# EXECUTIVE SUMMARY

## Introduction and Mission

The Food and Drug Administration (FDA), an agency of the Department of Health and Human Services, is responsible for protecting the public health by assuring the safety of America's foods, the safety, efficacy, and security of human and veterinary drugs, the safety of biological products and medical devices, and the safety and security of cosmetics and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines safer and more effective. FDA also provides the public with accurate, science-based information about medicines and foods to improve their health. Finally, FDA plays a significant role in protecting the homeland by ensuring the safety and security of the food supply.

FDA affects the lives of every American every day. Each year, consumers spend nearly $1.5 trillion on FDA-regulated products. This represents 20 percent of all consumer expenditures. FDA is a scientific regulatory agency that employs more than 10,000 scientific, technical, and professional staff to protect and advance public health.

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&C Act) of 1938 extended FDA responsibility to cosmetics and therapeutic medical devices. The FD&C Act also granted FDA important new authorities, including the requirement that manufacturers demonstrate the safety of drugs before they are marketed.

Over the years, Congress expanded FDA's regulatory responsibilities to cover food additives, medical devices, and blood and vaccine products. FDA's mission also expanded in the area of counterterrorism and homeland security under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Project Bioshield Act of 2004. Most recently, the FDA Amendments Act of 2007 reauthorized user fees for prescription drugs and medical devices and provided new authority to promote development of safe and effective treatments for children, enhance drug safety, and ensure food safety.

Today, FDA carries out its mission through a diverse range of programs related to foods, human drugs, biologics, medical devices and radiological health, animal drugs and feeds, toxicological research that supports FDA's regulatory programs. FDA also operates interdisciplinary programs such as combination products, international programs, products to treat pediatric patients, and women's health.

In 2003, the Office of Management and Budget (OMB) assessed FDA programs. FDA received a moderately effective rating. The OMB review cited five major attributes about FDA's regulatory program:

- 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 measures performance results and 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 since with FY 2003.
- FDA is improving collaborative efforts with stakeholders and other Federal agencies.

OMB encouraged FDA to develop long-term outcomes related to the FDA mission. FDA completed this assignment and achieved progress on a group of Long Term Outcome Goals. During 2005, FDA began to develop a new efficiency measure related to human drug safety surveillance. Under the Prescription Drug User Fee Program, FDA conducted studies to evaluate the new human drug review program. FDA expects that these studies will improve the efficiency and effectiveness of new human drug review. The studies will also contribute to FDA achieving long-term outcome goals for new drug approval. FDA also improved processes that will increase the productivity of the generic drugs program. During 2007, FDA reinvigorated its strategic planning process to ensure that annual performance goals align with a coherent framework of strategic and long-term outcome goals. For more information on programs evaluated based on the PART process, see www.ExpectMore.gov.

## FY 2009 Budget Overview

The fiscal year (FY) 2009 President's Budget request for FDA is $2,399,633,000. This represents a total program level increase of $129,702,000 above the amount enacted into law for FY 2008. The total program level request includes new budget authority, current law user fees, and new proposed user fees. The FY 2009 increase for user fees is $78,993,000. The FY 2009 increase in budget authority is $50,709,000, of which $25,000,000 is for the cost of living pay increase.

The FY 2009 budget supports the Administration's November 6, 2007, Action Plan for Import Safety, the President's Management Agenda, the President's Emergency Plan for AIDS Relief, the President's Initiative to Secure the Homeland, the FDA Food Protection Plan, and HHS Priorities for personalized health care, prevention, and preparedness. The budget request will also allow FDA to fulfill its many responsibilities that advance medical product safety and development.

The following information summarizes the FDA budget changes for FY 2009.

### FY 2009 Increases

Foods Program: The FY 2009 budget contains a program level increase of $32.7M (+$32.7M in budget authority). The increase contains funds to implement the activities and achieve the performance commitments in the FDA Food Protection Plan. This increase also includes the

cost of living pay increase for FDA workforce at the Center for Food Safety and Applied Nutrition (CFSAN) and the workforce that conducts the Field Foods Program in the Office of Regulatory Affairs (ORA).

Human Drugs Program: The FY 2009 budget contains a program level increase of $58.5M (+$4.7M in budget authority; +$53.8M in user fees). The increase contains funds to implement the Medical Products Safety and Development Initiative. Specifically, the increase supports the ability of ORA Field components to implement targeted import safety activities. The increase also includes the cost of living pay increases for FDA workforce at the Center for Drug Evaluation and Research (CDER) and the ORA workforce in the Human Drugs Program. Finally, the increase includes additional user fees (+$53.8M in user fees) to meet performance commitments under the Prescription Drug User Fee Act and the proposed authorization of user fees for generic drug review.

Biologics Program: The FY 2009 budget contains a program level increase of $9.5M (+$2.9M in budget authority; +$6.6M in user fees). The increase contains funds to implement the Medical Products Safety and Development Initiative. Specifically, the increased supports enhancements for the Human Tissue and Blood Safety Programs. The increase also includes the cost of living pay increase for FDA workforce at the Center for Biologics Evaluation and Research (CBER) and the ORA workforce in Biologics Program. Finally, the increase includes additional user fees (+$6.6M in user fees) to meet performance commitments based on the reauthorization of the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

Animal Drugs and Feeds Program: The FY 2009 budget contains a program level increase of $10.8M (+$6.5M in budget authority; +$4.3M in user fees). The increase contains funds to implement the activities and achieve the performance commitments under the FDA Food Protection Plan. The increase also contains funds to carry out the provisions of the Minor Use and Minor Species (MUMS) Animal Health Act, which is a component of the FY 2009 Medical Product Safety and Development Initiative. The increase also includes the cost of living pay increase for FDA workforce at the Center for Veterinary Medicine (CVM) and the ORA workforce in the Animal Drugs and Feeds Program. Finally, the increase also includes funds (+$4.3M in user fees) to meet performance commitments under the Animal Drug User Fee Act and the proposed Animal Generic Drug User Fee program.

Devices and Radiological Health Program: The FY 2009 budget contains a program level increase of $7.1M (+$3.9M in budget authority; +$3.2M in user fees). The increase includes funds for ORA field workforce in the Device Program to perform targeted activities under the Action Plan for Import Safety. The increase also includes the cost of living pay increase for FDA workforce at the Center for Devices and Radiological Health (CDRH) and the ORA workforce in the Devices Program. Finally, the increase includes user fees (+$3.2M in user fees) to meet performance commitments based on the Mammography Quality Standards Act and the reauthorization of the Medical Device User Fee and Modernization Act.

National Center for Toxicological Research (NCTR): The FY 2009 budget contains a program level increase of $1.8M. The increase contains funds for NCTR research activities that support the FDA Food Protection Plan. The increase also includes cost of living pay increases for the FDA workforce at NCTR.

Headquarters and Office of the Commissioner: The FY 2009 budget contains a program level increase of $5.8M (+$1.9M in budget authority; +$3.9M in user fees). The increase contains funds to enhance FDA's emergency preparedness and coordination capabilities, in support of the Food Protection Plan and other FDA programs. The increase also includes the cost of living pay increase for FDA workforce in the Office of the Commissioner. Finally, the increase includes additional user fees (+$3.9M in user fees) to support units in the Office of the Commissioner that conduct work to support user fee programs.

Buildings and Facilities: The FY 2009 budget contains a program level decrease of $3.7M (–$3.7M in budget authority). The reduction in this program reflects the discontinuation of a program begun in FY 2008. Under this reduction, the base funding carried over into FY 2009 due to Section 734 of Consolidated Appropriation Act, 2008 (PL 110-161) is redeployed to fund FDA priority initiatives.

## FDA FY 2009 Priorities

FDA is proposing six initiatives for FY 2009: Protecting America's Food Supply, Modernizing Medical Product Safety and Development, Administrative Savings and Management Efficiencies, Current Law User Fees, and two proposed medical product user fees (Generic Drug Review and Animal Generic Drug Review). FDA is also proposing user fees to reinspect facilities that fail to meet Good Manufacturing Practices and to pay the cost of export certifications for food and feed. These initiatives lay the foundation for meeting the President's and Secretary's health priorities. The initiatives permit FDA to achieve its performance commitments, preserve FDA user fee programs, and meet comprehensive FDA public health responsibilities. The following is a synopsis of the six initiatives.

**Protecting America's Food Supply Initiative (+$42,232,000)**

FDA is responding to food defense and food safety challenges with the Food Protection Plan (FPP), a risk-based, production-to-consumption strategy announced on November 6, 2007. The FPP will help ensure the safety of domestic and imported food. FPP integrates food and feed safety with food and feed defense.

The Protecting America's Food Supply initiative provides essential resources to implement the FPP. The initiative also includes $12,038,000 for the cost of living pay increase for the FDA food defense and food safety programs.

The FDA strategy under the Protecting America's Food Supply initiative focuses on preventing foodborne illness outbreaks, intervening when vulnerabilities surface or problems emerge, and rapidly responding to threats. With the investments in this FY 2009 initiative, FDA will work with the Department of Homeland Security, the U.S. Department of Agriculture, the Centers for Disease Control and Prevention, state, local, and foreign governments, and the domestic and international food industry to safeguard America's food and the national infrastructure of vital food commodities.

The FDA Protecting America's Food Supply Initiative will allow FDA to achieve significant food protection accomplishments under the FDA Food Protection Plan in FY 2009 and FY 2010. These accomplishments will provide a foundation for substantially reducing illnesses caused by contamination of the food supply in the following years.

**Modernizing Medical Product Safety and Development Initiative (+$17,395,000)**

The Medical Product Safety and Development Initiative advances FDA's core responsibility to protect the public health. The initiative allows FDA to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, and animal drugs and medicated feed. The investments in this initiative will increase FDA's ability to monitor the safety of medical products, including imported products.

In addition to assuring safety, the FDA mission to promote public health requires that we assist medical product manufacturers as they develop new products to treat life-threatening diseases and conditions. The investments in this initiative allow FDA to help innovators overcome product development challenges and maintain America's world leadership in medical innovation. The initiative also includes $12,962,000 for the cost of living pay increase for FDA's medical product programs.

The Medical Product Safety and Development initiative will promote the safety of medical products used to prevent, treat, and cure serious diseases and conditions. The initiative allows FDA to meet the priorities for the Action Plan for Import Safety, Project Bioshield, and the President's Emergency Plan for AIDS Relief.

**Administrative Savings and Management Efficiencies (-$8,918,000)**

FDA is redirecting productivity savings to fund FY 2009 priority initiatives. These savings flow from management efficiencies due to reengineered business processes, streamlined administrative services, and past investments in information systems. Under this initiative, FDA is also reallocating base funding carried over into FY 2009 due to Section 734 of Consolidated Appropriation Act, 2008 (PL 110-161).

**Current Law User Fees: + $57,534,000**

Three FDA user fees programs facilitate premarket review for human and animal drugs and human devices. Three other user fee programs support the mammography facilities inspection program and provide certification services for color additives and for drug and device products exported from the United States.

The budget request includes inflationary increases for FDA user fee programs as well as other increases authorized by law under the prescription drug and medical device user fee programs. The increase for the Prescription Drug User Fee program also includes $14,000,000 to support a program authorized by Congress to collect user fees from companies that seek FDA advisory review of their Direct-to-Consumer (DTC) television advertising for drug products.

The Animal Drug User Fee Act (ADUFA) will expire on September 30, 2008, and must be reauthorized. The FY 2009 amount for ADUFA only reflects a current law inflationary increase.

**Proposed Generic Drug User Fee: + $16,628,000**

The proposed user fee for Generic Drug Review will provide additional resource to improve generic drug review process and to respond to the growing number of generic drug applications.

**Proposed Animal Generic Drug User Fee: +$4,831,000**

The proposed user fee for Animal Generic Drug Review will provide additional resources to improve the animal generic drug review process and to respond to the growing number of Abbreviated New Animal Drug Applications.

**Proposed Reinspection User Fee: +$23,276,000[1]**

The proposed reinspection user fee will cover the cost to reinspect FDA-regulated facilities that fail to meet good manufacturing practices or related FDA requirements. FDA currently funds these inspections through discretionary appropriations.

**Proposed Food and Animal Feed Export Certification User Fee: +$3,741,000[2]**

The proposed user fee for Food and Animal Feed Export Certificates allows FDA to collect user fees for issuing food and animal feed export certificates within 20 days of receiving a request for an export certificate. FDA currently funds these inspections through discretionary appropriations.

**FDA Business Case for the FY 2009 Initiatives**

The FDA business case papers justifying the funding requests for these initiatives appear below. The business case papers describe the need for the funding, the specific activities that FDA will fund, the risks of not funding the initiatives, how the initiatives support public health priorities, and the projected annual accomplishments under the initiatives.

[1] The FY 2009 budget includes budget authority to fund reinspection activities. Upon enactment of the user fee legislation, user fee receipts will offset the budget authority for reinspections.

[2] The FY 2009 budget includes budget authority to fund export certificate activities for food and animal feed. Upon enactment of the user fee legislation, user fee receipts will offset the budget authority for food and animal fees certificates.