program Level.
** This level is compared to the FY 2006 enacted and includes supplemental appropriation from PL 109 – 148.

Alignment with Administration Priorities

FDA's public health initiatives directly contribute to the Secretary's 500-Day priorities. Moreover, our FY 2007 budget request will enable FDA to advance important Presidential priorities. FDA initiatives support Presidential proposals for healthcare reform, health information technology, healthier living, protecting the homeland, Project Bio-Shield and the President's Emergency Plan for HIV/AIDS relief. We also believe FDA's success in meeting the Secretary's 500-Day Priorities will measurably contribute to the success of Presidential initiatives, and thereby improve the health and security of the American public. Table 4 shows budget items arrayed by Secretarial priorities and the infrastructure support that also contributes to core public health initiatives.

Table 4 – Budget Summary Supporting Secretary Leavitt's 500-Day Priorities And Core Public Health Activities

Secretary's 500 Day Priority and *FDA Responsibilities*	FDA Budget Item	Dollar Amount
	Specific FY 2007 Initiatives	
Transforming Healthcare *-- Adverse Drug Incident Reporting* *-- Drug Safety Board*	1. Drug Safety	+$3,960,000
	2. Human Tissues	+$2,475,000
	3. Trigger Needs for ADUFA and MDUFMA	+$7,425,000
Advancing Medical Research *-- Enhance medication safety based on patient's personal characteristics* *-- Improving clinical research and product development*	4. Critical Path to Personalized Medicine	+$5,940,000
Securing the Homeland *-- Prepare for potential H5N1 Flu pandemic* *-- Support efforts to improve the size & readiness of the Strategic National Stockpile* *-- Improve awareness of, and effective response to, a potential terrorist attack on the food supply.*	5. Pandemic Preparedness	+$30,490,000
	6. Food Defense	+$19,873,000
	Infrastructure Support for Core Public Health Activities	
[Infrastructure for core activities directly supports FDA responsibilities under the Secretary's-500 day priorities.]	Cost of Living/Pay	+$20,267,000
	UFMS	+$1,180,000
	Infrastructure	+$14,265,000
	Current Law User Fees	+$20,170,000
	Proposed New User Fees - Reclassified	$25,536,000

The six FDA public health initiatives for FY 2007 identified above directly support three of the Secretary's 500-Day Priorities: Transforming Healthcare, Advancing Medical Research and Securing the Homeland.[1]

FY 2007 Initiatives and Offsets

We present an overview of the FY 2007 Initiatives and Offsets in Table 5. Following Table 5, we present business case papers that justify the fund for the FY 2007 initiatives. These business case papers describe our initiatives and explain the public health benefits we will achieve with the funds we request. We have also included papers presenting our justification for recurring infrastructure items.

[1] In the case of the Secretarial fourth priority "Advancing the human condition around world," the six FDA initiatives as well as activities funded by FDA's base programs advance this initiative.

Table 5 – Overview of FY 2007 Initiatives and Offsets

Initiative	Amount	FTE	Synopsis
Pandemic Preparedness	$30,490,000	85	Provide a comprehensive program to prepare and respond to the pandemic flu outbreak.
Food Defense	$19,873,000	6	Protect the nation's food supply by developing improved methods to screen food and feed imports; update prevention strategies and plans; conduct outreach to industry, state and local stakeholders.
Critical Path to Personalized Medicine	$5,940,000	6	Improve medical product development by developing review standards, tools, and methods necessary for meeting FDA review requirements.
Drug Safety	$3,960,000	8	Modernize the Adverse Event Reporting System and integrate with Centers for Medicare and Medicaid Services (CMS) to obtain access to drug safety information housed in the CMS population-based database.
Tissues	$2,475,000	18	Improve the human safety of cell and tissue products and monitor human tissue transplant adverse events.
Trigger Needs for MDUFMA and ADUFA	$7,425,000	45	Maintain animal drug and medical devices user fee programs and meet performance commitments negotiated with industry.
Cost of Living	$20,267,000	0	Provide the cost of living increase for agency personnel, enabling them to continue FDA's mission.
Unified Financial Management System	$1,180,000	0	Support FDA's efforts to fully utilize UFMS across the agency and improve the quality and timeliness of financial information in agency decision-making.
Infrastructure	$14,265,000	0	Enable FDA to pay for its GSA's rental charges for FDA's GSA space. Provide the building fit-out and move costs associated with the relocation to the White Oak Federal Research Center.
Budget Authority Offsets	($52,277,000)	(189)	Provide resources for FDA's high priority initiatives through strategic redeployment of resources from base programs and activities.
Buildings and Facilities Offsets	($2,970,000)	0	FDA will provide for the repair and maintenance of its facilities through the FY 2007 Budget request of $4,950,000 and remaining unobligated balances.
Current User Fees	$20,170,000	56	Enable FDA to review medical products in a timely manner and reimburse FDA for two services (color certification and export certificates) that we provide to industry.
Proposed User Fees Reclassified as Mandatory	$25,536,000 (Non Add)	141	Proposed new user fees to reimburse for two services (reinspection of FDA-regulated facilities and issuing of food and feed export certificates).

PANDEMIC PREPAREDNESS
$30,490,000

Why is this initiative necessary?

FDA plays a unique and vital role in the Nation's preparedness for an influenza pandemic. We facilitate the development and availability of safe and effective vaccines and we safeguard America's animal health and food safety systems in the event of an outbreak of avian and pandemic influenza.

The Pandemic Preparedness Initiative responds to the impending threat of pandemic influenza. It builds on the $20,000,000 emergency supplemental appropriation provided to FDA by Congress in Public Law 109-148 and base funds that support preparedness for pandemic and annual influenza.

The FDA request supports the comprehensive DHHS plan to expand the Nation's capacity to increase the availability of vaccine, antivirals, and other countermeasures to protect against an influenza pandemic. The programs and activities in this initiative will support increased vaccine manufacturing capacity to ensure the ability to produce pandemic influenza vaccine for the entire Nation within a six-month period. The request also supports research on promising new vaccine technologies and antivirals, methods to deliver vaccine more effectively and efficiently, and improved surveillance to rapidly identify outbreaks of disease in the United States and abroad.

The Agency also has significant responsibilities in preparing for pandemic-related impacts on the animal and food sectors that FDA regulates. The reported use of antiviral products in poultry, for example, raises concerns about possible drug resistance and the unknown human health effects. FDA must develop or asses test methods used to determine the safety of the food supply. We must also evaluate data on the technologies and cooking methods industry and the public can rely upon to kill the avian virus. FDA must also have surveillance capability to detect and intervene if such a virus is found in the food supply and to integrate its surveillance into the coordinated effort outlined in the President's National Strategy for Pandemic Influenza. To ensure comprehensive pandemic preparedness, the Agency will expand coordination with the U.S. Department of Agriculture (USDA) in preparing and exercising animal health and food related pandemic response and quarantine contingency plans.

Pandemic Preparedness Funding History

FDA	FY 2005	FY 2006*	FY 2007	
			Total	+/- FY 2006
Pandemic Influenza.....	$4.735	$24.793	$55.283	+$30.490
Vaccine-related Influenza.....	4.735	24.793	39.938	+15.145
Human and Animal Health.....	--	--	15.345	+15.345

* FY 2006 funding includes $20 M in supplemental appropriations from PL 109-148

How does this initiative support Executive Branch public health priorities?

FDA's Pandemic Preparedness Initiative achieves the three pillars of the President's National Strategy for Pandemic Influenza. Through this initiative, the Agency will:

- Enhance preparedness to safeguard human and animal health.
- Conduct effective surveillance and detection of highly pathogenic pandemic viruses and antiviral resistant strains.
- Improve response and containment measures to limit the spread of an outbreak.

FDA's initiative also responds to the key actions for an effective pandemic response, as outlined in the HHS Pandemic Influenza Plan. The pandemic preparedness initiative also directly supports the HHS Secretary's priority of Securing the Homeland by preparing for a potential H5N1 (strain) flu pandemic. Moreover, FDA's animal health activities align with a recent joint World Health Organization (WHO)/Food and Agriculture Organization/World Organization for Animal Health recommendations for control of avian influenza (H5N1) and the use of antivirals in poultry.

FDA will conduct activities in this initiative in collaboration with the Centers for Disease Control and Prevention (CDC), USDA, the Department of Homeland Security, the Department of State, and other Federal agencies responsible for preparing our Nation's fight against pandemic influenza.

What are the risks of not proceeding with the initiative?

Scientists believe it is only a matter of time until the next influenza pandemic strikes. Failure to adequately prepare for the human and animal health and the food issues associated with a pandemic could have profound public health and economic impacts for the nation. Modeling studies suggest that, in the absence of effective control measures, a medium–level pandemic in the U.S. could cause up to 200,000 deaths and nearly 50 million illnesses, and could have an economic impact of up to $160 billion.

Without funding for FDA's Pandemic Preparedness Initiative, the Agency will be unable to develop and maintain an adequate infrastructure to rapidly review or act on applications for promising pandemic influenza vaccines. We also will not be able to provide extensive technical assistance to facilitate development of new technologies to increase manufacturing flexibility and capacity. Resource gaps also would limit FDA's efforts to prepare the specific pandemic influenza reagents (substance used in a chemical reaction to help determine potency) necessary for manufacturing vaccines or developing the tools necessary to generate vaccine strains.

Failure to address pandemic-related food and animal health issues also could have significant impacts. FDA's ability to develop a methodology for screening residues is linked to the availability of resources to conduct this work. Without funding to develop, integrate and exercise FDA pandemic response plans for animal health and food issues and for contingency planning for quarantine, FDA's pandemic preparedness – and, thus, the Nation's public health and animal health preparedness – will be severely compromised.

What activities will these funds support?

FDA requests funding to conduct the following Pandemic Influenza Preparedness Initiative activities:

Vaccine-related activities ($15,145,000)

- Assess vaccine manufacturing and advise manufacturers and HHS on manufacturing issues.
- Provide extensive outreach and training in manufacturing quality. This includes conducting timely and efficient inspections of manufacturing facilities to assure product quality and preventing problems that threaten safety or availability of products essential to respond to the pandemic threat.
- Develop and assess new technologies and novel adjuvants (a nonspecific simulator of immune response) and delivery systems for antigen sparing (techniques that may allow use of less vaccine protein to get an effective immune response).
- Monitor the safety and effectiveness of pandemic vaccines administered to patients using improved information technology systems, electronic reporting mechanisms, and analytic tools to identify vaccine safety signals.
- Through reverse genetics and other emerging technologies, prepare a library of pandemic influenza virus high growth reassortants (seed strains) for rapid manufacturing when a pandemic strikes.
- Assure that all strains and reagents used for manufacturing are high quality, safe, and suitable for high-yield, large-scale manufacturing.
- Develop and implement improved, rapid tests for vaccine safety and potency, including a new generation of tests for emerging technologies such as recombinant and cell culture based vaccines.

- Continue to work closely with CDC, WHO, and others to develop materials that facilitate vaccine production like high growth reassortant viruses and reagents for standardization and evaluation of influenza vaccine.
- To speed and increase the efficiency of the development of safe and effective new pandemic vaccines FDA is working with WHO and regulatory agencies around the world in efforts, including 2 global regulators meetings planned in 2006, to develop consensus approaches and increased global harmonization in requirements for flu vaccine development and evaluation FDA is also providing technical assistance to WHO to assist other countries.

Human and animal health-related activities ($15,345,000)

- Develop and validate methods to detect antiviral products in poultry, including the antiviral products reportedly used in China. Transfer methods to test imported poultry and support the export of U.S. poultry products to countries that demand assurance that U.S. poultry is free of antiviral agents.
- Coordinate with USDA on sampling and testing poultry products at import inspection stations and poultry processing plants for traces of antiviral residues.
- Ensure that drugs are not used in veterinary medicine that increase drug resistance and thus compromise the treatment the American public during an influenza pandemic.
- Issue Custom Alerts to prevent the illegal importation of antivirals into the U.S.
- Provide technical assistance to industry on pandemic-related biosecurity activities by identifying high-risk conditions and measures for reducing the risk of avian influenza contamination.
- Develop and implement plans for containment and disposal of animal feed that has or may have been contaminated with avian flu agents.
- Develop, integrate and execute FDA animal and food response plans and quarantine activities, in coordination with USDA and CDC.
- Conduct research on possible foodborne transmission of the pandemic influenza virus to assure that the virus is not present or, if present, to assure that the food can be properly treated to ensure safety.
- Equip field labs and support technology transfer and training of field scientists to ensure adequate capacity to respond to outbreaks of avian influenza.
- Improve FDA's capacity to conduct domestic and import surveillance and respond to reports of food or foodborne illness associated with viruses.
- Support national pandemic influenza surveillance integration efforts with a comprehensive system to detect highly pathogenic strains of avian influenza.
- Provide technical assistance to industry and conduct public education on the potential risks of foodborne avian influenza and measures to prevent illness.

What results will FDA achieve?

Vaccine-related activities

- Facilitate increased domestic manufacturing capacity to provide needed pandemic influenza vaccine to meet the 20/20 Preparedness Plan for critical workers.
- Conduct timely and efficient inspection of manufacturing facilities while performing effective post-market safety and efficacy monitoring.
- Develop a library of pandemic influenza seed strains, test and approve manufacturers' seed viruses for new strains and prepare strain-specific reagents.
- Provide expertise to conduct and review highly technical and complex inspections of influenza vaccine and drug manufacturers and to conduct associated bioresearch monitoring activities.

Human and animal health-related activities

- Achieve pandemic surge production capacity to provide vaccine for the U.S. population using a combination of current egg-based and new high-volume, rapid response cell-based production.
- Develop analytical methods to detect, identify and quantify antiviral residues in poultry.
- Take steps to **e**nsure that drugs are not used in veterinary medicine that increase drug resistance and thereby the treatment of people for avian influenza.
- Consult with industry, other government agencies, and external stakeholders on biosecurity strategy and create best practice systems.
- Educate producers, veterinarians, feed industry, and others about the public health threat posed by avian influenza and the proper techniques for disposal of contaminated animal feed.
- Disseminate biosecurity best practices to regulated industry, through various outreach tools. Provide technical assistance to industry as they implement biosecurity measures.
- Develop FDA response plan for animal and food pandemic issues. Develop contingency plans for quarantine of animals and articles under the Public Health Service Act, in collaboration with USDA and CDC**.**
- Integrate quarantine and response planning into FDA's pandemic preparedness strategies.
- Integrate and exercise FDA response plan and work with USDA and CDC to coordinate quarantine plans.
- Develop and validate detection methods for avian influenza (H5N1 strain) in foods.

- Develop and deliver effective outreach/education messages for consumption, safe handling, and cooking foods of concern. Implement new and modified detection methods. Conduct training through field laboratories.
- Integrate analytical reporting from surveillance, as appropriate, into larger biosurveillance efforts.

Food Defense
+$19,873,000

Why is this initiative necessary?

The food supply is part of the Nation's critical infrastructure and contributes about 20 percent to the U.S. Gross National Product. A terrorist attack on the food supply could have catastrophic public health and economic consequences. The funds requested would continue to improve laboratory preparedness and food defense field operations, food defense research, surveillance, and incident management capabilities. Through this initiative, FDA will enhance its capacity to prevent, prepare for, respond to, and mitigate the effects of a terrorist attack, a major disaster or other emergency on the food supply.

The requested increases will allow FDA to:

- Continue to establish the Food Emergency Response Network (FERN), a national network to increase analytic surge capacity in the event of terrorist attack. FERN is designed to ensure adequate laboratory testing capacity for biological, chemical and radiological threats.
- Continue field support of food defense operations.
- Conduct targeted food defense research efforts by focusing on food counterterrorism technologies, laboratory methods development, and infectious dose thresholds for food contaminated with bioterror agents.
- Improve coordination and integration of food surveillance capabilities with the Department of Homeland Security (DHS) under the government-wide Bio-Surveillance Initiative.
- Upgrade Crisis Incident Management capabilities.

Additionally, FDA will continue to dedicate base resources to targeted risk-based inspections using FDA's Prior-Notice Center (PNC), as authorized in the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Bioterrorism Act).

Food Defense Historical Funding [1]

		FY 2005 (estimate)	FY 2006 (enacted)	FY 2007 Increase	FY 2007 Total
$	**CFSAN**	$20,954,000	$24,528,000	$990,000	$25,518,000
	Field	$121,425,000	$125,337,000	$17,398,000	$142,735,000
	Other Activities (OC)	$1,488,000	$1,473,000	$1,485,000	$2,958,000
	CVM	$1,165,000	$1,153,000	--	$1,153,000
	Field	$3,517,000	$3,482,000	--	$3,482,000
	NCTR	$1,403,000	$2,379,000	--	$2,379,000
	Total	**$149,952,000**	**$158,352,000**	**$19,873,000**	**$178,225,000**
FTE	**CFSAN**	52	59	--	59
	Field	680	684	4	688
	Other Activities	2	2	2	4
	CVM	8	8	--	8
	Field	35	35	--	35
	NCTR	1	1	--	1
	Total	**778**	**789**	**6**	**795**

[1] ***Includes base funding appropriated in the FY 2002 Emergency Supplemental.***

How does this initiative support Executive Branch public health priorities?

As a component of an interagency effort involving DHS, USDA's Food Safety Inspection Service, and other government agencies, FDA's Food Defense Initiative is critical to the President's Homeland Security Presidential Directive (HSPD)-9 goal of "providing the best protection possible against a successful attack on the U.S. agriculture and food system." Specifically, this initiative supports the HSPD-9 food defense objectives of developing awareness and early warning capabilities, mitigating vulnerabilities, enhancing screening procedures, and enhancing response and recovery procedures.

FDA's food defense effort also meets the objectives of HSPD-5, HSPD-7, HSPD-8, and HSPD-10 by enhancing the Nation's capacity to prevent, prepare for, respond to, and recover from attacks, disasters, and emergencies. Finally, these activities are also consistent with Secretary Leavitt's 500-Day Priority of securing the homeland, and they align with the HHS Strategic Goal of enhancing the ability of the Nation's health care system to respond effectively to bioterrorism and other public health challenges.

What are the risks of not proceeding with the initiative?

Safeguarding the food supply is an increasingly complex responsibility, in large part because the volume of imported food shipments is growing dramatically and because the food system is extensive, open and at risk of contamination. Armed with new authorities under the Bioterrorism Act, FDA has made progress in improving the safety of the food supply and in addressing vulnerabilities in the food system.

The failure to adequately fund food defense research, conduct vulnerability assessments, biosurveillance activities, support FERN and critical Field food defense operations, and

upgrade the agency's emergency crisis/incident management capabilities will limit FDA's ability to shield the food supply and provide adequate laboratory capacity to rapidly analyze food samples for the presence of threat agents. In short, the failure to provide this funding will compromise FDA's awareness of, and effective response to, an attack on the food supply.

What activities will these funds support?

FDA requests funding for the following Food Defense activities:

- Cooperative agreements with State laboratories to support participation in the Food Emergency Response Network (FERN), a nationwide network of Federal and State laboratories capable of testing foods for biological, chemical, and radiological contamination. The FERN network builds vital analytic surge capacity for responding to a terrorist attack on food.
- Support for FERN laboratories through validated food testing methods, proficiency testing samples, training programs for laboratory personnel, and coordinated communications and reporting through the Electronic Laboratory Exchange Network (eLEXNET).
- Support the Field's risk-based food imports operations, including efforts to continue to monitor food imports through PNC/Prior Notice Import Security Reviews, intelligence information, records of FDA inspections, discrepancies in Prior Notice submissions, and other data and information on foods that pose the highest potential terrorism risks.
- Short-term research projects to address data gaps identified through vulnerability assessments.
- Improvements to existing surveillance and detection systems, as appropriate, to integrate reporting into a comprehensive national biosurveillance system.
- A comprehensive system for managing food-related emergencies and incidents through integration of multiple data streams to produce actionable information.

What results will FDA achieve?

Foods Field and Lab Preparedness Activities +$15,400,000

- Expand the FERN system to include a total of 16 State laboratories, provide cooperative agreements and technical support to these laboratories, and build analytic surge capacity to respond to a terrorist attack. By 2007, there will be a total of 26 FERN labs in operation (10 existing Federal and 16 funded by cooperative agreements with States).
- Manage, through the National Program Office, FERN's ability to respond for a terrorist attack on (or threat to) the food supply or other food-related emergency by creating capability in FERN laboratories through training and proficiency testing.

- Enhance lab preparedness activities, including CFSAN laboratories that are part of FERN.
- Accelerate the validation of the microbiological and chemical methods currently being developed for inclusion in the FERN system.
- Continue Field support of food defense operations, including the targeting of potentially high-risk imported foods through Prior Notice Import Security Reviews based on intelligence, FDA inspection reports, discrepancies in prior notice reporting and sample collection and analysis.

Food Defense Research +$513,000

- Conduct research to address data gaps identified during vulnerability assessments. Develop reagents for joint food defense and food safety assignments.

Office of Crisis Management—Emergency Operations Network (EON) +$1,485,000

- Enhance FDA's EON capability to provide incident tracking and coordinated information management through knowledge management tools and a Geographic Information System mapping and impact assessment.

Biosurveillance—Field +$2,475,000

- Based on existing eLEXNET and FERN systems to capture data, develop nationally recognized standards for integrating analytical reporting into a comprehensive national biosurveillance system.

Critical Path To Personalized Medicine
+$5,940,000

Why is this initiative necessary?

Despite many serious unmet needs for new medical treatments and significant investments in basic biomedical research, a new wave of medical products capable of saving and extending lives is not reaching patients (or the FDA). The pace of new discoveries moving from the laboratory to clinical settings is not accelerating. FDA has a crucial and unique role to play in changing this situation.

Under the FDA Modernization Act of 1997 (P.L. 105-115), Congress expanded the FDA mission to include the promotion of public health, not only through the timely and efficient review of clinical research, but also though collaborations with partners in government, academia, and industry to further medical product development. Since then, FDA has made significant progress in accelerating the timeliness of premarket product review. However, the number of applications for new innovative products reaching the FDA has not accelerated.

The productivity of the medical product industry – the sector responsible for turning new scientific discoveries into treatments – is low and not improving. Despite advances in discovery, a drug starting human trials in 2000 was no more likely to reach the market than one entering trials in 1985 (roughly an 8 percent chance). Moreover, for pharmaceuticals, the product failure rate in phase 3 trials has increased to nearly 50 percent.

To correct this deficiency, there is an urgent need to modernize the medical product development process – the Critical Path – to make product development more predictable and less costly. Without a parallel focus and investment in the science of product development, we will not reap a full return on our investment in biomedical discovery – in the form of new products for patients.

FDA's Critical Path initiative will stimulate industry-wide efforts to identify the essential biomarkers and improved clinical trial designs that will accelerate product development. The initiative will also generate the information that the health care community needs to identify patients likely to benefit from a treatment and patients more likely to respond adversely to a product. Without clinically proven biomarkers and innovative trial designs, we cannot modernize medical product development and realize the potential of personalized medicine.

FDA is the only entity that sees the entire spectrum of scientific hurdles to effective project development, industry-wide. Thus, we are best positioned to identify projects and advance collaborations needed to overcome product development bottlenecks and support personalized medicine.

Critical Path to Personalized Medicine Funding History

	FY 2005 (estimate)	FY 2006* (enacted)	FY 2007 Increase
$		$0	+$5,940,000
FTE		-	6

* $743,000 in earmarked, external funding provided in FY 2006

How does this initiative support Executive Branch public health priorities?

Accelerating the movement of discoveries into products will have benefits across a wide spectrum of health care products. For example, the Critical Path investment will lead to more rapid development of products that prevent or treat pandemic influenza and products that treat illnesses caused by bioterror agents, two Administration priorities. New trial designs and clear guidelines for using efficacy and safety biomarkers in product development will increase the pace and reduce the cost of developing safe and effective medical products.

In addition, this initiative advances medical research by:

- Enabling the development of key tools, such as clinically proven biomarkers necessary to make medications safer and more effective because they are chosen based on the patient's personal characteristics.

- Supporting FDA and industry's ability to translate research results more quickly into benefits for patients.

- Accomplishing these goals through interdisciplinary and interagency collaboration.

What are the risks of not proceeding with the initiative?

The consequences of not receiving funds for this initiative include:

- Continued stagnation in the success rate for new products and the rate that we translate new scientific knowledge into health benefits.

- An inability to achieve the benefits of personalized medicine and further delay in the better health care outcomes it could bring.

- Continued focus on "blockbusters" to pay for high failure rate and inadequate attention to products aimed at many serious and fatal diseases.

What activities will these funds support?

FDA will use these funds to:

- Expand, stimulate and manage scientific partnerships and targeted research that will modernize medical product development. The goal is to stimulate a new generation of scientific tools to: 1) enable product sponsors to predict and evaluate the safety and effectiveness of candidate products, 2) make product development less risky, and 3) enable individualization of therapy to improve effectiveness and avoid side effects

- Translate the science developed by this initiative into FDA guidance to manufacturers that clarify the regulatory path for bringing products to market.

What results will FDA achieve?

The projects supported by these funds will produce an array of outputs, ranging from new biomarkers to technical standards; from the creation of publicly available databases and computer modeling tools, to new FDA guidances to assist industry with drug development. Examples include:

- Medical Imaging Initiative - In FY 2007 FDA will support clinical trials to validate the use of positron emission tomography (PET) imaging as a surrogate endpoint for developing new cancer drugs. This activity will be a collaboration with NCI, CMS and other partners. We will also expand collaboration with NCI on qualifying cancer imaging for drug development to include additional imaging technologies. FY 2007 deliverables also include publishing technical standards (e.g., instrument calibration and settings) necessary to reliably use these technologies in drug development. This is a collaborative venture with professional groups and other government agencies. The goal is to publish additional standards for additional technologies over several years. These tools will enable drug developers to improve the efficacy of cancer drugs.

- Improving Cardiac Drug Eluting Stent Design and Use - FY 2007 deliverables include developing preliminary components of a simulation model of drug eluting stent behavior in adults and children. A stent is a small, flexible, spring-like device used to support artery walls. Drug eluting stents (also known as drug coated stents or medicated stents), are coated with a drug that interferes with arterial re-blocking. Also in FY 2007, we will work to develop open source imaging software to assess drug-eluting stent performance and begin to develop guidance for industry on using the simulation model to predict device performance. The purpose of this project is to improve product performance and safety by predicting and avoiding product failures.

- ECG Warehouse: Improving Drug Safety - FY 2007 deliverables include completing analytic tools to permit searches of electrocardiogram (ECG) data in new drug submissions for patterns associated with unsafe drugs. Also in FY 2007, we will establish partnerships with academia and industry for additional data analyses. The purpose of this initiative is to

improve the ability to identify cardiac safety concerns before a drug is approved for marketing.

- Other Outputs -- FY 2007 deliverables include publishing concept papers and draft guidances for industry on the framework for qualifying new safety and efficacy biomarkers for drug development, such as genomic and proteomic assays.

Improving Drug Safety
+$3,960,000

Why is this initiative necessary?

This initiative will enable FDA to continue to transform the healthcare system by reducing occurrences of drug side effects. Drug safety problems cause more than 2.1 million injuries and 100,000 deaths per year. The estimated annual costs of drug-related morbidity and mortality are as high as $76 billion.

Funding this initiative will allow FDA to modernize the Adverse Event Reporting System (AERS) and establish "AERS II" as the primary source for drug product adverse event data. The initiative will also allow FDA to enhance AERS data through further integration efforts with the Centers for Medicare and Medicaid Services (CMS). This will give FDA valuable drug safety information housed in CMS population-based databases. This collaboration with CMS will be known as the Sentinel System.

The Sentinel System will create a seamless platform for gathering and evaluating information about adverse events related to the use of medical products. This will enable FDA to gather more information from the point of care about potential safety problems. It will provide a framework for turning this raw data into useful knowledge about the safe use of products so that consumers and healthcare providers have the most accurate and up-to-date information to guide their decisions. CMS, through its role in handling large volumes of information about the use of medical products, particularly drugs as part of the new Part D drug benefit, offers an increasingly powerful repository of information about drug use. This information will feed into the Sentinel System and FDA will use it to turn observations into greater understanding about drug safety.

Drug Safety Investments

	FY 2005 (estimate)	FY 2006 (enacted)	FY 2007	Increase
Center	$17,000,000	$25,700,000	$29,264,000	+$3,564,000
Other Activities (OC)			$396,000	+$396,000
User Fees (PDUFA)	$7,600,000	$8,800,000	$9,540,000	+$740,000
Total	$24,600,000	$34,500,000	$39,200,000	+$4,700,000

*These amounts do not include field resources. For example, the amounts do not include field resources devoted to pre-market drug safety (e.g., clinical investigator and human subject protection inspections) or post-market drug safety (e.g., good manufacturing practices and adverse event inspections). In general, more than half of the staff resources in the FDA drug program are devoted to drug safety activities.

How does this initiative support Executive Branch public health priorities?

Improving FDA's ability to access, analyze, and disseminate drug safety information will contribute to the President's vision of a "healthier and more hopeful America," by reducing the number of preventable injuries and deaths caused by adverse drug reactions. This will ensure that

Americans continue to have confidence in the safety and quality of the products available to them.

What are the risks of not proceeding with the initiative?

Not funding this initiative will:

- Limit access to vital drug safety information that holds the potential to reduce negative health affects experienced by consumers.
- Compromise FDA's ability to efficiently and effectively identify, investigate, and notify consumers of possible drug safety concerns.
- Impair consumer confidence in FDA and the U.S. drug safety system.
- Allow preventable injuries and deaths due to adverse drug reactions to continue unabated.

What activities will these funds support?

Clinical trials that lead to product approvals only begin to quantify the safety and efficacy of a pharmaceutical compound or biological product. FDA must collect and analyze data throughout the entire life cycle of the product in order to identify adverse events or "side effects" that could not have been predicted during clinical trials.

FDA requests additional funds to continue to modernize its AERS system and create "AERS II" – a replacement web-accessible computer system that will enable FDA to maintain the current level of AERS functionality, while providing enhancements in several areas. These enhancements include adding capabilities planned in the original AERS, but not developed due to funding constraints. With over 5 years of experience with the database, we have identified areas of critical new functionality, including generating web-accessible adverse event information.

The current AERS system is FDA's principal post-marketing monitoring tool. It allows FDA to identify events that were not observed or recognized before approval. It allows FDA to identify adverse events that might be happening because patients and prescribers are not using the drug as anticipated. This current monitoring system, by itself, is not adequate for a successful, state-of-the-art drug safety program. To appropriately monitor drug safety after marketing, it is essential that FDA have access to a wide range of clinical, pharmacy, and administrative databases, including databases maintained by:

- The Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), the Department of Defense (DoD) and the Indian Health Service (IHS).
- Clinical and hospital networks and insurers (e.g., health maintenance organizations, preferred provider organizations, Blue Cross/Blue Shield).
- Pharmacy benefit management organizations (e.g., Advance PCS, Premier).

FDA is actively evaluating the utility and feasibility of conducting specific studies of high priority safety issues using linked databases. Studies conducted on these types of databases will provide more evidence about drug use in a broader range of conditions, including more detailed evidence about drug safety in subgroups of patients. Additional resources in FY 2007 will enable us to develop robust methodologies to obtain this safety information and to validate findings by evaluating more than one data source.

These funds will also support collaboration between FDA and CMS, to access the Medicare database and conduct studies of high priority safety issues in the Medicare population. Access to the CMS database would provide a data source rich in information on medical product use in the elderly and in patients with multiple medical conditions.

What results will FDA achieve?

FDA will:

- Modernize adverse event reporting and better detect drug safety signals.
- Conduct timelier and more complete drug safety review and analysis to determine the root cause of adverse events. This will enable us to take action to minimize future errors.
- Communicate vital safety information to health care practitioners, consumers and the research community in a more timely and user-friendly way.
- Work with CMS on a Sentinel System and integrate CMS safety data into our safety analysis. The CMS collaboration will provide a rich source of safety data for analysis and response.

Human Tissues
+$2,475,000

Why is this initiative necessary?

The number of human tissue transplants[1] has increased from approximately 350,000 in 1990, to more than 1,000,000 annually, and this number will likely increase in the future. A single donor may yield more than 100 tissue products. Consequently, many individuals are at risk when communicable disease risk assessments and controls are inadequate.

FDA is implementing a new, risk-based approach to assure the safety of the human cells, tissues, and cellular and tissue-based products (HCT/Ps) involved in these human tissue transplants. This initiative will allow FDA to address issues related to safety and effectiveness of a rapidly growing industry.

Over the past decade, advancing technology and improved techniques have expanded the therapeutic uses of cells and tissues. However, the clinical safety and effectiveness of many of these advances must be addressed. Tissue transplants have recently caused multiple cases of bacterial and fungal infections, sometimes resulting in severe illness and death. In addition, emerging infectious disease transmission from donors remains a concern. Tissues may also become contaminated while they are recovered and processed. To ensure the safety of HCT/Ps, FDA must carefully assess new tissue technologies, ensure industry compliance with regulatory standards, conduct adverse event analysis and respond to outbreaks of infection associated with HCT/Ps.

Human Tissue Funding History

Description	FY 2005 Est.	FY 2006 Est.	FY 2007 Increase Request	FY 2007 Total Request
FDA	$5,378,000	$5,405,000	+$2,475,000	$7,880,000

How does this initiative support Executive Branch public health priorities?

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[1] FDA's human tissues program covers transplantable tissues to include bone, skin, corneas, tendons, ligaments, and heart valves. FDA's regulatory program does not include certain bone marrow or whole organs for transplant. Whole organ transplants involve the replacement of organs--the kidneys, liver, heart, lungs, pancreas, or intestine. These are managed under separate programs in the Health Resources and Services Administration of the Department of Health and Human Services.

The activities in this initiative directly support the Secretary's vision for transforming health care. New HCT/P products hold the potential of providing important therapies for cancer, AIDS, Parkinson's disease, hemophilia, anemia, diabetes, and other serious conditions. Many of these products are also critical to our preparedness for war and terrorism. Therefore, the initiative also supports the Administration priority of securing the homeland.

What are the risks of not proceeding with the initiative?

Without this initiative, the American public risks an increase in preventable transmission of new and emerging infectious diseases. Efforts to prevent and detect dangerous microbial contaminants during tissue manufacturing will also stall. This will undermine the confidence of patient and medical providers in the products and practices of the tissue industry, and limit innovation and the availability of promising new products.

What activities will these funds support?

FDA is requesting resources to implement the new risk-based comprehensive approach for assuring the safety of HCT/Ps. These funds will support:

- Detection, analysis and response to actual or potential disease transmission.
- Improved IT systems and procedures to support investigation, analysis and follow-up on adverse reaction reports.
- Outreach to industry and education for the medical community and the public about human tissue safety.
- Research, review and pre-licensure inspections for products that require Investigative New Drug and Biologic License Applications
- Training of FDA investigators and staff.
- High quality inspections and compliance activities for manufacturing and processing facilities.

What results will FDA achieve?

With these resources, FDA will:

- Conduct 75 additional tissue inspections and thereby significantly increase coverage among the approximately 2,000 registered firms.
- Ensure that tissue establishments demonstrate clinical safety and efficacy of their products and that there is appropriate review of HCT/Ps.

- Prevent injuries and death by rapidly detecting, analyzing and responding to adverse events involving tissue contamination.

- Rapidly review, track, and analyze tissue deviation reports submitted to the Agency by HCT/P manufacturers.

- Develop and issue program and policy documents for tissue inspections and imported tissue, as well as new regulatory procedures for compliance actions.

- Develop and issue guidance for industry on a broad array of topics related to donor eligibility and good tissue practices.

Funding For MDUFMA And ADUFA Triggers
+$7,425,000

Why is this initiative necessary?

FDA requests $4,950,000 in new budget authority for the Devices and Radiological Health program and $2,475,000 for the Animal Drugs and Feeds program. These funds will allow the agency to meet statutory requirements, known as triggers, and enable FDA to continue to collect user fees in FY 2007.

FDA continues to make great strides in reducing the time it takes for safe and effective human drugs to reach the market using the resource enhancements funded from user fees under the Prescription Drug User Fee Act (PDUFA). Following the PDUFA model, Congress authorized similar user fee programs for medical devices under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and for animal drugs under the Animal Drug User Fee Act of 2003 (ADUFA).

A significant feature of these programs is the requirement that the Federal government appropriate and spend a minimum amount on the process for reviewing these medical products. This minimum amount is indexed to the cost of living, and failing to meet these statutory triggers means that FDA cannot collect the user fees. If we do not receive the $7,425,000 in additional budget authority, the MDUFA and ADUFA user fee programs will be out of compliance with conditions of the Acts, thus requiring the orderly closure of activities financed by the user fees.

Budget Authority Resources($)

	FY 2007 Increase	**FY 2007 Total**
CDRH	+$2,901,000	$170,977,000
Field	+$2,049,000	$58,357,000
Total Medical Devices and Radiological Health	**+$4,950,000**	**$229,334,000**
CVM	**+$2,475,000**	**$59,716,000**

FDA user fees supplement appropriated funds and allow FDA to hire additional scientific and technical review staff, improve the review process, and modernize the information technology infrastructure that supports these activities. In return, the Secretary of Health and Human Services has committed to specific FDA performance goals for the review process. These goals are designed to reduce the time required to bring safe and effective medical products to market.

The additional budget authority requested meets the statutory triggers identified below.

MDUFMA -- FDA's Salaries and Expense Appropriation line for Devices and Radiological Health, exclusive of user fees, must be $205,720,000, plus statutory adjustments.	
	Appropriated Levels
FY 2005 Actual	$214,966,000
FY 2006 Minimum Requirement	$222,654,000
FY 2007 Minimum Requirement	$229,334,000
ADUFA --FDA must spend at least as much from appropriations (exclusive of fees) on the process for review of animal drug applications as it spent in FY 2003, plus statutory adjustments.	
	Appropriated Levels
FY 2005 Actual	$33,497,000
FY 2006 Minimum Requirement	$34,673,000
FY 2007 Minimum Requirement	$35,713,000

How does this request support Executive Branch public health priorities?

The request supports the Administration's vision of advancing medical research and rapid approval of medical products for longer, healthier and better lives. Because some of these products are medical countermeasures, it will also enhance the ability of the nation's health care system to respond effectively to bioterrorism and other public health threats. Finally, this initiative also supports the important goal of increasing access to innovative technologies to advance health.

MDUFMA: FDA regulates a wide array of medical devices intended to advance the health of consumers. The following facts highlight the public health significance of the domestic medical device industry:

- This is a $320 billion a year industry, with 15,000 manufacturers.
- It produced 8,897 premarket submissions (applications) for medical devices in 2004.
- More than 7 million Americans receive device implants each year.

FDA faces challenges respond to a growing industry, the accelerating pace of technology, increasing postmarket issues including product recalls and new and more complex medical device technologies. Devices are getting smaller, as miniaturization, new materials and nanotechnology become common. Smarter devices are fueling development of personalized medicine, combination products, information-rich therapeutics, intelligent devices and the biotechnology revolution. MDUFMA user fees are critical to FDA's ability to meet these challenges while ensuring continued high quality reviews.

ADUFA: The animal health industry is a $4 billion industry. The Center for Veterinary Medicine (CVM) is responsible for regulating drugs, devices and food additives for more than one hundred million companion animals, and millions of poultry, cattle, swine, and minor animal species. (Minor animal species include animals other than cattle, swine, chickens, turkeys, horses, dogs, and cats.)

CVM regulates the activities of nearly 300 animal drug manufacturers and other sponsors of animal drug applications and Type-A medicated articles, about 6,600 feed manufacturers and related firms, thousands of livestock and poultry producers, and a variety of specialized industry firms or groups. The drugs CVM approves help the nation's 69,000 veterinarians accomplish their task of maintaining the health of the nation's animals.

What are the risks of not proceeding with the initiative?

- If we do not receive $7,425,000 to meet the MDUFMA and ADUFA statutory triggers, FDA will lose $55,330,000 in user fees.
- Without the support of user fees, FDA will be forced to execute draconian personnel reductions. Review performance will plummet as morale collapses.
- It will take many years to recover from the exodus of highly skilled review and managerial staff, and once again achieve a high-performance organization.
- Critical FDA work supporting the President's vision of a Healthier America will be delayed or will go undone.
- The flow of potentially life saving medical devices will decline, limiting the availability of safe products, including those for untreated conditions.
- A growing U.S. medical device industry will suffer significant economic disruption.
- Failure to promote safe and effective new animal drugs will lead to more compliance problems with illegal animal drug use, illegal compounding of unapproved animal drugs, the use of unapproved drugs in food-producing animals, leading to greater human health risks associated with increased tissue residue in food-producing animals.

What activities will these funds support and what results will be achieved?

MDUFMA: Under MDUFMA, user fee support significantly improves the level of performance for the device review process. This, in turn, reduces the time required to complete clinical trials and speeds products to market that save lives, reduce suffering and enhance quality of life. MDUFMA user fee support has enabled FDA to achieve ambitious performance goals required by MDUFMA. Continued user fee support would allow the agency to meet the FY 2007 medical device premarket review performance commitments made by the Secretary in a formal letter to the Congress on November of 2002. Examples of performance commitments made include:

- Increasing the decision goal for Expedited Original Pre-Market Approval (PMA) submissions from 80% in 300 days in FY 2006 to 90% in FY 2007.

- Increasing the decision goal for Original PMA submissions from 80% in 320 days in FY 2006 to 90% in FY 2007.

- Increasing the decision goal for 180-Day PMA Supplement submissions from 80% in 180 days in FY 2006 to 90% in FY 2007.

ADUFA: Under ADUFA, the Agency was authorized to collect fees needed to enhance and modernize the animal drug review program and agreed to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. Over a five year period (FY 2004-FY 2008), CVM must achieve a set of progressive performance goals for the review of six specific types of applications, with each year requiring FDA to review and act in shorter periods of time.

As a result of ADUFA, additional benefits are also expected:

*For the **Animal drug industry**, earlier time to market provides*:

- Cost savings for pharmaceutical sponsors and shorter drug development times.
- Economic benefits for animal drug manufacturing firms due to increased revenues.
- Incremental savings that allow a reinvestment of dollars into the research and development of new products.

*For **Farmers, ranchers, processors and the public**, reduced time to market provides**:***

- A public health benefit through earlier access to safe and effective drug treatments resulting in improved health of livestock and companion and service animals.

*For **CVM,*** performance and management process improvements provide:

- Increased capacity to resolve new and rapidly emerging scientific issues that impact approval decisions.
- Increased opportunities for pre-submission meetings and consultation and guidance development for industry, leading to more high-quality applications and fewer review cycles.

Cost of Living Pay Increase
+$20,267,000

What is the purpose of this Initiative?

This initiative will provide the necessary cost of living increases for agency personnel to enable FDA to continue to transform the healthcare system and maintain FDA's ability to fulfill its public health mission.

Requested Increases for FY 2007

Program	Center	Field	Increase Amount
Foods	$2,131,000	$4,746,000	+ $6,877,000
Human Drugs	$3,338,000	$1,536,000	+ $4,874,000
Biologics	$1,421,000	$516,000	+ $1,937,000
Animal Drugs and Feeds	$748,000	$551,000	+ $1,299,000
Devices and Radiological Health	$2,386,000	$948,000	+ $3,334,000
NCTR	$533,000	--	+ $533,000
Other Activities	$1,413,000	--	+ $1,413,000
Total	**$11,970,000**	**$8,297,000**	**+ $20,267,000**

What is the problem we are trying to solve?

The public trusts FDA to ensure that food on the family table will be safe and wholesome, that new medical products, drugs, biological products, medical devices, and radiological products are available in a timely manner with demonstrated benefits that outweigh risks, and that product information is useful and understandable.

FDA's personnel are essential to achieve these goals. Because of its product review, inspection, enforcement, and education focus, FDA is more people-intensive than many government agencies, with payroll accounting for more than 60 percent of its total budget. In our field operations, the payroll ratio is even more dramatic. More than 80 percent of the field budget funds payroll costs, and these employees are dedicated to "front line" efforts, such as inspections for food safety, BSE and FDA-regulated products, coordination with states, and cooperative education programs.

The $20,267,000 reflects a pay increase of 2.2 percent that will help FDA sustain its current programs, such as:

- Increasing the availability of counterterrorism tools and accelerating the availability of medical products (drugs, devices, vaccines).

- Providing support to the CDC to manage the quantity and quality of stockpiled drugs and vaccines.

- Maintaining the ability to assure the safety of regulated products, inspecting and investigating domestic and foreign manufacturers, and participating in Mutual Recognition Agreements with countries to establish global standards for foods and pharmaceuticals.

- Supporting the application review of human drugs and biological products to meet promised performance commitments.

- Maintaining preparedness and support for emergency operations in response to natural or man-made events, and providing appropriate public health support to other Federal agencies, state and local governments, and other entities.

- Achieving the Agency's regulatory mandate to protect the public health. Achieving this mandate is an inherently governmental function.

- Maintaining inspectional responsibilities that require hands-on coverage domestically and internationally.

- Supporting FDA's product review functions, which require numerous interdependent specialists in product areas who interact with industry on a regular basis.

- Continuing regulatory responsibilities, which require staff to monitor the entire life cycle of all FDA-regulated products. For example, our regulatory responsibility for human drug products includes monitoring clinical trials, performing review of drug applications, reviewing drug promotion and advertising materials, and monitoring drug product safety after products reaches the market.

How does this Initiative Support Secretary Leavitt's 500 Day Plan?

FDA contributes to three Secretarial goals: Transforming Healthcare, Advancing Medical Research, and Securing the Homeland. These goals promise to significantly improve the Nation's public health. The cost of living increase will enable FDA to continue its sustained progress in achieving these important goals. Examples of FDA's progress include:

- Supporting surveillance systems to enhance patient safety, counterterrorism, food defense, the new Unified Financial Management System, and other Presidential Management Agenda items.

- Maintaining the capability to respond to emergencies such as terrorist attacks or outbreaks of BSE.

- Maintaining effort related to the Obesity Initiative.

- Ensuring coverage of inspections at the borders.

- Sampling and inspecting foods including dietary supplements, animal drugs, medical devices, and radiological products.

- Maintaining inspections in FDA's radiological health program that currently covers only five percent of all x-ray, sunlamp, and laser products, and tests only one percent of all other radiation products.

Why should we invest in this important activity for the health of Americans?

FDA has instituted strategies to prepare the next generation of agency leaders, to employ workplace policies providing flexibility to employees in managing career and family, and to train and develop the regulatory and scientific expertise needed to perform mission-critical work.

With the coming wave of retirements, FDA is using various leadership and succession planning initiatives, such as the FDA Leadership Program, DHHS Emerging Leaders Program, and the Presidential Management Fellows Program, to create opportunities for mid-career and entry-level personnel.

Even with these innovative human resource strategies, the cost of living pay initiative is necessary for FDA to ensure stability in its workforce environment. One consequence of not receiving that support would weaken the public trust in FDA's ability to carry out its mission.

In 2006, FDA is celebrating 100 years of service to the Nation. During this century of service, the American public has become increasingly confidence in FDA's ability to ensure the integrity of the food supply, medical products, and other regulated products. For the public, that assurance translates into knowing that FDA is performing its mission – protecting and promoting the public health.

Unified Financial Management System (UFMS)
+$1,180,000

What is the purpose of UFMS?

Through the UFMS project, HHS seeks to establish a unified approach for enhancing financial management performance across the Department's 12 component agencies and the Program Support Center. UFMS will eliminate duplication, streamline and standardize processes, and establish a common IT infrastructure for financial management.

The investment also will help HHS achieve the following strategic objectives:

- Eliminate five redundant and outdated financial systems by implementing a modern integrated HHS-wide system that consolidates core financial management functions into a shared services environment.
- Produce accurate, timely, reliable, and relevant financial information to help HHS managers more accurately assess the cost of HHS programs, make fact-based operational decisions and prepare financial reports and statements.
- Strengthen internal controls by instituting standard business rules, data requirements, and accounting policies across HHS.
- Streamline operational activities to achieve more efficient and cost effective business performance.

What is the problem we are trying to solve?

The UFMS investment is intended to eliminate HHS's reliance on the multiple financial legacy systems used by HHS component agencies, as well as a large number of computer system interfaces to its administrative systems. The existing enterprise architecture for financial management in the Department consists of disparate, decentralized reporting systems, which are mainframe-based, rely on a mix of manual and automated processes, and are supported by varying functional and technical practices among component agencies. Since HHS and its supporting operating divisions implemented these systems, both the executive and legislative branches of the federal government have enacted statutes and implemented regulations to enhance accountability and results through improved financial management. Central agencies such as the Office of Management and Budget and the Department of Treasury, as well as organizations such as the Joint Financial Management Improvement Program and the Federal Accounting Standards Advisory Board, also have issued financial management policies, standards, and other mandates that require improvements in federal financial management systems.

In addition to the continued changes in federal financial management regulations that are driving HHS toward a more comprehensive approach to meeting its financial management obligations,

the Department's auditors have reported that HHS's underlying financial systems from which financial statements are reported and prepared do not meet all applicable requirements.

Rapid advances in technology, a compliance environment that increasingly emphasizes more accountability, and evolving customer needs and expectations are other factors driving HHS's move toward implementing modern, integrated financial management systems and operations.

How will FDA use the funds for UFMS?

During FY 2007, the Department will continue to implement the remaining operating divisions into the UFMS environment. To accomplish this, FDA will also need to continue its involvement with the Global Program Management Office and the Operations and Maintenance Center of Excellence in all testing activities associated with new UFMS releases. The Service and Supply Fund will support the Operations and Maintenance activities of UFMS. In FY 2007, FDA will also use funds for:

- Contractor support to achieve system enhancements and updates.
- Training for new hires and refresher or advanced training for FDA users.
- Vendor support for reporting tools and licenses.
- Continued stabilization efforts.

Communications and Change Management will continue to play a major role in the effectiveness of UFMS. Information about system and process changes needs to be communicated throughout the FDA in a timely manner so users can remain productive. Additionally, communications to the entire FDA regarding system enhancements, updates, outages, and new releases must be maintained. FDA must also continue its change Management efforts relating to workplace and workforce changes brought about by UFMS.

Projected Funding Provided by UFMS and Service and Supply Fund (SSF)

Program	FY 2006 Enacted [1]	FY 2007 Estimate
UFMS Project	$4,285,000	$2,328,000
UFMS O & M/Post Deployment	$3,273,000	$3,163,000
Agency Specific	$5,338,000	$7,103,000
Administrative System Coordination and Implementation	$0	$1,482,000
Total	$12,896,000	$14,076,000

[1] Includes the 1 percent rescission.

Infrastructure to Support Critical Agency Operations
GSA Rent + 10,468,000 and White Oak +3,797,000 in Budget Authority
-$2,950,000 in Buildings and Facilities

Why is this initiative necessary?

The proposed increase will allow FDA to improve management and provide for rising GSA rent, Other Rent and Rent-Related, and White Oak costs without redirecting resources from core, mission-critical public health activities.

GSA Rent, White Oak and Buildings and Facilities Funding History

Program	FY 2005 Actual	FY 2006 Enacted	FY 2007 Estimate	+/- FY 2006
GSA Rent	$127,495,000	$133,677,000	$146,013,000	+$12,336,000
Budget Authority	*$113,479,000*	*$116,403,000*	*$126,871,000*	*+$10,468,00*
User Fee	*$14,016,000*	*$17,274,000*	*$19,142,000*	*+$1,868,000*
White Oak	$27,938,000	$21,755,000	$33,740,000	+$11,985,000
Budget Authority	*$17,846,000*	*$21,755,000*	*$25,552,000*	*+$3,797,000*
User Fee [1/]	*$15,092,000*	*$0*	*$8,188,000*	*+$8,188,000*
Buildings and Facilities	$2,199,000	$7,920,000	$4,950,000	-$2,970,000

[1/] In FY 2005, $12,092,000 FDA used in PDUFA carryover fees and $3,000,000 from FY 2005 PDUFA Collections. In FY 2007, we plan to use $8,188,000 in PDUFA carryover fees to fund the White Oak Consolidation Project.

How does this initiative support Executive Branch public health priorities?

The rental properties that provide office and laboratory space for the Agency's 10,000 employees are essential facilities that allow FDA to perform its vital public health mission. FDA's consolidation at White Oak directly links to the President's Management Agenda by providing an environment that encourages efficiency, creativity, and superior performance, while strategically using our human capital.

White Oak will allow FDA to attract and retain premier scientists by enabling them to conduct top-quality work as part of effective product review teams. Under the expanded e-Government Initiative, the use of the shared data center at White Oak will reduce computer servers from over 700 to as few as 100. The consolidation at White Oak will also make government citizen-centered, providing a readily identifiable location for citizens to interact with FDA.

The Buildings and Facilities program supports the repair and maintenance of FDA facilities. This is fundamental to FDA's mission, since specific facilities must be fully accredited in order to support ongoing scientific protocols. Managing a nationwide inventory of leased and owned real property assets that include a substantial amount of laboratory facilities requires regular repair, improvement and maintenance activities on a preventative, as needed and emergency basis. Modifying these spaces to accommodate programs and maintaining the buildings as they age allows FDA employees to perform their duties in a safe, healthful and productive work place.

What are the risks of not proceeding with the initiative?

It is important that FDA keep its infrastructure strong and provide a highly functional place to perform our regulatory mission. The inflationary costs associated with GSA rental space and the costs to move to White Oak place pressure on FDA's resources. In the case of White Oak, if we do not receive full funding for relocating, we will be responsible for paying both the new rent at White Oak and rent on facilities we currently occupy.

What Activities will these funds support?

The agency currently occupies over 6.7 million square feet of GSA space, including parking. Approximately half of the GSA rent charges for government-owned or GSA-leased space are for facilities in the Washington, DC area. The largest amounts include charges for the Parklawn complex, Module II in Beltsville, CFSAN's College Park complex, and the newly occupied buildings at the White Oak, Maryland campus. In addition, FDA-occupied space includes over 200 leased offices, including District Offices, Regional Offices, laboratories, and resident posts that are strategically located across the nations.

The White Oak campus will replace existing fragmented facilities with new, state-of-the art laboratories, office buildings and support facilities. To date, over 2,000 employees are onsite at White Oak, and the final phase of the consolidation is currently scheduled for FY 2010. The proposed increase, along with the base funding and PDUFA carryover funds of $8,188,000, will allow FDA to continue core, mission-critical public health activities. These resources will provide funding the CDER Office II building, Consolidated Data Center and auxiliary facilities. These costs include: decommissioning vacated office space; moves; project management services; security; furniture; document management and audio/video equipment, communications equipment; cabling and uninterrupted power supply; IT engineering support; and, desktop computer preparation and relocation.

The Buildings and Facilities program supports the repair and maintenance of FDA facilities. Managing a nationwide inventory of leased and owned real property assets that include a substantial amount of laboratory facilities requires regular repair, improvement and maintenance activities on a preventive, as needed and emergency basis. Modifying these spaces to accommodate programs and maintaining the buildings as they age allows FDA employees to perform their duties in a safe, healthful and productive work place. FDA will provide for the repair and maintenance of its facilities through the FY 2007 Budget request of $4,950,000 and remaining unobligated balances.

What results will FDA achieve?

Fully funding the GSA Rent and White Oak relocation will allow the programs to focus their resources on high impact public health priorities. Transforming systems and infrastructure to support critical agency operations is a priority. The consolidation at White Oak will allow FDA to standardize and modernize document handling and shared use activities such as libraries and conference areas. We will also reduce redundancies in a wide range of administrative management tasks and achieve conversion to a single computer network. This will create a stronger FDA by reducing operating costs, reducing travel time among FDA organizations, and increasing convenient access to FDA by the public.

FDA Strategic Redeployment
-$52,277,000 / -189 FTE

What is the strategic deployment?

FDA is proposing a total budget authority increase of $52,277,000 in FY 2007. This increase will allow the agency to fund six critical initiatives: pandemic preparedness, food defense, drug safety, critical path to personalized medicine, human tissues and additional budget authority to maintain animal drug and medical devices user fee programs.

To fund these initiatives and essential infrastructure requirements at FDA, our budget reflects a strategic redeployment of resources from lower priority programs to the priority initiatives that we have proposed for FY 2007. Our strategic redeployment will achieve program savings of $52,277,000, and thereby enable the Agency to fund new high priority initiatives.

Budget Authority Offset

Program	Center	Field	Offset Amount
Foods	($14,324,000)	($8,323,000)	($22,647,000)
Human Drugs	($5,430,000)	($1,661,000)	($7,091,000)
Biologics	($7,568,000)	($198,000)	($7,766,000)
Animal Drugs and Feeds	($1,469,000)	($1,260,000)	($2,729,000)
Devices and Radiological Health [1]	$486,000	0	$486,000
NCTR	($7,033,000)	--	($7,033,000)
Other Activities	($5,497,000)	--	($5,497,000)
Total	**($40,835,000)**	**($11,442,000)**	**($52,277,000)**
FTE	**-141**	**-48**	**-189**

Why is this redeployment necessary?

FDA determined that funding its priority initiatives required a strategic redeployment of resources from base programs and activities. To accomplish this strategic redeployment, FDA reduced base programs to provide the necessary resources to fund the Agency's

[1] The Devices and Radiological Health Program received an increase to ensure that FDA maintains sufficient budget authority to comply with the Medical Device User Fee and Modernization Act [FD&C Act section 738(h)(2)(A)(ii)].

high priority initiatives. These initiatives will provide the greatest benefit to the American public by ensuring the safety of the food supply, medical products, and human tissues, preparing for and combating the spread of the pandemic influenza outbreak, and promoting innovation in the development of new medical products that can lead to an era of personalized medicine. A program-by-program summary of our strategic redeployment follows:

Foods Program

To fund FY 2007 priority initiatives such as such as food defense and pandemic influenza, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, CFSAN reductions include: Research, Cosmetics, Dietary Supplements, Proficiency Testing, Outreach and Standard Setting, Regulatory Support, Premarket Food and Color Additives, and Food Contact Substances Notification. The Field – Foods reductions include lower levels of effort in these activities: analysis of low-risk domestic and import samples (FDA will continue to analyze high risk samples, including those flagged by the Prior Notice Center), research related to laboratory analytical methods, compliance and recall functions and management, supervisory, and coordination personnel at multiple locations.

Human Drugs Program

To fund FY 2007 priority initiatives such as Drug Safety and the Critical Path to Personalized Medicine, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, Human Drugs reductions include: generic drugs research contracts, animal care contract services, research/lab scientists, laboratory upkeep, and communications, staff for FOI requests, management services, and information processing modernization for the generic drugs program.

Biologics Program

To fund FY 2007 priority initiatives such as Pandemic Preparedness and the Human Tissues Initiative, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, Biologics reductions include: guidance development, early interactions with sponsors, non-emergency communications and outreach, activities related to blood and to cell and gene therapy products, and certain related post-market, safety, research, and international harmonization activities.

Animal Drugs and Feeds Program

To fund FY 2007 priority initiatives such as Pandemic Preparedness, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, Animal Drugs and Feeds reductions include: research, postmarket activities, and the Generally Recognized as Safe (GRAS) notification system.

Field Activities Support

To fund FY 2007 priority initiatives such as Pandemic Preparedness, Food Defense, and Human Tissues Initiatives, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, ORA's Field Activities reductions include: the analysis of domestic and import samples of food and human and veterinary drug products; inspection of preapproval and bioresearch monitoring inspections of veterinary drugs; inspections of veterinary feed manufacturers and human drugs manufacturers; regulatory research related to the development of laboratory analytical methods for foods, human drug, and animal feed products; compliance and recall functions involving food, human drugs, and animal drugs and feeds; and the management, supervisory, and coordination of personnel at multiple locations involved in the food, human drugs, and animal drug and feeds areas.

National Center for Toxicological Research Program

To fund FY 2007 priority initiatives such as Food Defense, Pandemic Preparedness, and Human Tissues Initiatives, FDA re-deployed resources from base programs. To accomplish this strategic redeployment and fund new, high priority initiatives, NCTR reductions include: infrastructure and contract support, and research support services including animal care/diet preparation pathology and scientific information technology. NCTR is also reducing studies in the areas of systems biology, genetic and reproductive toxicology, and rapid identification methods for biohazards.

Other Activities Program

To fund FY 2007 priority initiatives such as activities such as Pandemic Preparedness, Food Defense, and Drug Safety, the Other Activities program will reduce the number of the FTE through attrition, selective replacement of vacant positions, and other workforce restructuring strategies,.

Current Law User Fee Increases
+$20,170,000

Why is this request necessary?

The budget request includes increases in current law user fees to implement statutorily prescribed fee increases as follows:

- $15,268,000 for Prescription Drug User Fee Act (PDUFA) fees.
- $3,426,000 for Medical Device User Fee Modernization Act (MDUFMA) fees.
- $286,000 for Animal Drug User Fee Act (ADUFA) fees.
- $349,000 for Mammography Quality Standards Act (MQSA).
- $661,000 for Drugs and Devices Export Certification.
- $180,000 for Color Certification User Fees.

How does this request support Executive Branch public health priorities?

The user fees FDA currently collects support the Executive Branch's vision of transforming health care and improving access to FDA-regulated products through enhanced performance funded by user fees. This permits FDA to reduce the time it takes for safe and effective human and animal drugs, medical devices, and other FDA-regulated products to reach the market. The user fees supplement appropriated dollars and enabling programs to hire additional scientific review staff and review process managers, improve the review process, reduce review time, and provide essential information technology to support the review process.

What are the risks of not providing the request?

Without additional resources, FDA would not:

- Meet the performance commitments for faster medical device review (MDUFMA) and faster human drug (PDUFA) and animal drug review (ADUFA). The requested resources would help provide the public with earlier access to safe and effective medical products, thereby saving lives, relieving suffering, and improving the quality of life.

- Sustain patient access to safe and effective new products by providing rapid, transparent, and predictable review of marketing applications.

- Maximize safe and effective use of medical products by communicating benefits and risks more effectively.

- Prevent harm from regulated products by improving problem detection and minimizing the time between detection and appropriate risk management response.

- Increase availability of FDA experts to expand and improve consultation and outreach to industry, thereby reducing drug development time.

What activities will these funds support?

PDUFA: +$15,268,000

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 products. This authority is effective for five years and directs FDA to strengthen and improve the review and monitoring of drug safety. The law also requires FDA to expand interaction with sponsors during the review of drugs and biologics intended to treat serious and life-threatening diseases and develop principles for improving drug and biologic review.

Based on current information and established PDUFA formulas, the statute authorizes fee increases of $15,268,000 in FY 2007 to support drug review. This increase is based on inflation and workload factors associated with FDA's drug review program.

PDUFA Increase for FY 2007

Program	
CDER	$9,844,000
CBER	$2,068,000
Field Activities	$399,000
Rent	$1,801,000
Other Activities	$1,156,000
Total	**$15,268,000**

The fees that the agency collects support the following FDA performance goals:

- Preventing harm from regulated products by improving problem detection and minimizing the time from detection to appropriate risk management action.

- Sustaining access to safe and effective new products by providing rapid, transparent, and predictable review of marketing applications.

- Preventing harm from regulated products by increasing the likelihood of detection and interception of substandard manufacturing processes and products, through efficient and effective risk-targeting, external partnering and collaboration.

MDUFMA: +$3,426,000

Enacted in 2002, MDUFMA is patterned on the success of PDUFA, and is designed to improve the quality and timeliness of the medical device review process. It authorizes FDA

to collect user fees to supplement the appropriated portion of the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications.

Based on current information and established MDUFMA formulas, the statute authorizes fee increases of $3,426,000 in FY 2007 to support this program. This increase is based on inflation and workload factors for the device review program.

MDUFMA Increase for FY 2007

Program	
CBER	$715,000
CDRH	1,885,000
Field Activities	101,000
Rent	339,000
Other Activities	386,000
Total	**$3,426,000**

Fees collected support the following FDA performance goals:

- Increasing safe and effective use of approved medical products.

- Increasing access to safe and effective new medical products for unmet public health needs, including untreated conditions, emerging infectious diseases, and medical countermeasures, by increasing the number and quality of marketing applications.

- Maximizing medical product quality through improved manufacturing practices using new scientific and technical standards and systems.

ADUFA: + $286,000

Enacted in November 2003, ADUFA has improved the availability of safe and effective animal drugs. As a result, it allows food animal producers to maintain healthy animals with the assurance that food products derived from those animals will be safe, wholesome, and free of drug residue. Making safe and effective drugs accessible also ensures that companion, service animals that assist the disabled, and animals such as zoo animals will live healthier and longer lives.

Based on current information and established ADUFA formulas, the statute authorizes fee increases of $286,000 in FY 2007 to support this program. This increase is based on inflation and workload factors for the FDA animal drug review program.

ADUFA Increase for FY 2007

Program	
Veterinary Medicine	$236,000
Other Activities	50,000
Total	**$286,000**

Fees collected support the FDA performance goal of promoting safe and effective animal drug availability and ensuring public and animal health by meeting ADUFA performance goals.

MQSA: +$349,000

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 women will contract breast cancer during their lifetime. MQSA, which Congress reauthorized in October 2004, addresses the public health need for safe and reliable mammography. MQSA required that FDA certify mammography facilities by October 1994, and inspected facilities 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.

The statute authorizes FDA to collect fees to pay for the costs of the annual inspections. In FY 2007, FDA is requesting a $349,000 increase. This increase is based on inflation and workload factors for the medical device review program.

MQSA Increase for FY 2007

Program	
Medical Devices	$108,000
Field Activities	237,000
Other Activities	4,000
Total	**$349,000**

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): +$661,000

FDA is required to issue certificates to any person wishing to export a drug, animal drug, or device. These certificates state that the product meets certain requirements of 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 $661,000 increase will cover program inflationary costs.

Color Certification: +$180,000

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 2007 increase of $180,000 will cover the program inflationary costs and ensure that the program has adequate reserve funding.

Base Resources/Investment-Budget Request ($)

Description	FY 2005 Est.	FY 2006 Est.	FY 2007 Increase Request	FY 2007 Total Request
PDUFA	284,394,000	305,332,000	+15,268,000	320,600,000
MDUFMA	33,938,000	40,300,000	+3,426,000	43,726,000
ADUFA	8,354,000	11,318,000	+286,000	11,604,000
MQSA	16,919,000	17,173,000	+349,000	17,522,000
Export Certification	1,615,000	1,639,000	+661,000	2,300,000
Color Certification	5,223,000	6,001,000	+180,000	6,181,000
Total	**350,443,000**	**381,763,000**	**+20,170,000**	**401,933,000**

Food And Animal Feed Export Certification User Fee
+$3,536,000 (Mandatory User Fee)

Why is this initiative necessary?

In FY 2007, FDA estimates that the agency will issue 37,000 food and animal feed export certificates. FDA currently funds this activity through discretionary appropriations.

The Administration is proposing legislation authorizing FDA to collect user fees for issuing food and animal feed export certificates within 20 days of the receipt of a request. Under this proposal, these activities will be reclassified as mandatory user fees in FY 2007. Imposing a fee would generate an estimated $3,536,000 in revenue, an amount sufficient to cover the cost of issuing certificates. Private sector exporters would bear the cost of the program, but would reap its benefits through the agency's enhanced ability to facilitate exports of their products.

Reclassification of Resources from Discretionary Budget Authority to Mandatory User Fees – Food and Animal Feed Export Certification User Fees

Description	FY 2005	FY 2006	FY 2007 Discretionary	FY 2007 Mandatory User Fee
	Est.	Est.	$	$
CFSAN			-906,000	+906,000
CVM			-63,000	+63,000
Field			-2,567,000	+2,567,000
Total	**0**	**0**	**-3,536,000**	**+3,536,000**

How does this initiative support Executive Branch public health priorities?

Section 801 (e)(4)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) authorizes FDA to collect user fees for export certificates for human drugs, animal drugs, and devices. However, this section does not extend to collecting user fees for export certificates for foods and animal feed. FDA expends significant resources annually to issue these certificates, and the agency needs to focus its resources on activities that are central to its public health mission.

What activities will these funds support?

The agency's ability to issue certificates in a timely fashion depends on FDA securing the resources necessary to offset the costs associated with issuing export certificates for foods and feeds. Thus, for FY 2007, the FDA proposes $3,536,000 in mandatory user fees to support FDA activities associated with facilitating international trade.

What results will FDA achieve?

The user fee proposal would allow FDA to issue an estimated 37,000 food and animal feed export certificates in FY 2007. In its *Affirmative Agenda for International Activities report*, FDA's Center for Food Safety and Applied Nutrition stated its intent to try to find effective and

resource-efficient approaches to issuing export certificates for foods.

The purpose of this proposal is to cover the agency’s resources needed to issue food and feed export certificates benefiting U.S. food and feed manufacturers and exporters.

Reinspection User Fee
+$22,000,000 (Mandatory User Fee)

Why is this initiative necessary?

FDA proposes a new mandatory user fee that requires establishments that FDA inspects to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements. FDA currently funds this activity through discretionary appropriations.

When FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. Agency procedures usually require that the agency conduct a follow-up inspection of the firm within 90 days of issuing a warning letter. The proposed initiative ensures that facilities that fail to comply with health and safety standards bear the cost of reinspection.

Reclassification of Resources from Discretionary Budget Authority to Mandatory User Fees – Reinspection User Fees

Description	FY 2005	FY 2006	FY 2007 Discretionary	FY 2007 Mandatory User Fee
	Est.	Est.	$	$
Field			-12,300,000	+12,300,000
Other Activities			-7,100,000	+7,100,000
GSA Rent and Other Rent-Related Activities			-2,600,000	+2,600,000
Total	**0**	**0**	**-22,000,000**	**+22,000,000**

How does this initiative support Executive Branch public health priorities?

FDA protects 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. FDA conducts inspections and evaluates laboratory analyses to ensure that FDA products comply with the laws and regulations that the FDA enforces.

This initiative enhances public health by providing mandatory user fee resources for reinspections to determine if previously identified out-of-compliance firms have returned to compliance and to establish if the agency needs to take further Agency regulatory action.

What are the risks of not proceeding with the initiative?

If facilities that fail to comply with FDA regulations do not bear the cost of reinspections, FDA must shift resources from other high-priority program activities to conduct reinspections.

Examples of these priority public health activities include drug safety efforts and efforts to protect the nation's food supply from potential terrorist acts.

While it is good business practice for firms to ensure the safety of products before they reach consumers, the Food, Drug, and Cosmetic Act, and FDA enforcement inspections requires the safety of products before they reach consumers. This initiative provides an additional incentive for facilities to remain in compliance with regulations.

What activities will these funds support?

Costs recovered from industry to fully fund the reinspection user fee program include:

- $12.3 million for 102 field inspectors.
- $7.1 million for indirect and support costs (e.g., legal, science review, IT).
- $2.6 million for GSA Rent and Rent Related costs.

FDA's Office of Regulatory Affairs (ORA) conducts postmarket inspections of foods, human drugs, biologics, animal drugs and feeds, and medical device manufacturers to assess their compliance with Good Manufacturing Practice requirements. ORA conducts these inspections of domestic and foreign facilities. Revenue from the user fee would reimburse FDA for costs associated with the 118 FTE and related expenses required to reinspect firms that fail to comply with FDA regulations designed to protect the public from unsafe products.

What results will FDA achieve?

FDA estimates that the user fee revenue will fund approximately 1,270 reinspections in FY 2007.

FDA's Implementation of the 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 to deliver results to the American people. It reflects the Administration's commitment to achieve concrete and measurable results in the near term, while focusing on remedies to serious problems, and commits to implement them fully.

The five mutually reinforcing government-wide goals are Strategic Management of Human Capital, competitive Sourcing, Improved Financial Performance, Expanded E-government, and Budget and Performance Integration.

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.

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 PMA goals 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 these initiatives.

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. Post-course Forums are also recent additions to the FAME program. The Forums are designed to help FAME graduates transfer learning from the FAME courses to their jobs and to foster networking. One Forum is open to managers, supervisors and team leaders. The other Forum is open to non-supervisory employees who are graduates of the Supervisory Potential Program.

FDA also launched a new Leadership Development Program designed to groom internal employees at the GS-13-15 levels and equivalent, as future leaders of FDA. This program, an integral part of the FDA succession plan, includes a formal Senior Executive Development component that is delivered by George Washington University.

Special Recruiting

FDA is continuing to advance its strategic recruitment outreach initiative aimed at improving diversity among various minority populations; especially the Hispanic community. FDA is also developing an agency-wide "Diversity Recruitment Outreach and Retention Plan" to support workforce diversity.

Workforce Analysis and Workforce Planning

A strategic workforce restructuring plan was submitted during the 2005 budget process outlining FDA's on-going restructuring initiatives to right-size FDA's workforce, with a smaller, centralized unit providing administrative and support services customized according to component's needs and funded on a reimbursable basis.

In addition, the FDA is conducting an Organizational Assessment of the Office of the Commissioner (OC) in order to determine high-level alignment of resources to execute the OC's core functions and fulfill the OC mission. The goals of this initiative are to clarify the operational vision and priorities of the OC; manage within the OC annual budget; improve alignment of OC core functions with customer and stakeholder needs; and improving operational; efficiency and effectiveness.

FDA is also 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

To improve upon our Human Capital Management Initiative, FDA prepared a Strategy for Human Capital Planning in order to identify key critical positions, forecast critical vacancies, analyze competencies of our leaders and mission critical staff, and develop a strategy for filling positions.

The Human Capital Strategy developed for FDA will provide a framework to improve FDA's business practices and ensure that FDA continue to have trained and competent employees, supervisors and managers to accomplish its mission and to guide its growth.

FDA continues to receive 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.

FDA also plans to offer Voluntary Separation Incentives to employees in FY 2006 in administrative positions.

Accountability

In FY 2005, all FDA employee performance contracts and plans were linked to Agency and Departmental program goals and management objectives. This requirement will continue in FY 2006.

Improved Financial Performance

FDA has focused efforts on modernizing financial systems and improving its internal controls.

Erroneous Payments

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

Financial Management Improvement

With the launching of the UFMS, the Division of Accounting reassigned staff and created a financial operation group composed of senior and journeyman subject matter experts responsible for the monthly close-out process, performing quality control, and other work necessary to ensure the integrity of various UFMS modules (including accounts receivable; accounts payable; general ledger; budget execution; and commitment and obligation). The financial operation group also collaborates with the Office of Shared Services for their purchasing and accounts payable activities.

FDA has been working through a temporary decline in office productivity stabilization associated with the UFMS implementation. FDA is making necessary changes in procedures and policies to adjust to the new system's operation.

Financial Systems

During the agency's financial statement audit, the OIG determined that FDA's financial management systems do not substantially comply with Federal Financial Management Improvement Act (FFMIA). As UFMS achieves full stabilization, FDA believes compliance will be realized. 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.

In FY 2006, FDA plans to implement an ad hoc reporting tool while developing plans for a business intelligence model implementation in FY 2007. FDA will continue to streamline user fee business processes and reporting with E-GOV initiatives. FDA plans to implement the HHS E-travel system with a pilot in April/May 2006 and complete it by June 2006.

Financial Enterprise Solution

- The Agency completed implementation of the financial user fee solution. These included PDUFA, MDUFMA, ADUFA, MQSA, Color certification, and export certification payment information. These accomplishments include:
    - Providing a web portal for industry customers to enter applicant user fee activity.
    - Providing an interface for pertinent financial data to the accounts receivable module of the new financial system.
    - Providing internal FDA components pertinent receipt and customer information to their data systems.
    - Providing reports of user fee activities through a Business Objects solution.
- Completed the implementation of the Purchase Request Information System (PRISM) by:
    - Working with FDA contracting staff to develop requirements for the contracts implementation, and,
    - Completed the implementation of i-Procurement software with appropriate interfaces with PRISM and UFMS.

Travel Manager and the HHS-348 Sponsored Travel Module

- Completed implementation of the Travel Manager System that provides an automated travel system for the FDA traveler, reviewing officials, and travel audit staff.
- Completed implementation of the Sponsored Travel Module, as a primary subsystem within the Travel Manager, which is used for processing non-Federal sponsored travel.
- Worked with GSA in adapting FDA's Sponsored Travel Module for use in other Federal agencies to process non-federal sponsored travel in their Gov Trip Travel System.

Integrate Financial and Performance Management Systems

FDA has interfaced several FDA financial management applications (user fees, travel, property, procurement, requisitioning, payroll, and grants) with UFMS. These applications have met all federal financial management, certification and accreditation requirements.

OMB Circular A-11 requires the integration of performance and financial information for reporting purposes. Since there is no reporting capability identified in UFMS, FDA will be developing a customized reporting solution using the Oracle Federal Financial software. In FY 2006, FDA will pilot an activity-based costing application as mandated by the third reauthorization of PDUFA.

The purpose of this pilot is to improve the accuracy and reliability of cost information that is derived from expenditures used to perform the PDUFA drug review. The User Fee Financial Team collects cost information from PDUFA organizations (CDER, CBER, OC, and ORA). They analyze and provide information and decision-making support to agency leadership. Timely and accurate information on PDUFA costs may help FDA determine its annual fee requirements; make adjustments and take corrective action, including reprogramming actions; and enable the design of more responsive fee structure when it is negotiating user fee reauthorization every five years.

Expanded E-Government

IT Consolidation

FDA sustained progress in the consolidation of its IT infrastructure through collaboration with HHS in achieving its "One HHS" goals and objectives; ongoing efforts to accomplish the IT consolidation goals mandated by the reauthorization of PDUFA; and the continued maturing of the IT Shared Services organization established in FY 2004 to manage the FDA's consolidated IT infrastructure. To this end, FDA has:

- Commenced on October 1, 2004, the Single Source Infrastructure Service Support Contract which will provide efficiencies and savings through consolidation of services and management of contractors; in fact, the contract consolidated 15 IT Infrastructure Service contracts, which will result in nearly $10 million in savings over the next five years;

- Launched the Enterprise Infrastructure Consolidation Program; in the first phase completed an assessment of servers and storage area networks deployed in the 30+ dispersed sites across the Metropolitan area that will eventually merge into the White Oak Data Center; from this assessment an acquisition plan has been derived, and the FDA is in the process of identifying the best approach for reducing its 700+ servers;

- Awarded the contract to develop the Electronic Submissions Gateway, which is intended to provide a single point of entry for electronic regulatory submissions to the FDA; the system will be in production for receiving electronic drug adverse event reports in September 2005 and PDUFA reports in October 2005;

- Gathered, through use of prototypes, the requirements for developing an IT cost reporting model that integrates with FDA financial applications, categorizes IT spending by investment/system/project and activity, and reveals the true cost of infrastructure services;

- Awarded the contract to implement electronic standards for structured product labeling (SPL) as part of the FACTS@FDA program, which provides the foundation for a number of Health Information Technology (HIT) initiatives including electronic prescribing, clinical decision support, and post marketing medication adverse event surveillance; release 1a, was implemented in October 20005 and includes the Substance Registration System (SRS) and the Electronic Labeling Processing System (ELIPS); and

- Acquired, as a result of an alternative analysis, a COTS tool to implement new Electronic Common Technical Document (eCTD) specifications, thus providing enhanced functionality for submitting and reviewing drug applications. Implementation was completed at the end of June 2005.

Enterprise Architecture (EA) – IT Projects

- Developed a draft target architecture that will be the planning framework for future enhancements to the IT environment; this also enabled FDA to meet GAO and OMB mandates for Agencies to demonstrate a level of maturity (level 3) in their EA processes;

- Finalized the System Development Life Cycle (SDLC) version 2 to further standardize systems development in the Agency and initiated stage gate reviews using the SDLC to ensure conformance;

- Implemented earned value management for major IT investments; this will provide a single view of cost and performance of a project for use in stage gate reviews and reporting to the CIO, HHS and OMB; and

- Launched parallel activities to enable FDA better command of the total cost of IT; one activity will focus on aligning cost to IT projects and activities; the other activity will provide more exact costs of the infrastructure services currently being provided by the IT Shared Services; both activities will leverage UFMS that is currently in production, with the target implementation date October 2005.

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.

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.

FDA is positioned to migrate from an agency public comments system to a government-wide solution in FY2006. This will require the replacement of FDA's Dockets 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 2005, 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, with 100 percent of its operational systems certified and accredited as properly secured. FDA also developed and tested an IT Disaster Recovery plan, including a Disaster Recovery assessment of its operational systems.

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; also, FDA was the first OPDIV to transition to the new network, and then coordinated the deployment of other segments throughout HHS; finally, FDA relinquished control in October when the network became 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; lastly the FDA has finalized, in cooperation with HHS, the design for its component of the Enterprise Email System (EES), with migration slated for FY2006.

Competitive Sourcing

FAIR Act Inventory

In accordance with the Federal Activities Inventory Reform (FAIR) Act of 1998, FDA submitted its 2005 FAIR Act inventory, which identified 1,495 FTE as commercial and 8,815 FTE as inherently governmental. The development of the FY 2005 FAIR Act inventory began in March 2005.

Competition Schedule

The A-76 Executive Steering Committee made a decision to study the Office of Information Technology Shared Services (OITSS) that was confirmed by Agency leadership in December 2005. The study of 175 FTE will begin by September 15, 2006. Preliminary planning has begun and a functional analysis of OITSS will start mid- January 2006.

Status of On-Going Activities

Clerical Support Services -- FDA finished the development of the Most Efficient Organization (MEO) for the 350 FTE Clerical Support Services Study and forwarded the agency tender to contracting office for source selection. The performance decision was announced in February 2005 awarding the competition to the FDA's MEO. This decision initiated a formal transition

process beginning in May 2005. The team is currently defining the methodology for monitoring performance, cost, and workload that will be used by the MEO.

FDA clerical workforce will pilot the post-MEO monitoring system in early FY 2006. Phase-In of the Clerical Support Services MEO will begin on or about February 18, 2006, with full performance expected 60 days after the start of the Phase-In period. The first quarterly QAE inspection will occur one month later followed at three-month intervals by successive quarterly evaluations. Self reported clerical workload and task times will be collected by the web-based data collection system mentioned above.

Phase I and Phase II Studies -- All Phase I and II cost competitions resulted in awards to in-house government proposals. FDA is performing post-MEO monitoring on all six of the MEOs. Initial Quality Control Plans and Quality Assurance Surveillance Plans for all studies were comprehensively reviewed and revised to configure them for use in monitoring MEOs. Quality Assurance Evaluator (QAE) inspections were conducted and formal reports were issued for all MEOs for the third and fourth quarters of the first performance period. QAE reports were given to the responsible Contracting Officer for inclusion as part of the official contract file. Quarterly Evaluations and Annual Audits will continue throughout the fiscal year.

Annual Audits for Six MEOs -- FDA performed annual audits of the first performance period of each of the six MEOs. The audits confirmed the MEOs are performing successfully and, in most cases, were operating below the cost estimated for the first performance period. HHS conducted an independent audit of the savings reported in the FDA audits of the Bioscience Library and Real Property Management MEO. The independent audits validated the savings reported in the FDA audits.

Function	Baseline in Dollars	Actual in Dollars	Savings in Dollars
Library	2,465,482	1,665,751	799,731
Graphics	936,626	935,785	841
TV Studio**	993,576	1,053,379	-59,803
Real Property	2,934,996	2,188,832	746,164
General Accounting#	1,868,594	1,805,632	62,962
Lab Technicians	5,988,751	5,234,071	754,680
TOTAL	15,188,025	12,880,779	2,307,246

** TV Studio exceeded the MEO baseline due to pay retention provisions on some positions that are not included in the A-76 baseline.
# Revise to add the Pacific Supervisor to the actual costs.

Budget and Performance Integration

FDA continues to make progress in achieving the intent of the Budget and Performance Integration initiative. The OMB PART evaluation and Agency follow-up efforts have improved performance management throughout FDA components. Specific activities include:

Evaluation of Performance Management Framework and New Strategic Planning Effort

Based on a review of current business processes and core mission activities, FDA identified areas where the existing performance management framework could be improved to better address the requirements of the PART evaluation process as well as the requirements specified in OMB Circular A-11 on strategic and performance planning. FDA envisions a multi-year improvement effort that will allow sufficient time to create long-term outcome goals that cover FDA's mission areas more completely, while providing adequate time to develop baseline performance information so that measures and targets are specified appropriately.

During the early part of 2005, FDA held a series of strategic planning sessions to develop the outline of the revised strategic and performance management framework. FDA revised its formulation of strategic goals so that they align more directly with three core business processes and a crosscutting goal for transforming FDA operations to achieve greater productivity and implement e-Government initiatives. The resulting four strategic goals encompass all aspects of FDA's public health mission. FDA also drafted a second tier of long-term goals and objectives within each strategic goal area, which clarifies how FDA plans to implement the strategy and provides a basis for establishing performance measures and targets to guide agency activities. For example, FDA's vital counter-terrorism responsibilities, which cut across all of FDA's programs, are addressed through long-term goals and objectives in each strategic goal area.

In FY 2006, FDA plans to complete a new strategic plan that will include long-term goals and objectives. Over the next few years, FDA will work to bring its annual goals and long-term outcome goals into closer alignment with the new strategic goal framework.

Senior Management Using Performance Information for Decision-making

Center and agency leadership have used performance information as one of the many criteria for making resource decisions. For example, FDA programs that implement user fee programs (e.g., drugs, medical devices, and animal drugs) carefully monitor their performance information to ensure compliance with their commitments made under PDUFA, MDUFMA, and ADUFA. All FDA centers hold regular management team meetings during which they use performance information to monitor program performance, make resource adjustments, and evaluate staffing plans.

Marginal Cost Pilot

FDA developed a marginal cost methodology that enables program managers to determine performance and cost impacts of various budget scenarios. The Animal Drugs and Feeds Program was selected as the agency pilot, using the animal drug user fee program as the basis for estimating marginal improvements in performance that could be achieved through increases in funding. The methodology showed that an increase in resources obtained through the collection of user fees provided to the new animal drug review program yielded significant decreases in review times needed for evaluating various types of new animal drug applications, thereby making new animal drug therapies available on the market sooner. Decision-makers are now

equipped with a useful tool for evaluating program initiatives based on projected performance and resource levels. OMB requested FDA to continue to track progress in using the marginal cost methodology in the agency pilot program. Animal drug review program performance and cost information will be provided annually through the ADUFA annual reports and FDA's performance budget submissions.

FDA plans to formally complete the marginal cost pilot in FY 2008, when the performance and cost data for FY 2007 become available. In the mean time, FDA will continue to apply the methodology internally in the course of annual performance budget decision making and strategic planning.

Using PART Ratings to Justify Performance Budget Requests

FDA received a rating of moderately effective after its FY 2005 PART evaluation. Building on this success, FDA leadership instituted a series of improvements intended to monitor agency progress in meeting the PART outcome goals promised to OMB and to DHHS; and to understand how the agency's performance framework contributed to the outcome goals' accomplishment. FDA has included the FY 2005 PART rating in its justification material for each successive budget year.

Improving Performance Presentation in the Budget Submission

FDA's effort to create an integrated performance budget for the FY 2006 congressional justification submission received recognition from OMB and DHHS for having successfully incorporated performance information throughout the document. Nevertheless, the document's size was identified as a target for further improvement, through streamlining, greater integration, and consolidation. FDA conducted a post-cycle evaluation, found opportunities for consolidation, and made changes in conformance with DHHS FY 2007 budget instructions. This resulted in a streamlined budget submission for FY 2007 that consolidated performance information, tailored and highlighted budget information, and pruned material contained in the budget overview. This budget submission was revised to communicate Agency performance and resource needs in a more concise manner. FDA will conduct a post-cycle evaluation after the submission of the congressional justification to evaluate and improve the integration and presentation of performance and budget information.

Accountability

Beginning in FY 2004, FDA changed its performance appraisal system to link the Departmental and Agency goals to its performance contracts – starting with FDA senior executives and now cascaded to all employees. All individual performance appraisals now provide a document containing a listing of the HHS goals and objectives which links the employee's work plan to the HHS goal(s). The accomplishment of the employee's work contributes to the ultimate achievement of the HHS goals.

Appropriation Language

THE BUDGET FOR FISCAL YEAR 2007
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Federal Funds
General and special funds:
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; [$1,838,567,000] *$1,916,329,000*: *Provided*, That of the amount provided under this heading, [$305,332,000] *$320,600,000* shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, shall be credited to this account and remain available until expended, and shall not include any fees pursuant to 21 U.S.C. 379h(a)(2) and (a)(3) assessed for fiscal year [2007] *2008* but collected in fiscal year [2006] *2007*; [$40,300,000] *$43,726,000* 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 [$11,318,000] *$11,604,000* 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 [2006] *2007*,

including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year [2006] *2007* limitation [: *Provided further,* That none of these funds 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) $443,153,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $520,564,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $178,714,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $99,787,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $245,770,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $41,152,000 shall be for the National Center for Toxicological Research; (7) $58,515,000 shall be for Rent and Related activities, of which $21,974,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (8) $134,853,000 shall be for payments to the General Services Administration for rent; and (9) $116,059,000 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: *Provided further,* That funds may be transferred from one specified activity to another with the prior approval of the Committees on Appropriations of both Houses of Congress].

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 Secretary may, contingent upon the enactment of authorizing legislation, charge a fee for conducting reinspections and issuing export certificates for food and animal feed: Provided, That such fees, in an amount not to exceed $25,536,000 shall be credited to this account, to remain available until expended for the purpose of such reinspections and issuance of export certificates for food and animal feed: Provided further, That the amount appropriated from the General Fund for fiscal year 2007 shall be reduced by the amount credited to this account under this paragraph so as to result in a final fiscal year 2007 appropriation from the General Fund estimated at not more than $1,545,349,000.

EMERGENCY SUPPLEMENTAL

*[*For an additional amount for ‘‘Food and Drug Administration, Salaries and Expenses’’, to prepare for and respond to an influenza pandemic, $20,000,000, to remain available until September 30, 2007: *Provided*, That of the total amount appropriated $18,000,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs, and $2,000,000 shall be for other activities including the Office of the Commissioner and the Office of Management: *Provided further*, That the amounts provided under this heading are designated as an emergency requirement pursuant to section 402 of H. Con. Res. 95 (109th Congress), the concurrent resolution on the budget for fiscal year 2006.*]*

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, [$8,000,000] *$4,950,000*, to remain available until expended.

COLOR CERTIFICATION

FDA certifies color additives for use in foods, drugs, and cosmetics. It also lists color additives for use in foods, drugs, medical devices, and cosmetics (21 U.S.C. 346a, 356, 357, 376). These services are financed wholly by fees paid by the industries affected.

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 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 includes funding for counterterrorism 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 funding for pandemic preparedness, food defense, drug safety, tissue safety, the critical path to personalized medicine, medical device and animal drug review, and headquarters consolidation in White Oak, Maryland.

EXPLANATORY NOTES

In an attempt to simplify the appropriations language, we are identifying the overall appropriation levels for the agency. To achieve simplification, we have not enumerated appropriations for the individual programs that are funded through the overall appropriation.

The Administration is proposing authorizing legislation that requires establishments to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements. Under this proposal, these activities will be reclassified as mandatory user fees in FY 2007. FDA currently funds this activity through discretionary appropriations. Imposing a fee would generate $22,000,000 in revenue, an amount sufficient to fully fund reinspections.

The Administration is proposing legislation authorizing FDA to collect user fees for issuing food and animal feed export certificates. Under this proposal, these activities will be classified as mandatory user fees in FY 2007. FDA currently funds this activity through discretionary appropriations. Imposing a fee would generate $3,536,000 million in revenue, an amount sufficient to fully fund the export certification program. Private sector exporters would bear the cost of the program, but would reap its benefits through the Agency's enhanced ability to facilitate exports of their products. The Administration will work with Congress to reclassify these fees as discretionary in 2008.

Food and Drug Administration
Summary of Base Resources

Summary of Base Resources for Requested Increases in FY 2007	FY 2005 Actuals[1]	FY 2006 Enacted[2]	FY 2007 Request	Requested Increase
Pandemic Preparedness	4,735,000	24,793,000	55,283,000	30,490,000
Food Defense	149,952,000	158,352,000	178,225,000	19,873,000
Critical Path		-	5,940,000	5,940,000
Drug Safety[3]	24,600,000	34,500,000	38,460,000	3,960,000
Human Tissues Safety	6,578,000	6,512,220	8,987,220	2,475,000
Trigger Needs for MDUFMA and ADUFA[4]			7,425,000	7,425,000
Cost of Living			20,267,000	20,267,000
UFMS			1,180,000	1,180,000
Infrastructure			14,265,000	14,265,000
Strategic Redeployment			(52,277,000)	(52,277,000)
Buildings and Facilities			(2,970,000)	(2,970,000)
TOTAL BA INCREASES				50,628,000
User Fees:				
PDUFA	269,434,000	305,332,000	320,600,000	15,268,000
MDUFMA	27,161,000	40,300,000	43,726,000	3,426,000
ADUFA	8,489,000	11,318,000	11,604,000	286,000
MQSA	13,185,000	17,173,000	17,522,000	349,000
Export Certification	1,425,000	1,639,000	2,300,000	661,000
Color Certification	5,506,000	6,001,000	6,181,000	180,000
TOTAL USER FEE INCREASES				20,170,000
TOTAL FDA INCREASES				70,798,000

[1/] Includes 0.80 percent rescission from FY 2005 Appropriations.

[2/] Includes 1.0 percent rescission from FY 2006 Appropriations and supplemental appropriations from PL 109-148.

[3/] These amounts do not include field resources. For example, the amounts do not include field resources devoted to pre-market drug safety (e.g., clinical investigator and human subject protection inspections) or post-market drug safety (e.g., good manufacturing practices and adverse event inspections). In general, more than half of the staff resources in the FDA drug program are devoted to drug safety activities.

[4/] 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 2007 Congressional Justification Submission

	Budget Authority	User Fees	Program Level	Program Level FTE
FY 2006 Appropriated	**$1,489,617,000**	**$381,763,000**	**1,871,380,000**	**10,006**
FY 2006 Rescission	**($14,896,000)**	**$0**	**($14,896,000)**	**0**
FY 2006 Pandemic Influenza Supplemental	**$20,000,000**		**$20,000,000**	**85**
FY 2006 Enacted [2]	**$1,494,721,000**	**$381,763,000**	**$1,876,484,000**	**10,091**
FY 2007 Built in Changes:				
Cost of Living Increases	$39,658,000		$39,658,000	
Pay Absorptions	($19,391,000)		($19,391,000)	
Subtotal: Cost of Living Changes	***$20,267,000***		***$20,267,000***	
FY 2006 Program Changes:				
Budget Authority				
Pandemic Preparedness	$30,490,000		$30,490,000	85
Food Defense	$19,873,000		$19,873,000	6
Critical Path to Personalized Medicine	$5,940,000		$5,940,000	6
Inmproving Drug Safety	$3,960,000		$3,960,000	8
Human Tissues Safety	$2,475,000		$2,475,000	18
Appropriated User Fee Trigger Needs of MDUFMA and ADUFA	$7,425,000		$7,425,000	45
UFMS	$1,180,000		$1,180,000	
Infrastructure	$14,265,000		$14,265,000	
Buildings and Facilities	($2,970,000)		($2,970,000)	
Strategic Redeployment	($52,277,000)		($52,277,000)	(189)
Subtotal: Budget Authority Program Changes	***$30,361,000***		***$30,361,000***	***(21)***
Total Budget Authority Changes from FY 06 Enacted to FY 07 Estimat	**$50,628,000**		**$50,628,000**	**(21)**
FY 2007 User Fee Changes:				
PDUFA ($14,501,000 for GSA Rent and Rent Related Activities)		$15,268,000	$15,268,000	38
MDUFMA ($3,476,000 for GSA Rent and Rent Related Activities)		$3,426,000	$3,426,000	12
ADUFA ($1,371,000 for GSA Rent)		$286,000	$286,000	-
MQSA		$349,000	$349,000	-
Color Certification		$180,000	$180,000	1
Export Certification		$661,000	$661,000	3
Reinspection User Fee (non-add, mandatory)		*$22,000,000*	*$22,000,000*	
Food and Animal Feed Export Certification Fee (non-add, mandatory)		*$3,536,000*	*$3,536,000*	
Total User Fee Changes from FY 2006 Enacted to FY 2007 Estimate		**$20,170,000**	**$20,170,000**	**54**
Net Program Level Change from FY 2006 Enacted to FY 2007 Estimate	**$50,628,000**	**$20,170,000**	**$70,798,000**	**33**
TOTAL FDA REQUEST FOR FY 2007	**$1,545,349,000**	**$401,933,000**	**$1,947,282,000**	**10,124**

[1] Does not include 85 reimbursable FTE estimated for FY 2006 and FY 2007.
[2] Includes a one percent rescission.

3/ The discretionary budget authority total will decrease to $1,519.813 million upon enactment of proposed mandatory user fees and receipt of estimated collections of $25.536 million. FDA program level funding will remain unchanged.

Food and Drug Administration
FY 2007 Crosswalk to Summary of Change - Budget Authority
(Dollars in Thousands)

Program	BUDGET AUTHORITY INCREASES																		OFFSETS		TOTAL	
	Pandemic Preparedness		Food Defense		Critical Path		Drug Safety		Tissues		Trigger Needs for ADUFA and MDUFMA		Cost of Living		UFMS		Infrastructure	Buildings and Facilites	Strategic Redeployment		Total Budget Authority Change	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	$000	$000	FTE	$000	FTE	$000
Foods	**15**	**$8,348**	**4**	**$18,388**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$6,877**					**(105)**	**($22,647)**	**(86)**	**$10,966**
Center	*5*	*$5,998*	*0*	*$990*	*0*	*$0*			*0*	*0*	*0*	*$0*	*0*	*2,131*					*(69)*	*($14,324)*	*(64)*	*($5,205)*
Field Activities	*10*	*$2,350*	*4*	*$17,398*	*0*	*$0*			*0*	*0*			*0*	*4,746*					*(36)*	*($8,323)*	*(22)*	*$16,171*
Human Drugs	**0**	**$0**	**0**	**$0**	**6**	**$5,940**	**6**	**$3,564**	**0**	**$0**	**0**	**$0**	**0**	**$4,874**					**(20)**	**($7,091)**	**(8)**	**$7,287**
Center			*0*	*$0*	*6*	*$5,940*	*6*	*3,564*					*0*	*3,338*					*(14)*	*($5,430)*	*(2)*	*$7,412*
Field Activities	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*0*	*0*	*0*			*0*	*1,536*					*(6)*	*($1,661)*	*(6)*	*($125)*
Biologics	**56**	**$14,920**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**18**	**$2,475**	**0**	**$0**	**0**	**$1,937**					**(30)**	**($7,766)**	**44**	**$11,566**
Center	*56*	*$14,884*			*0*	*$0*			*8*	*1,237*	*0*		*0*	*1,421*					*(30)*	*($7,568)*	*34*	*$9,974*
Field Activities	*0*	*$36*			*0*	*$0*			*10*	*1,238*	*0*		*0*	*516*					*0*	*($198)*	*10*	*$1,592*
Animal Drugs and Feeds	**14**	**$4,868**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**17**	**$2,475**	**0**	**$1,299**					**(8)**	**($2,729)**	**23**	**$5,913**
Center	*6*	*$3,223*	*0*	*$0*							*17*	*2,475*	*0*	*748*					*(2)*	*($1,469)*	*21*	*$4,977*
Field Activities	*8*	*$1,645*	*0*	*$0*	*0*				*0*	*0*	*0*		*0*	*551*					*(6)*	*($1,260)*	*2*	*$936*
Devices and Radiological Health	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**28**	**4,950**	**0**	**$3,334**					**0**	**$486**	**28**	**$8,770**
Center	*0*	*$0*	*0*	*$0*							*15*	*2,901*	*0*	*2,386*					*0*	*$486*	*15*	*$5,773*
Field Activities	*0*	*$0*	*0*	*$0*					*0*	*0*	*13*	*2,049*	*0*	*948*					*0*	*$0*	*13*	*$2,997*
National Center for Toxicological Research	**0**	**$0**	**0**	**$0**	**0**	**$0**				**$0**		**$0**	**0**	**$533**					**(7)**	**($7,033)**	*(7)*	*($6,500)*
Other Activities	**0**	**$2,354**	**2**	**$1,485**	**0**	**$0**	**2**	**$396**	**0**	**$0**	**0**	**$0**	**0**	**$1,413**		**$1,180**			**(19)**	**($5,497)**	**(15)**	**$1,331**
Office of the Commissioner	*0*	*$2,218*	*2*	*$1,485*	*0*	*$0*	*1*	*198*	*0*		*0*		*0*	*527*					*(12)*	*($3,364)*	*(9)*	*$1,064*
Office of Management	*0*	*$136*	*0*	*$0*	*0*	*$0*			*0*	*0*	*0*		*0*	*670*		*$1,180*			*(7)*	*($2,076)*	*(7)*	*($90)*
Office of External Relations	*0*	*$0*	*0*	*$0*	*0*	*$0*			*0*	*0*	*0*		*0*	*119*					*0*	*($33)*	*0*	*$86*
Office of Planning and Policy			*0*	*$0*	*0*	*$0*	*1*	*198*	*0*	*0*	*0*		*0*	*97*					*0*	*($24)*	*1*	*$271*
Central Services	*0*	*$0*	*0*	*$0*	*0*	*$0*			*0*	*0*	*0*		*0*						*0*	*$0*	*0*	*$0*
Other Rent and Rent Related						**$0**															*0*	*$0*
GSA Rental Payments						**$0**											**$10,468**				*0*	*$10,468*
FDA White Oak Consolidation		**$0**		**$0**		**$0**				**$0**							**$3,797**				*0*	*$3,797*
Buildings and Facilities		**$0**		**$0**	**0**	**$0**		**0**		**$0**		**$0**						**($2,970)**			*0*	*($2,970)*
TOTAL, Salaries & Expenses	**85**	**$30,490**	**6**	**$19,873**	**6**	**$5,940**	**8**	**$3,960**	**18**	**$2,475**	**45**	**$7,425**	**0**	**$20,267**	**0**	**$1,180**	**$14,265**		**(189)**	**($52,277)**	**(21)**	**$50,628**
Non-Field Activities	*67*	*26,459*	*2*	*2,475*	*6*	*5,940*	*8*	*3,960*	*8*	*1,237*	*32*	*5,376*	*0*	*11,970*	*0*	*1,180*	*3,797*		*(141)*	*($40,835)*	*(18)*	*$17,762*
Field Activities	*18*	*4,031*	*4*	*17,398*	*0*	*0*	*0*	*0*	*10*	*1,238*	*13*	*2,049*	*0*	*8,297*	*0*	*0*	*0*		*(48)*	*($11,442)*	*(3)*	*$21,571*
Rent Activities, B&F and White Oak	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*		*0*	*0*	*0*	*0*	*0*	*10,468*	**($2,970)**	*0*	*$0*	*0*	*$11,295*

Food and Drug Administration
FY 2007 Crosswalk to Summary of Change - User Fee
(Dollars in Thousands)

Program	PDUFA [1/]		MDUFMA		ADUFA		MQSA		Export Certification		Color Certification		Total User Fee, Discretionary		*Proposed Reinspection User Fee -- Mandatory Non-Add*		*Proposed Food Export Certification User Fee -- Mandatory Non-Add*	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	*FTE*	*$000*	*FTE*	*$000*
Foods													-	-	***44***	***5,215***	***23***	***3,473***
Center													-	-	-	-	*6*	*906*
Field Activities													-	-	*44*	*5,215*	*17*	*2,567*
Human Drugs	**25**	**$10,117**											**25**	**$10,117**	***16***	***2,009***	**-**	**-**
Center	*24*	*9,844*											*24*	*9,844*	-	-		
Field Activities	*1*	*273*											*1*	*273*	*16*	*2,009*		
Biologics	**10**	**$2,194**	***3***	**$748**									***13***	**$2,942**	***3***	***410***	**-**	**-**
Center	*9*	*2,068*	*3*	*715*									*12*	*2,783*	-	-		
Field Activities	*1*	*126*	*0*	*33*									*1*	*159*	*3*	*410*		
Animal Drugs and Feeds					***0***	**$236**							***0***	**$236**	***17***	***2,050***	**-**	***63***
Center					*0*	*236*							-	*236*	-	-	-	*63*
Field Activities					*0*	*0*							-	-	*17*	*2,050*		
Devices and Radiological Health			***8***	**$1,953**			**-**	**$345**					***8***	**$2,298**	***22***	***$2,616***	***0***	***$0***
Center			*7*	*1,885*			*0*	*108*					*7*	*1,993*	-	-		
Field Activities			*1*	*68*			*0*	*237*					*1*	*305*	*22*	*2,616*		
Other Activities	**3**	**$1,156**	***1***	**$386**	**0**	**$50**	**0**	**$4**					***4***	**$1,596**	***16***	***$7,100***	***0***	***$0***
Office of the Commissioner	*1*	*325*	*0*	*67*	*0*	*10*	*0*	*0*					*1*	*402*	*10*	*2,000*		
Office of Management	*2*	*465*	*1*	*281*	*0*	*40*	*0*	*4*					*3*	*790*	*6*	*5,100*		
Office of External Relations	*0*	*164*	*0*	*15*	*0*	*0*	*0*	*0*					-	*179*	*0*	*0*		
Office of Planning and Policy	*0*	*202*	*0*	*23*	*0*	*0*	*0*	*0*					-	*225*	*0*	*0*		
Central Services	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*					-	-				
GSA Rental Payments		**$1,801**		**$67**		**$0**							**-**	**$1,868**		***$1,800***		
Other Rent and Rent Related Activities				**$272**									**-**	**$272**		***$800***		
Export Certification									**3**	**$661**			**3**	**$661**				
Color Certification											**1**	**$180**	**1**	**$180**				
Total	**38**	**$15,268**	***12***	**$3,426**	***0***	**$286**	**-**	**$349**	**3**	**$661**	**1**	**$180**	**54**	**$20,170**	***118***	***$22,000***	***23***	***$3,536***
Non-Field	*36*	*13,068*	*11*	*2,986*	*0*	*286*	*-*	*112*	*3*	*661*	*1*	*180*	*51*	*17,293*	*16*	*7,100*	*6*	*969*
Field	*2*	*399*	*1*	*101*	*0*	*0*	*-*	*237*	-	-	-	-	*3*	*737*	*102*	*12,300*	*17*	*2,567*
Rent/B&F	-	*1,801*	*0*	*339*	*0*	*0*	*-*	-	-	-	-	-	*0*	*2,140*	*0*	*2,600*	*0*	*0*

1/ $8,188,000 in PDUFA Carryover Fees will be used to fund the White Oak Consolidation Project in FY 2007. $6,560,000 will fud the fit-out and CDER Move and $1,628,000 will fund the fit-out of the Shared Data Center.

Food and Drug Administration
FY 2007 Crosswalk to Summary of Change - Program Level
(Dollars in Thousands)

Budget Authority																						
Program	Pandemic Preparedness		Food Defense		Critical Path		Drug Safety		Tissues		Trigger Needs for ADUFA and MDUFMA		Cost of Living		UFMS		Buildings and Facilities	Infrastructure	Budget Authority Offsets		Total Budget Authority Change	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000		$000	FTE	$000	FTE	$000
Foods	**15**	**$8,348**	**4**	**$18,388**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$6,877**	**0**	**$0**			**(105)**	**($22,647)**	**(86)**	**$10,966**
Center	*5*	*$5,998*	*0*	*$990*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$2,131*	*0*	*$0*			*(69)*	*($14,324)*	*(64)*	*($5,205)*
Field Activities	*10*	*$2,350*	*4*	*$17,398*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$4,746*	*0*	*$0*			*(36)*	*($8,323)*	*(22)*	*$16,171*
Human Drugs	**0**	**$0**	**0**	**$0**	**6**	**$5,940**	**6**	**$3,564**	**0**	**$0**	**0**	**$0**	**0**	**$4,874**	**0**	**$0**			**(20)**	**($7,091)**	**(8)**	**$7,287**
Center	*0*	*$0*	*0*	*$0*	*6*	*$5,940*	*6*	*$3,564*	*0*	*$0*	*0*	*$0*	*0*	*$3,338*	*0*	*$0*			*(14)*	*($5,430)*	*(2)*	*$7,412*
Field Activities	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$1,536*	*0*	*$0*			*(6)*	*($1,661)*	*(6)*	*($125)*
Biologics	**56**	**$14,920**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**18**	**$2,475**	**0**	**$0**	**0**	**$1,937**	**0**	**$0**			**(30)**	**($7,766)**	**44**	**$11,566**
Center	*56*	*$14,884*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*8*	*$1,237*	*0*	*$0*	*0*	*$1,421*	*0*	*$0*			*(30)*	*($7,568)*	*34*	*$9,974*
Field Activities	*0*	*$36*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*10*	*$1,238*	*0*	*$0*	*0*	*$516*	*0*	*$0*			*0*	*($198)*	*10*	*$1,592*
Animal Drugs and Feeds	**14**	**$4,868**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**17**	**$2,475**	**0**	**$1,299**	**0**	**$0**			**(8)**	**($2,729)**	**23**	**$5,913**
Center	*6*	*$3,223*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*17*	*$2,475*	*0*	*$748*	*0*	*$0*			*(2)*	*($1,469)*	*21*	*$4,977*
Field Activities	*8*	*$1,645*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$551*	*0*	*$0*			*(6)*	*($1,260)*	*2*	*$936*
Devices and Radiological Health	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**28**	**$4,950**	**0**	**$3,334**	**0**	**$0**			**0**	**$486**	**28**	**$8,770**
Center	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*15*	*$2,901*	*0*	*$2,386*	*0*	*$0*			*0*	*$486*	*15*	*$5,773*
Field Activities	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*13*	*$2,049*	*0*	*$948*	*0*	*$0*			*0*	*$0*	*13*	*$2,997*
National Center for Toxicological Research	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$533*	*0*	*$0*			*(7)*	*($7,033)*	*(7)*	*($6,500)*
Other Activities	**0**	**$2,354**	**2**	**$1,485**	**0**	**$0**	**2**	**$396**	**0**	**$0**	**0**	**$0**	**0**	**$1,413**	**0**	**$1,180**		**$0**	**(19)**	**($5,497)**	**(15)**	**$1,331**
Office of the Commissioner	*0*	*$2,218*	*2*	*$1,485*	*0*	*$0*	*1*	*$198*	*0*	*$0*	*0*	*$0*	*0*	*$527*	*0*	*$0*			*(12)*	*($3,364)*	*(9)*	*$1,064*
Office of Management	*0*	*$136*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$670*	*0*	*$1,180*			*(7)*	*($2,076)*	*(7)*	*($90)*
Office of External Relations	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$119*	*0*	*$0*			*0*	*($33)*	*0*	*$86*
Office of Planning and Policy	*0*	*$0*	*0*	*$0*	*0*	*$0*	*1*	*$198*	*0*	*$0*	*0*	*$0*	*0*	*$97*	*0*	*$0*			*0*	*($24)*	*1*	*$271*
Central Services	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*	*0*	*$0*			*0*	*$0*	*0*	*$0*
Other Rent and Rent Related Activities	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**			*0*	*$0*	*0*	*$0*
GSA Rental Payments	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**		**$10,468**	*0*	*$0*	*0*	*$10,468*
FDA White Oak Consolidation	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**	**0**	**$0**		**$3,797**	*0*	*$0*	*0*	*$3,797*
Export Certification																					*0*	*$0*
Color Certification																					*0*	*$0*
Buildings and Facilities	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	*($2,970)*		*0*		**0**	**($2,970)**
Total	**85**	**$30,490**	**6**	**$19,873**	**6**	**$5,940**	**8**	**$3,960**	**18**	**$2,475**	**45**	**$7,425**	**-**	**$20,267**	**-**	**$1,180**	**($2,970)**	**$14,265**	**(189)**	**($55,247)**	**(21)**	**$50,628**
Non Field	*67*	*26,459*	*2*	*2,475*	*6*	*5,940*	*8*	*3,960*	*8*	*1,237*	*32*	*5,376*	*-*	*11,970*	*-*	*1,180*	*$0*	*$3,797*	*(141)*	*(43,805)*	*(18)*	*17,762*
Field	*18*	*4,031*	*4*	*17,398*	*0*	*0*	*0*	*0*	*10*	*1,238*	*13*	*2,049*	*0*	*8,297*	*0*	*0*	*$0*	*$0*	*(48)*	*(11,442)*	*(3)*	*21,571*
Rent, B&F and White Oak	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*($2,970)*	*$10,468*	*0*	*0*	*0*	*11,295*

1/ $8,188,000 in PDUFA Carryover Fees will be used to fund the White Oak Consolidation Project in FY 2007. $6,560,000 will fud the fit-out and CDER Move and $1,628,000 will fund the fit-out of the Shared Data Center.

Food and Drug Administration
FY 2007 Crosswalk to Summary of Change - Program Level
(Dollars in Thousands)

Program	USER FEES										TOTAL		Proposed Fees - Non-Add			
	PDUFA [1/]		MDUFMA		ADUFA		Indefinate User Fees		Total User Fee		TOTAL PROGRAM LEVEL REQUEST		Proposed Reinspection User Fee		Proposed Food Export Certification User Fee	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods									**0**	**$0**	**(86)**	**$10,966**	**44**	**5,215**	**23**	**3,473**
Center									*0*	*$0*	*(64)*	*($5,205)*	-	-	*6*	*906*
Field Activities									*0*	*$0*	*(22)*	*$16,171*	*44*	*5,215*	*17*	*2,567*
Human Drugs	**25**	**$10,117**							**25**	**$10,117**	**17**	**$17,404**	**16**	**2,009**	**-**	**-**
Center	*24*	*9,844*							*24*	*$9,844*	*22*	*$17,256*	-	-	-	-
Field Activities	*1*	*273*							*1*	*$273*	*(5)*	*$148*	*16*	*2,009*	-	-
Biologics	**10**	**$2,194**	**3**	**$748**					**13**	**$2,942**	**57**	**$14,508**	**3**	**410**	**-**	**-**
Center	*9*	*2,068*	*3*	*715*					*12*	*$2,783*	*46*	*$12,757*	-	-	-	-
Field Activities	*1*	*126*	*0*	*33*					*1*	*$159*	*11*	*$1,751*	*3*	*410*	-	-
Animal Drugs and Feeds					**0**	**$236**			**0**	**$236**	**23**	**$6,149**	**17**	**2,050**	**-**	**63**
Center					*0*	*236*			*0*	*$236*	*21*	*$5,213*	-	-	-	*63*
Field Activities					*0*	*0*			*0*	*$0*	*2*	*$936*	*17*	*2,050*	-	-
Devices and Radiological Health			**8**	**$1,953**			**0**	**$345**	**8**	**$2,298**	**36**	**$11,068**	***22***	**$2,616**	***0***	**$0**
Center			*7*	*1,885*			-	*108*	*7*	*$1,993*	*22*	*$7,766*	-	-	-	-
Field Activities			*1*	*68*			*0*	*237*	*1*	*$305*	*14*	*$3,302*	*22*	*2,616*	-	-
National Center for Toxicological Research									**0**	**$0**	*(7)*	*($6,500)*				
Other Activities	**3**	**$1,156**	**1**	**$386**	**0**	**$50**	**0**	**$4**	**4**	**$1,596**	**(11)**	**$2,927**	***16***	**$7,100**	***0***	**$0**
Office of the Commissioner	*1*	*325*	*0*	*67*	*0*	*10*			*1*	*$402*	*(8)*	*$1,466*	*10*	*2,000*	-	-
Office of Management	*2*	*465*	*1*	*281*	*0*	*40*	*0*	*4*	*3*	*$790*	*(4)*	*$700*	*6*	*5,100*	-	-
Office of External Relations	-	*164*	*0*	*15*	*0*	*0*			*0*	*$179*	*0*	*$265*	-	-	-	-
Office of Planning and Policy	-	*202*	*0*	*23*	*0*	*0*			*0*	*$225*	*1*	*$496*	-	-	-	-
Central Services	-	-	*0*	*0*	*0*	*0*			*0*	*$0*	*0*	*$0*	-	-	-	-
Other Rent and Rent Related Activities	**-**			**$272**		**$0**			**0**	**$272**	*0*	*$272*		**$800**		
GSA Rental Payments		**$1,801**		**$67**					**0**	**$1,868**	*0*	*$12,336*		**$1,800**		
FDA White Oak Consolidation									**0**	**$0**	*0*	*$3,797*				
Export Certification							**3**	**$661**	**3**	**$661**	*3*	*$661*				
Color Certification							**1**	**$180**	**1**	**$180**	*1*	*$180*				
Buildings and Facilities									**0**	**$0**	*0*	*($2,970)*				
Total	**38**	**$15,268**	**12**	**$3,426**	**0**	**$286**	**4**	**$1,190**	**54**	**$20,170**	**33**	**$70,798**	**118**	**$22,000**	**23**	**$3,536**
Non Field	*36*	*13,068*	*11*	*2,986*	*0*	*286*	*4*	*953*	*51*	*17,293*	*33*	*$35,882*	*16*	*7,100*	*6*	*969*
Field	*2*	*399*	*1*	*101*	*0*	*0*	*0*	*237*	*3*	*737*	*0*	*$22,308*	*102*	*12,300*	*17*	*2,567*
Rent, B&F and White Oak	*0*	*1,801*		*339*	*0*	*0*	*0*	*0*	*0*	*2,140*	*0*	*$12,608*	*0*	*2,600*	*0*	*0*

1/ $8,188,000 in PDUFA Carryover Fees will be used to fund th

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

PROGRAM	FY 2005 Actuals[1/]		FY 2005 Estimate[1/]		FY 2006 Enacted[1/, 2/]		FY 2007 [1/,3/]	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**2,943**	**$435,517**	**2,950**	**$435,526**	**2,843**	**$438,721**	**2,757**	**$449,687**
Center	*884*	*152,260*	*894*	*152,002*	*881*	*153,568*	*817*	*148,363*
Field Activities	*2,059*	*283,257*	*2,056*	*283,524*	*1,962*	*285,153*	*1,940*	*301,324*
Human Drug	**1,837**	**$291,484**	**2,050**	**$291,488**	**1,914**	**$297,716**	**1,906**	**$305,003**
Center	*1,171*	*210,481*	*1,380*	*210,529*	*1,279*	*217,797*	*1,277*	*225,209*
Field Activities	666	*81,003*	670	*80,959*	635	*79,919*	*629*	*79,794*
Biologics	**768**	**$123,109**	**781**	**$123,112**	**836**	**$139,016**	**880**	**$150,582**
Center	*553*	*96,595*	*565*	*96,890*	*623*	*111,832*	*657*	*121,806*
Field Activities	215	*26,514*	216	*26,222*	213	*27,184*	*223*	*28,776*
Animals Drugs and Feeds	**571**	**$90,484**	**555**	**$90,486**	**537**	**$89,581**	**560**	**$95,494**
Center	*330*	*55,360*	*315*	*55,292*	*309*	*54,739*	*330*	*59,716*
Field Activities	241	*35,124*	240	*35,194*	228	*34,842*	*230*	*35,778*
Devices and Radiological Health	**1,367**	**$214,962**	**1,403**	**$214,965**	**1,378**	**$220,564**	**1,406**	**$229,334**
Center	*970*	*163,292*	*1,003*	*163,246*	*986*	*165,204*	*1,001*	*170,977*
Field Activities	397	*51,670*	400	*51,719*	392	*55,360*	*405*	*58,357*
National Center for Toxicological Research	**187**	**$40,206**	**225**	**$40,206**	**206**	**$40,740**	**199**	**$34,240**
Other Activities	**508**	**$87,230**	**597**	**$87,232**	**546**	**$86,905**	**531**	**$88,236**
Office of the Commissioner	*219*	*29,958*	*311*	*29,846*	*219*	*30,153*	*210*	*31,217*
Office of Management	*194*	*38,905*	*286*	*38,515*	*239*	*38,070*	*232*	*37,980*
Office of External Relations	*53*	*6,454*	*0*	*6,873*	*52*	*6,804*	*52*	*6,890*
Office of Planning and Policy	*42*	*5,090*	*0*	*5,175*	*36*	*5,123*	*37*	*5,394*
Central Services	*0*	*6,823*	*0*	*6,823*	*0*	*6,755*	*0*	*6,755*
FDA Consolidation at White Oak		**$17,846**		**$17,846**		**$21,755**	**0**	**$25,552**
Other Rent and Rent Related Activities		**$35,758**		**$35,758**	**0**	**$35,400**	**0**	**$35,400**
GSA Rental Payments		**$113,479**		**$113,479**	**0**	**$116,403**	**0**	**$126,871**
TOTAL, Salaries & Expenses	**8,181**	**$1,450,075**	**8,561**	**$1,450,098**	**8,260**	**$1,486,801**	**8,239**	**$1,540,399**
Non-Field Activities	*4,603*	*805,424*	*4,979*	*805,397*	*4,830*	*830,785*	*4,812*	*848,547*
Field Activities	*3,578*	*477,568*	*3,582*	*477,618*	*3,430*	*482,458*	*3,427*	*504,029*
Rent Activities	*0*	*167,083*	-	*167,083*	-	*173,558*	-	*187,823*
Buildings and Facilities	**0**	**$2,199**	**0**	**$0**	**0**	**$7,920**	**0**	**$4,950**
TOTAL Budget Authority	**8,181**	**$1,452,274**	**8,561**	**$1,450,098**	**8,260**	**$1,494,721**	**8,239**	**$1,545,349**

[1/] Does not include 83 reimbursable FTE in FY 2005, or an estimated 85 fte in FY 2006 or 2007.

[2/] Includes one percent rescission and $20 million supplemental for pandemic influenza.

[3/] The discretionary budget authority total will decrease to $1,519.813 million upon enactment of proposed mandatory user fees and receipt of estimated collections of $25.536 million. FDA program level funding will remain unchanged.

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

PROGRAM	FY 2005 Actuals		FY 2005 Estimate		FY 2006 Enacted		FY 2007	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses, Definite Appropriations:								
Prescription Drug User Fee Act (PDUFA):								
Human Drugs (PDUFA)	**1,081**	**$190,650**	**1,043**	**$204,808**	**1,110**	**$219,841**	**1135**	**$229,958**
Center	*1,049*	*185,555*	*1,015*	*199,762*	*1,081*	*213,908*	*1,105*	*223,752*
Field	*32*	*5,095*	*28*	*5,046*	*29*	*5,933*	*30*	*6,206*
Biologics (PDUFA)	**250**	**$42,218**	**226**	**$40,441**	**242**	**$47,675**	**252**	**$49,869**
Center	*243*	*41,175*	*214*	*38,353*	*230*	*44,933*	*239*	*47,001*
Field	*7*	*1,043*	*12*	*2,088*	*12*	*2,742*	*13*	*2,868*
Other Activities (PDUFA)	**124**	**$14,020**	**146**	**$23,738**	**133**	**$25,116**	**136**	**$26,272**
Office of the Commissioner	*32*	*4,115*	*33*	*6,590*	*34*	*7,055*	*35*	*7,380*
Office of Management	*52*	*5,265*	*71*	*9,717*	*57*	*10,105*	*59*	*10,570*
Office of External Relations	*18*	*2,082*	*19*	*3,334*	*19*	*3,570*	*19*	*3,734*
Office of Planning and Policy	*22*	*2,558*	**23**	*4,097*	*23*	*4,386*	*23*	*4,588*
Central Services	*0*	*0*	**-**	*0*	*0*	*0*	*0*	*0*
FDA Consolidation at White Oak 1/	**0**	**$3,000**	**-**	**$3,000**	*0*	***0***		
GSA Rental Payments (PDUFA)		***$11,212***	-	***$12,407***	*0*	***$12,700***	-	***$14,501***
Other Rent and Rent Related (PDUFA)		***$8,334***						
Subtotal PDUFA	**1,455**	**$269,434**	**1,415**	**$284,394**	**1,485**	**$305,332**	**1,523**	**$320,600**
Medical Device User Fee and Modernization Act (MDUFMA):								
Biologics (MDUFMA)	**23**	**$5,357**	**38**	**$8,169**	**32**	**$8,801**	**35**	**$9,549**
Center	*22*	*5,260*	*36*	*7,850*	*30*	*8,412*	*33*	*9,127*
Field	*1*	*97*	*2*	*319*	*2*	*389*	*2*	*422*
Devices and Radiological Health (MDUFMA)	**115**	**$16,361**	**160**	**$18,379**	**131**	**$22,978**	**139**	**$24,931**
Center	*108*	*15,492*	*152*	*17,786*	*124*	*22,173*	*131*	*24,058*
Field	*7*	*869*	*8*	*593*	*7*	*805*	*8*	*873*
Other Activities (MDUFMA)	**15**	**$2,644**	**20**	**$4,061**	**19**	**$4,535**	**20**	**$4,921**
Office of the Commissioner	*4*	*867*	*2*	*734*	*5*	*785*	*5*	*852*
Office of Management	*8*	*1,292*	*16*	*2,908*	*11*	*3,302*	*12*	*3,583*
Office of External Relations	*2*	*199*	*1*	*169*	*2*	*180*	*2*	*195*
Office of Planning and Policy	*1*	*286*	*1*	*250*	*1*	*268*	*1*	*291*
Central Services	*0*	*$0*						
Other Rent and Rent Related Activities (MDUFMA)		***$562***	**-**	***$686***		***$783***	***0***	***1,055***
GSA Rental Payments (MDUFMA)		***$2,237***	**-**	***$2,643***		***$3,203***	***0***	***3,270***
Subtotal (MDUFMA)	**153**	**$27,161**	**218**	**$33,938**	**182**	**$40,300**	**194**	**$43,726**
Animal Drug User Fee Act (ADUFA):					**76**	**$9,301**	**82**	**$10,233**
Center for Veterinary Medicine	**39**	**$7,538**	**58**	**$7,748**	**76**	**$9,301**	**76**	**9,537**
Other Activities (ADUFA)	**3**	**$384**	**2**	**235**	**6**	**$646**	**6**	**$696**
Office of the Commissioner	**0**	**-**	**-**	**-**			**-**	*0*
Office of the Commissioner	1	**142**			*1*	*67*	*1*	*77*
Office of Management	*1*	*125*	*2*	*235*	*5*	*523*	*5*	*563*
Office of External Relations	*1*	*46*				*22*	*0*	*22*
Office of Planning and Policy	*0*	*71*				*34*	*0*	*34*
Central Services	*0*	*0*						
GSA Rental Payments (ADUFA)		***$567***	-	***$371***		***$1,371***	**0**	***$1,371***
Subtotal (ADUFA)	**42**	**$8,489**	**60**	**$8,354**	**82**	**$11,318**	**82**	**$11,604**
Total Definite Appropriations	**1,650**	**$305,084**	**1,693**	**$326,686**	**1,749**	**$356,950**	**1,799**	**$375,930**
Indefinite Appropriations:								
Mammography Quality and Standards Act (MQSA):								
Center for Devices and Radiological Health	**34**	**$12,959**	**48**	**$16,717**	**34**	**$16,961**	**34**	**$17,306**
Center	*26*	*4,373*	*32*	*5,174*	*26*	*5,337*	*26*	*5,445*
Field Activities	*8*	*8,586*	*16*	*11,543*	*8*	*11,624*	*8*	*11,861*
Other Activities - Office of Management and Systems (MQSA)	**2**	**$226**	**2**	**$202**	**2**	**$212**	**2**	**$216**
Office of Management and Systems	*2*	*226*	*2*	*202*	*2*	*212*	*2*	*216*
Subtotal (MQSA)	**36**	**$13,185**	**50**	**$16,919**	**36**	**$17,173**	**36**	**$17,522**
Export Certification	**8**	**$1,425**	**13**	**$1,615**	**8**	**$1,639**	**11**	**2,300**
Color Certification Fund	**35**	**$5,506**	**38**	**$5,223**	**38**	**$6,001**	**39**	**6,181**
Total Indefinite Appropriations	**79**	**$20,116**	**101**	**$23,757**	**82**	**$24,813**	**86**	**$26,003**
Total User Fees	**1,729**	**$325,200**	**1,794**	**$350,443**	**1,831**	**$381,763**	**1,885**	**$401,933**
Mandatory Proposed User Fees -- Non-Add:								
Reinspection User Fee:								
Office of Regulatory Affairs	***0***	**-**	**-**	**-**	**-**	**-**	***102***	***$12,300***
Foods Program Estimate	***0***	**-**	**-**	**-**	**-**	**-**	*44*	*$5,215*
Human Drugs Program Estimate	***0***	**-**	**-**	**-**	**-**	**-**	*16*	*$2,009*
Biologics Program Estimate	***0***	**-**	**-**	**-**	**-**	**-**	*3*	*$410*
Animal Drugs and Feeds Program Estimate	***0***	**-**	**-**	**-**	**-**	**-**	*17*	*$2,050*
Devices and Radiological Health Program Estimate	*0*	-	-	-	-	-	*22*	*$2,616*
Other Activities	*0*	-	-	-	-	-	***16***	***$9,700***
Office of the Commissioner	*0*	-	-	-	-	-	*10*	*$2,000*
Office of Management	*0*	-	-	-	-	-	*6*	*$5,100*
GSA and Other Rent Related Activities	*0*	-	-	-	-	-		*$2,600*
Subtotal Reinspection User Fee	*0*	-	-	-	-	-	***118***	***$22,000***
Food and Animal Feed Export Certification Fee:	*0*	-	-	-	-	-		
Center for Food Safety and Applied Nutrition	*0*	-	-	-	-	-	*6*	*$906*
Center for Veterinary Medicine	*0*	-	-	-	-	-	-	*$63*
Office of Regulatory Affairs (Foods Program)	*0*	-	-	-	-	-	*17*	*$2,567*
Subtotal Food and Animal Feed Export Cetification Fee	*0*	-	-	-	-	-	***23***	***$3,536***
Total New User Fees	**-**	**$0**	**-**	**$0**	**-**	**$0**	**141**	**$25,536**

1/ $8,188,000 in PDUFA Carryover Fees will be used to fund the White Oak Consolidation Project in FY 2007. $6,560,000 will fud the fit-out and CDER Move and $1,628,000 will fund the fit-out of the Shared Data Center.

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

PROGRAM	FY 2005 Actuals[2/]		FY 2005 Estimate[2/]		FY 2006 Enacted[2/]		FY 2007[2/,3/]	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses:								
Foods	**2,943**	**$435,517**	**2,950**	**$435,526**	**2,843**	**$438,721**	**2,757**	**$449,687**
Center	*884*	*152,260*	*894*	*152,002*	*881*	*153,568*	*817*	*148,363*
Field	*2,059*	*283,257*	*2,056*	*283,524*	*1,962*	*285,153*	*1,940*	*301,324*
Human Drug	***2,918***	***482,134***	**3,093**	**$496,296**	**3,024**	**$517,557**	**3,041**	**$534,961**
Center	*2,220*	*396,036*	*2,395*	*410,291*	*2,360*	*431,705*	*2,382*	*448,961*
Field	*698*	*86,098*	*698*	*86,005*	*664*	*85,852*	*659*	*86,000*
Biologics	**1,041**	**$170,684**	**1,045**	**$171,722**	**1,110**	**$195,492**	**1,167**	**$210,000**
Center	*818*	*143,030*	*815*	*143,093*	*883*	*165,177*	*929*	*177,934*
Field	*223*	*27,654*	*230*	*28,629*	*227*	*30,315*	*238*	*32,066*
Animals Drugs and Feeds	**610**	**$98,022**	**613**	**$98,234**	**613**	**$98,882**	**636**	**$105,031**
Center	*369*	*62,898*	*373*	*63,040*	*385*	*64,040*	*406*	*69,253*
Field	*241*	*35,124*	*240*	*35,194*	*228*	*34,842*	*230*	*35,778*
Devices and Radiological Health	**1,516**	**$244,282**	**1,611**	**$250,061**	**1,543**	**$260,503**	**1,579**	**$271,571**
Center	*1,104*	*183,157*	*1,187*	*186,206*	*1,136*	*192,714*	*1,158*	*200,480*
Field	*412*	*61,125*	*424*	*63,855*	*407*	*67,789*	*421*	*71,091*
National Center for Toxicological Research	**187**	**$40,206**	**225**	**$40,206**	**206**	**$40,740**	**199**	**$34,240**
Other Activities	**652**	**$104,504**	**767**	**$115,468**	**706**	**$117,414**	**695**	**$120,341**
Office of the Commissioner	*256*	*35,082*	*346*	*37,170*	*259*	*38,060*	*251*	*39,526*
Office of Management	*257*	*45,813*	*377*	*51,577*	*314*	*52,212*	*310*	*52,912*
Office of External Relations	*74*	*8,781*	*20*	*10,376*	*73*	*10,576*	*73*	*10,841*
Office of Planning and Policy	*65*	*8,005*	*24*	*9,522*	*60*	*9,811*	*61*	*10,307*
Central Services	*-*	*6,823*	*-*	*6,823*	*-*	*6,755*	*-*	*6,755*
FDA Consolidation at White Oak1/		**$20,846**		**$20,846**	**-**	**$21,755**	**-**	**$25,552**
GSA Rent		**$127,495**		**$128,900**	**-**	**$133,677**	**-**	**$146,013**
Other Rent and Rent Related Activities		**$44,654**		**$36,444**		**$36,183**		**$36,455**
Export Certification	**8**	**$1,425**	**13**	**$1,615**	**8**	**$1,639**	**11**	**$2,300**
Color Certification Fund	**35**	**$5,506**	**38**	**$5,223**	**38**	**$6,001**	**39**	**$6,181**
TOTAL, Salaries & Expenses	**9,910**	**$1,775,275**	**10,355**	**$1,800,541**	**10,091**	**$1,868,564**	**10,124**	**$1,942,332**
Buildings and Facilities		**$2,199**		**$0**		**$7,920**		**$4,950**
Total Program Level	**9,910**	**$1,777,474**	**10,355**	**$1,800,541**	**10,091**	**$1,876,484**	**10,124**	**$1,947,282**
Less User Fees:								
Current Law:								
Prescription Drug User Fee Act (PDUFA)	*1,455*	*269,434*	*1,415*	*284,394*	*1,485*	*305,332*	*1,523*	*320,600*
Medical Devices (MDUFMA)	*153*	*27,161*	*218*	*33,938*	*182*	*40,300*	*194*	*43,726*
Animal Drugs (ADUFA)	*42*	*8,489*	*60*	*8,354*	*82*	*11,318*	*82*	*11,604*
Mammography Quality Standards Act (MQSA)	*36*	*13,185*	*50*	*16,919*	*36*	*17,173*	*36*	*17,522*
Export Certification	*8*	*1,425*	*13*	*1,615*	*8*	*1,639*	*11*	*2,300*
Certification Fund	*35*	*5,506*	*38*	*5,223*	*38*	*6,001*	*39*	*6,181*
SUBTOTAL User Fees	**1,729**	**$325,200**	**1,794**	**$350,443**	**1,831**	**$381,763**	**1,885**	**$401,933**
Total User Fees	**1,729**	**$325,200**	**1,794**	**$350,443**	**1,831**	**$381,763**	**1,885**	**$401,933**
TOTAL BUDGET AUTHORITY	**8,181**	**$1,452,274**	**8,561**	**$1,450,098**	**8,260**	**$1,494,721**	**8,239**	**$1,545,349**
Mandatory Proposed User Fees -- Non-Add:								
Reinspection User Fee:								
Office of Regulatory Affairs			**-**	**-**	**-**	**-**	***102***	***$12,300***
Foods Program Estimate			**-**	**-**	**-**	**-**	*44*	*$5,215*
Human Drugs Program Estimate			**-**	**-**	**-**	**-**	*16*	*$2,009*
Biologics Program Estimate			**-**	**-**	**-**	**-**	*3*	*$410*
Animal Drugs and Feeds Program Estimate			**-**	**-**	**-**	**-**	*17*	*$2,050*
Devices and Radiological Health Program Estimate			-	-	-	-	*22*	*$2,616*
Other Activities			-	-	-	-	***16***	***$9,700***
Office of the Commissioner			-	-	-	-	*10*	*$2,000*
Office of Management			-	-	-	-	*6*	*$5,100*
GSA and Other Rent Related Activities			-	-	-	-	*-*	*$2,600*
Subtotal Reinspection User Fee			-	-	-	-	**118**	**$22,000**
Food and Animal Feed Export Certification Fee:			-	-	-	-	*-*	*-*
Center for Food Safety and Applied Nutrition			-	-	-	-	*6*	*$906*
Center for Veterinary Medicine			-	-	-	-	*-*	*$63*
Office of Regulatory Affairs (Foods Program)			-	-	-	-	*17*	*$2,567*
Subtotal Food and Animal Feed Export Cetification Fee			-	-	-	-	**23**	**3,536**
Total Mandatory Proposed User Fees							**141**	**$25,536**

1/ $8,188,000 in PDUFA Carryover Fees will be used to fund the White Oak Consolidation Project in FY 2007. $6,560,000 will fud the fit-out and CDER Move and $1,628,000 will fund the fit-out of the Shared Data Center.

2/ Does not include 83 reimbursable FTE in FY 2005, or an estimated 85 fte in FY 2006 or 2007.

3/ The discretionary budget authority total will decrease to $1,519.813 million upon enactment of proposed mandatory user fees and receipt of estimated collections of $25.536 million. FDA program level funding will remain unchanged.