PERFORMANCE BUDGET IN BRIEF

Introduction

This budget submission presents the proposed budget for fiscal year (FY) 2008 for the Food and Drug Administration (FDA). FDA is an operating division of the U.S. Department of Health and Human Services (HHS). The FDA program level budget request for FY 2008 is $2,084,649,000. This amount is $105,806,000 higher than the President's FY 2007 budget request.

In this Performance Budget in Brief section, FDA presents an overview of the Performance Budget, which includes the statement of the FDA mission, a discussion of the FDA strategic plan, a summary of FDA performance, and an overview of FDA's FY 2008 budget request. The overview of the budget request includes justifications for initiatives in ten high-priority areas:

- **Ensure a Strong FDA: Pay Increase:** $21,773,000 to provide a pay increase for agency personnel, enabling FDA to maintain the strength of the scientific work force that performs FDA's mission

- **Ensure a Strong FDA: Rent:** $29,626,000 to enable FDA to pay General Services Administration (GSA) rental charges for GSA office space that FDA leases as well as other rent and rent-related costs

- **Ensure a Strong FDA: White Oak Consolidation:** $13,256,000 to prepare buildings, equip and outfit facilities, and pay environmental compliance and relocation costs

- **Modernizing Drug Safety:** $11,200,000 to modernize the processes for ensuring the safety of human drugs and biologics products when FDA evaluates new products prior to approval and after products reach the market

- **Strengthening Food Safety:** $10,644,000 to enhance FDA's ability to respond to possible outbreaks of foodborne illness, and to help States, local jurisdictions, and industry mitigate the risks of increased outbreaks, especially those attributed to fresh produce

- **Medical Device Safety and Review:** $7,164,000 to meet performance commitments for medical device review, to improve medical device and patient safety by conducting postmarket device safety analysis and industry outreach on safety issues, and to maintain the required appropriations level for the medical devices user fee program

- **Improving Generic Drugs Review Performance:** $5,561,000 to enhance the generic drug review process and respond to the growing number of generic drug applications submitted to FDA

- **Current Law User Fees:** a net $5,244,000 decrease to enable FDA to review medical products in a timely manner and to reimburse FDA for color certification and export certificate services provided to industry. In FY 2007, PDUFA collections included a one time increase of $31,600,000 for the final year adjustment under the PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by the PDUFA statute. The net decrease in FY 2008 is due to this one-time, non-recurring FY 2007 Final Year adjustment. Because FDA has not completed the public comment period on FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments

- **Proposed Generic Drug User Fee:** $15,701,000 to enhance the review process for generic drug products and to respond to the growing number of generic drug applications

- **Proposed Mandatory User Fees:** $23,276,000 to fund reinspections and $3,741,000 to fund to enable the FDA to issue timely export certifications.

Following the Performance Budget Overview, the Congressional Justification includes the appropriations language and analysis, a summary of base resources and changes, and budget All Purpose Tables. This Congressional Justification also includes tabbed sections that contain narrative descriptions of each of the FDA program areas, performance detail that satisfies FDA's annual performance reporting requirements under the Government Performance and Results Act, supporting budget exhibits, and State facts sheets.

PERFORMANCE BUDGET OVERVIEW

Background

This Performance Budget details the resources FDA needs to address public health challenges in FY 2008. Innovations in science and technology, shifting market trends in regulated industries throughout the global economy, emerging diseases, and other public health threats magnify the importance of FDA's role in protecting and advancing public health. At the same time, budget realities challenge FDA to formulate new approaches to meet the expanding scope and complexity of its public health mission.

These public health 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. During the past 100 years, FDA demonstrated a dedication to principles that have made it the world's "gold standard" for regulating food and medical products:

- dedication to assuring the safety of the products that FDA regulates
- dedication to protecting Americans against persistent and emerging public health threats
- commitment to advancing the public health by empowering consumers to make safe and healthy choices about medicine and nutrition
- commitment to accelerating the development and availability of promising new medical therapies and technologies that will extend and improve lives.

Statement of FDA Mission

FDA affects the lives of every American every day. Consumers spend nearly $1.5 trillion each year on FDA-regulated products, which represents 20 percent of all consumer expenditures. FDA is a scientific regulatory agency that employs more than 10,000 scientific, technical, and support staff who are responsible for protecting and advancing the public health in the United States.

FDA's mission derives from a variety of statutes, beginning with the Pure Food and Drugs Act of 1906 that prohibited interstate commerce in misbranded and

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.

adulterated foods, drinks, and drugs. The Food, Drug, and Cosmetics Act (FD&C Act) of 1938 extended FDA responsibility to cosmetics and medical devices. The FD&C Act also 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&C Act have expanded or clarified FDA responsibilities. For example, the Food Additives Amendment of 1958 required manufacturers of new food additives to establish their safety before marketing. The Delaney proviso prohibited the approval of any food additive shown to induce cancer in humans or animals. In 1962, the Kefauver-Harris Drug Amendments required drug manufacturers to prove to FDA the effectiveness of their products before marketing them.

The FDA mission also expanded in the areas 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. Today, FDA carries out its mission through a diverse range of programs covering foods, human drugs, biologics, medical devices and radiological health, animal drugs and feeds, and toxicological research that supports regulatory programs. FDA also conducts interdisciplinary programs that cross product areas, such as combination products, international programs, pediatric safety, and women's health.

FDA Strategic Action Plan

FDA advances its broad public health mission by working to achieve four comprehensive long-term strategic goals:

1. enhance patient and consumer protection and empower them with better information about regulated products

2. increase access to innovative products and technologies to improve health

3. improve product quality, safety, and availability through better manufacturing and product oversight

4. transform administrative systems and infrastructure to support FDA operations.

FDA has a strategic vision for transforming FDA operations that responds to emerging scientific, technological, and economic trends affecting our regulatory mission. This vision also reflects the principles of productivity and accountability embodied in the President's Management Agenda and the e-Government initiative.

To transform FDA operations, FDA is revising FDA's Strategic Action Plan in FY 2007. The new Strategic Action Plan will include a strategic goal framework that better aligns with FDA regulatory business processes, while simultaneously implementing the new DHHS Performance Management Appraisal Program. FDA developed a single, coherent framework of strategic goals, objectives, and strategies that encompass our annual performance goals and measures and near-term initiatives and action items. As FDA implements the new

DHHS Performance Management Appraisal Program, FDA will systematically assign annual performance goals and near-term action items to individual performance plans. This will ensure coordination and accountability for results.

Table 1 shows how FDA's three core regulatory business processes align with FDA's revised strategic goals.

Table 1: FDA's Core Business Processes Aligned with FDA's Revised Strategic Goals

FDA Core Business Processes	Revised Strategic Goals
Consumer and Patient Safety: Conducting post-marketing surveillance of product use to ensure that safety problems are detected and corrected quickly, and informing the public to ensure that consumers, patients, and health care providers know how to use FDA-regulated products safely	Enhance patient and consumer protection and empower them with better information about regulated products
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	Increase access to innovative products and technologies to improve health
Product Quality, 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	Improve product quality, safety, and availability through better manufacturing and product oversight
[operational support functions]	Transform administrative systems and infrastructure to support FDA operations.

As shown in Table 1, FDA's business processes directly align with and support the work to achieve FDA strategic goals. This provides a straightforward way to link day-to-day FDA activities that accomplish important public health outcomes.

Table 2 (see next page) shows how FDA's strategic goals and objectives align with HHS strategic goals and objectives. The information in table 2, when combined with the alignment of FDA business processes and strategic goals displayed in table 1, demonstrates how FDA activities and outputs help accomplish DHHS goals and initiatives. This, in turn, helps all FDA programs to more effectively implement the DHHS Performance Management Appraisal Program and ensure that individual performance is well-coordinated with FDA performance goals.

Table 2: FDA Strategic Goals and Objectives Aligned With HHS Strategic Goals and Objectives

(In order by FDA Strategic Goal)

FDA STRATEGIC GOALS AND OBJECTIVES		HHS STRATEGIC GOALS AND OBJECTIVES	
1. Enhance patient and consumer protection and empower them with better information about regulated products.	1.1. Improve safe and effective use of medical products with better information technology and effective risk/benefit communication. 1.2 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 other diet-related disease. 1.3 Improve the infrastructure for problem detection and product information dissemination, to strengthen consumer protection and take timely, effective risk management actions with all FDA-regulated products.	5. Improve the Quality of Health Care Services	• Reduce medical errors • Increase consumer and patient use of health care quality information • Improve consumer and patient protections
		4. Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	• Improve coordination, communication, and application of health research results • Strengthen mechanisms for ensuring protection of human subjects & the integrity of the research process
2. Increase access to innovative products and technologies to improve health.	2.1. Increase the number of safe and effective new products available to patients, including products for unmet medical and public health needs, emerging infectious diseases and counterterrorism. 2.2. Sustain availability of safe and effective new and generic products by improving rapid, transparent and predictable science-based review of marking applications. 2.3. Increase access to safe and nutritious food products, including products for unmet human health needs.	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 • Improve the safety of food, drugs, biological products, and medical devices
		4. Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	• Accelerate private sector development of new drugs, biologics therapies, and medical technology • Strengthen mechanisms for ensuring protection of human subjects & the integrity of the research process
3. Improve product quality, safety, and availability through better manufacturing and product oversight.	3.1. Maximize product quality, safety, and availability, by encouraging use of improved manufacturing technologies and product characterization techniques and by modernizing regulatory standards. 3.2. Prevent harm from products by increasing the likelihood of detection and interception of substandard manufacturing processes and products through efficient and effective risk targeting, external partnering, effective internal processes and collaboration.	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 • Improve the safety of food, drugs, biological products, and medical devices
		4. Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	• Improve coordination, communication, and application of health research results • Strengthen mechanisms for ensuring protection of human subjects & the integrity of the research process
4. Transform administrative systems and infrastructure to support FDA operations.	4.1. Strengthen 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 continuing improving. 4.3. Increase capability to efficiently and cost effectively maintain an information technology (IT) environment to support FDA business goals. 4.4. Coordinate and integrate operations to enhance consistency and quality of resource management, and to achieve economies of scale.	8. Achieve Excellence in Management Practices	

Overview of FDA Performance

FDA has a 100-year record of delivering high-level performance in protecting and promoting the public health. In FY 2005, FDA met or exceeded performance targets on 40 out of 43 (93 percent) performance goals where results are have been reported. FDA is still waiting for final data on one application review goal in the Medical Device Program. However, we expect to meet that goal as well when the data becomes final.

In FY 2006, FDA met 100 percent of the performance goals in cases where final results have been reported. There are fifteen FY 2006 performance goals that have not been reported on yet, but FDA continues to expect excellent performance as the data becomes available.

FDA met all of its inspection goals. Work conducted under these goals helps protect the public from harm by monitoring manufacturer compliance with safety and quality standards. FDA also met all but two of its marketing application review goals. These goals help bring to market safe and effective new products that enhance and extend life.

Explanations for Unmet Goals

Voluntary National Retail Food Program Standards (Foods Program) – The FY 2005 actual data for this goal showed improvement compared to the FY 2004 actual data. However, FDA narrowly missed the target because changes in one state's legislation did occur in time to adopt the Food Code during fiscal year 2005.

Priority New Drug Application (NDA) Review (Human Drugs Program) – In FY 2005, FDA fell just short of the performance goal for priority review of NDAs and Biologic Licensing Applications. Out of 32 priority applications filed, 4 missed their review goal, resulting in a success rate of 88 percent, compared to the target of 90 percent. Three of the four applications were submitted by the same company. Complex inspection issues with the company arose during the course of review. These inspection issues extended beyond the scope of these three applications, and prohibited FDA from taking a regulatory action until the issues were resolved.

Generic Drug Application Review (Human Drugs Program) – In FY 2005, FDA's Office of Generic Drugs (OGD) reviewed and acted upon 66 percent of 766 Abbreviated New Drug Applications (ANDAs), the applications used for generic drugs. This performance is short of the performance target of 90 percent. The primary reason for this performance level is the dramatic workload increase in the past few years. FDA experienced a 36 percent increase in the number of applications received between FY 2004 and FY 2005. This is part of a recent trend in which the number of applications received annually increased by 120 since FY 2002. FDA's FY 2008 budget request includes additional resources for OGD to address this increased workload. In the mean time, FDA has made important advances in the generic drug program to improve program efficiency and effectiveness. Despite a record number of new applications in FY 2006, FDA is making great strides in meeting and possibly exceeding FDA's target of approving or tentatively approving the fastest 70 percent of applications within an average of 16.4 months. In FY 2006, OGD also approved or tentatively approved a record 510 ANDAs. Moreover, 64 of those approvals occurred in the first review cycle, which avoids the delays that happen when

manufacturers must resubmit their application to address deficiencies. This first-cycle review performance represents an increase from 27 first-cycle approvals in FY 2005 and 3 first-cycle approvals in FY 2004. This improvement was a result of an increased effort by FDA to advise industry on how to submit more complete applications, increased direct communication with firms during the review process, and continuing efforts to ensure that FDA review staff are fully trained and mentored to increase their effectiveness and productivity.

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 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 use performance information to support resource allocation and other management decisions.

Overview of FDA's Budget Request

The Food and Drug Administration (FDA) program level budget request for FY 2008 is $2,084,649,000 which is $105,806,000 higher than the President's FY 2007 budget request. This budget request, which is funded through new budget authority and current law and proposed user fees, supports the President's public health and bioterrorism initiatives and Secretary Leavitt's 500-Day priorities.

Impact of a FY 2007 Continuing Resolution

The FY 2008 budget submission assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for FDA. For comparison purposes, the budget tables include a column that reflects an FY 2007 funding level under the current Continuing Resolution. This column permits comparisons in the event that Congress enacts appropriations at the current level of funding for the remainder of FY 2007.

If FDA receives the Continuing Resolution level of funding rather than the FY 2007 President's budget request, this represents an eight percent reduction in program resources. Such a funding decrease will have significant impact on FY2008 performance:

- FDA program areas will be forced to absorb non-discretionary increases in pay and benefit costs, GSA and other rent, and FDA consolidation at White Oak, which will significantly limit FDA's ability to perform its vital public health mission.

- FDA's food and medical product safety programs will have a limited ability to ensure the safety of the food supply and the safety and effectiveness of the medical products that FDA regulates and Americans rely upon each day.

- FDA will be unable to meet the statutory triggers for the Animal Drug User Fee Act (ADUFA) and the Medical Device User Fee and Modernization Act (MDUFA), which will mean that these fee programs will terminate.

Effects of Proposed Legislation

The FY 2008 budget submission assumes the passage of proposed legislation. In FY 2008, FDA requests authorization for three new user fees (two of which are being re-proposed from the FY 2007 President's Budget), and the reauthorization of three current law user fees. Total revenue from the proposed generic drug user fee and the current law user fees is $443,990,000. This represents 21.3 percent of FDA's total program level request of $2,084,649,000.

The new generic drug user fee will enhance the review process for Abbreviated New Drug Applications (ANDAs) for generic drug products and respond to the growing number of generic drug applications. In FY 2008, the estimated revenue from this user fee is $15,701,000.

The two proposed user fees are a reclassification of resources from discretionary budget to mandatory user fees. The first will reimburse FDA for reinspections of FDA-regulated facilities. Estimated revenue for FY 2008 is $23,276,000. The second proposed user fee reimburses FDA for issuing of food and feed export certificates. Estimated revenue for FY 2008 is $3,741,000.

In addition, FDA is also requesting reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). These statutes expire at the end of 2007. In FY 2008, revenue from PDUFA is estimated at $339,195,000 and revenue from MDUFMA is estimated at $47,500,000.

FY 2008 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 goals and priorities. FDA leadership established criteria to evaluate FY 2008 budget priorities based on whether they generate high-yield returns, advance the Secretary's 500-Day Priorities and DHHS strategic goals, and meet agency-wide public health priorities. After conducting this exercise and identifying priority initiatives, FDA leaders employed marginal cost principles to determine appropriate funding levels.

The FY 2008 program level increase of $105,806,000 will enable FDA to fund five urgent public health priorities: ensuring a strong FDA (which includes a pay increase, GSA rent, other rent, and consolidation at White Oak), modernizing drug safety, strengthening food safety, strengthening medical device safety and review, and improving generic drugs review performance. The FY 2008 program level also provides for increases to current law user fees and implements a new generic drug user fee. To partially fund these priorities and other important activities, FDA is proposing a reduction of resources in the areas of outreach, coordination, and research.

FDA's public health initiatives directly contribute to the Secretary's 500-Day Priorities, including transforming the health system and securing the homeland. The FY 2008 budget request will also enable FDA to advance important Presidential priorities, such as healthcare reform, healthier living, securing the homeland, Project Bio-Shield, the President's Emergency Plan for HIV/AIDS relief, and facilitating high quality and efficient health care.

FY 2008 Initiatives

Table 3 provides an overview of FDA's 2008 initiatives. The table identifies specific funding and FTE levels for each initiative, as well as synopsis of the initiative.

Table 3 - Overview of FY 2008 Initiatives

Initiative	Amount	FTE	Synopsis
Budget Authority			
Ensure a Strong FDA: Pay Increase	$21,773,000	0	Provide a pay increase for agency personnel, enabling them to conduct the FDA mission
Ensure A Strong FDA: Rent	$29,626,000		Enable FDA to pay GSA rental charges as well as other rent and rent related costs
Ensure A Strong FDA: White Oak Consolidation	$13,256,000		Provide funding to prepare buildings, equip and outfit facilities, and pay environmental compliance and relocation costs
Modernizing Drug Safety	$11,200,000	25	Modernize the processes for ensuring the safety of human drug products before FDA approval and after products reach the market
Strengthening Food Safety	$10,644,000	15	Strengthen FDA's ability to respond to possible foodborne outbreaks and assist industry mitigate the risks of increased outbreaks, especially those attributed to fresh produce
Medical Device Safety and Review	$7,164,000	0	Maintain medical devices user fee program and meet performance commitments negotiated with industry; strengthen device and patient safety by conducting postmarket device safety analysis and industry outreach on safety issues
Improving Generic Drug Review Performance	$5,561,000	13	Enhance the review process and respond to the growing number of generic drug applications
Outreach, Coordination, and Research Reduction	($3,875,000)	0	Reallocation of resources to high priority activities proposed in the FY 2008 budget
Current Law & Proposed User Fees			
Current Law User Fees	($5,244,000)	9	Enable FDA to review medical products in a timely manner and reimburse FDA for color certification and export certificates provided to industry[1]
Proposed Generic Drug User Fee	$15,701,000	34	Enhance the review process for Abbreviated New Drug Applications (ANDAs) for generic drug products and respond to the growing number of generic drug applications
Total Program Level	***$105,806,000***		
Proposed Mandatory User Fees (Non-Add)			
Reinspection User Fee	$23,276,000 (Non-Add)	118	Re-proposed new user fees to reimburse for reinspection of FDA-regulated facilities
Food and Animal Export Certification User Fee	$3,741,000 (Non-Add)	23	Re-proposed new user fees to reimburse for issuing food and feed export certificates
Total Proposed User Fees	***$27,017,000***		

[1] In FY 2007, PDUFA collections included a one time increase of $31,600,000 for the final year adjustment under the PDUFA III. For FY 2008, adjustments include increases for inflation and other increases authorized by the PDUFA statute. The decrease in FY 2008 is due to this one-time, non-recurring FY 2007 Final Year adjustment. Because FDA has not completed the public comment period regarding FDA's proposed recommendations for PDUFA reauthorization, the FY 2008 PDUFA estimate is based on straight reauthorization of PDUFA III with no programmatic enhancements or adjustments.

The targeted initiatives identified in table 3 will yield high public health impact while enabling FDA to meet its human capital and infrastructure needs.

More detailed information regarding each of FDA's FY 2008 initiatives can be found in the budget (business case) papers that follow. These papers include a description of the initiative, its public health impact, the risks of not funding the initiative, detailed information on the activities in the initiative, and the results that will be achieved.