HEADQUARTERS AND OFFICE OF THE COMMISSIONER[1]

Introduction

FDA's Headquarters and Office of the Commissioner Program summarizes the budget program requirements that justify a $121,947,000 request for FY 2008. The Headquarters and Office of the Commissioner program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Headquarters and Office of the Commissioner
- effects of the full year FY 2007 continuing resolution on the Headquarters and Office of the Commissioner Program
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Headquarters and Office of the Commissioner Program funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 budget request.

Headquarters and Office of the Commissioner Program Funding Table

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 - President's Budget	FY 2008 President's Budget	Increase or Decrease
Program Level	**$103,886,000**	**$100,636,000**	**$119,427,000**	**$121,947,000**	**$2,520,000**
FTE	**672**	**614**	**661**	**663**	**2**
Budget Authority	**$85,676,000**	**$85,591,000**	**$88,197,000**	**$88,577,000**	**$380,000**
Pay Increase	--	--	--	*$1,457,000*	*$1,457,000*
Strengthening Food Safety Outreach, Coordination and Research Reduction	--	--	--	*($1,721,000)*	*($1,721,000)*
Total FTE	**532**	**501**	**517**	**518**	**1**
User Fees	**$18,210,000**	**$15,045,000**	**$31,230,000**	**$33,370,000**	**$2,140,000**
PDUFA	*$14,829,000*	*$14,829,000*	*$25,397,000*	*$26,547,000*	*$1,150,000*
MDUFMA	*$2,654,000*	*$0*	*$4,921,000*	*$5,346,000*	*$425,000*
ADUFA	*$493,000*	*$0*	*$696,000*	*$732,000*	*$36,000*
MQSA	*$234,000*	*$216,000*	*$216,000*	*$227,000*	*$11,000*
Proposed User Fees					
Generic Drugs				*$518,000*	*$518,000*
Total FTE	**140**	**113**	**144**	**145**	**1**

[1] This is the new name for the Other Activities budget line.

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2004 Actuals	$114,296,000	$98,597,000	$154,699,000	709
2005 Actuals	$104,504,000	$87,230,000	$15,499,000	652
2006 Actuals	$103,886,000	$85,676,000	$18,210,000	672
2007 Continuing Resolution	$100,636,000	$85,591,000	$15,045,000	614
2007 President's Budget	$119,427,000	$88,197,000	$31,230,000	661
2008 President's Budget	$121,947,000	$88,577,000	$33,370,000	663

Statement of Budget Request

The Headquarters and Office of the Commissioner Program is requesting $121,947,000 in program level resources for accomplishing its mission activities, including:

- providing centralized program direction and management services for agency programs to ensure FDA’s public health hazard prevention efforts are effectively managed within its regulatory framework
- providing management expertise and direction to support standards development for regulated products to effectively serve consumers and our industry stakeholders
- developing agency-wide policy in legislation, consumer communications, public information, scientific coordination, and regulatory requirements
- providing direction in the management of financial, human, and information systems resources; knowledge management; and other critical infrastructure needs in support of FDA’s science-based work.

Program Description

The Headquarters and Office of the Commissioner Program provides agency-wide program direction and administrative services to ensure that FDA's consumer protection efforts are effectively managed and that available resources are put to the most efficient

use. The Office of the Commissioner consists of nine subordinate offices that provide policy making, program direction, coordination and liaison, and expert advice to agency leadership and programs. The following table provides a description of each office's functions.

OC Office	Description
Office of the Chief Counsel	Provides expert legal advice and review on statutory and regulatory interpretations affecting FDA enforcement and administrative actions.
Office of Crisis Management	Serves as FDA's focal point for coordinating emergency and crisis response activities, counterterrorism response, interagency and intra-agency coordination of emergency and crisis planning and management, and internal and external security.
Office of External Relations	Advises FDA leadership on activities and issues affecting FDA programs, projects, and strategies impacting on various constituencies – including the public, consumer groups, industry and trade associations, stakeholders, and governmental bodies.
Office of International Affairs and Strategic Initiatives	Serves as FDA's primary focal point on international activities, including negotiating and managing bilateral agreements; coordinating and participating in international harmonization activities; and coordinating and supporting multilateral organizations. Administers the combination products and pediatric therapeutics programs.
Office of Legislation	Coordinates FDA's response to authorizing committees' requests, reviews proposed legislation, prepares agency testimony, and facilitates clearance by the Department and the Office of Management and Budget (OMB).
Office of Management	Provides a variety of administrative and program support services, assures strategic and operational management of information technology, financial management expertise, and administrative support services to FDA programs.
Office of Policy and Planning	Provides advice and assistance in policy development and oversees FDA rulemaking; serves as the focal point for coordinating agency strategic, performance and business-process planning and evaluation; ensures that internal and external stakeholders clearly understand FDA's challenges, achievements, and future directions.
Office of Science and Health Coordination	Advises key officials on scientific issues that impact policy, direction, and long-range goals; and coordinates the responsibilities for women's health issues, good clinical practices program, and orphan product development program.
Office of Counterterrorism Policy and Planning	Provides focused leadership for FDA on the development and implementation of policies on counterterrorism and other emerging threats. Includes policies to safeguard food and medical products from intentional adulteration or disruption of supplies, and policies to facilitate the availability of safe and effective medical countermeasures.

Effects of the Full Year FY 2007 Continuing Resolution

The analysis in this justification assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for Headquarters and the Office of the Commissioner. For comparison purposes, FDA budget tables also include a column in the FDA budget tables that reflects an FY 2007 Continuing Resolution (CR) level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this 25 percent reduction in workforce and 21 percent reduction in resources will have significant impact on FY 2007 performance for Headquarters and the Office of the Commissioner:

- establishment of hiring freezes, including consideration of other personnel reduction actions
- reduced support to critical FDA programs causing delays in project and product review schedules
- elimination of planned infrastructure enhancements
- disruptions to the development of new programs, specifically Critical Path
- delays in response time for the Office of Crisis Management
- delays in communicating information to the public.

If FDA receives the CR level of funding rather than the FY 2007 President's Budget request, this will have the following impact on FY 2008 performance for the Headquarters and Office of the Commissioner Program:

- reduction of performance targets – e.g., number of combination products reviewed
- modified planned infrastructure outcomes for FY 2008 – such as system rollouts, infrastructure enhancements and equipment procurements – to account for activities not performed in FY 2007
- reprioritization of activities within shared service functions to address personnel losses during FY 2007
- less than optimum levels for high response activities such as Crisis Management as they strive to replenish reduced staffing levels
- missed performance goals by User fee programs because support systems will not reach necessary function levels until the end of the year.

Program Resource Changes

Budget Authority

Pay Increase: +$1,457,000

The FDA's request for pay inflationary costs is essential for FDA to accomplish its public health mission. Eighty percent of FDA's budget supports the agency's workforce. Of this, payroll costs account for almost sixty percent of the total budget. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. The total estimate for pay increases is $21,773,000. The Headquarters and Office of the Commissioner Program portion of this increase is $1,457,000. These resources are vitally important for FDA to fulfill its mission to

protect the public health by developing sound regulatory policy and by responding to emergencies and counterterrorism concerns, Secretarial and Presidential initiatives, and other priority public health concerns.

Strengthening Food Safety: +$644,000 and +1 FTE
FDA proposes a total of $10,644,000 for food safety activities, $644,000 of which is for the Office of Crisis Management (OCM), to enhance FDA's ability to help industry mitigate the risks of increased foodborne outbreaks. The resources would also improve FDA's ability to protect the public health by enhancing its ability to respond to possible foodborne outbreaks. The request would improve emergency response efforts by enhancing OCM's Geographic Information System (GIS) mapping and providing additional personnel to help manage the FDA Emergency Operations Center infrastructure.

Outreach, Coordination, and Research Reduction: - $1,721,000
This proposed reduction reallocates resources from lower priority activities to higher priority activities proposed in the FY 2008 budget. FDA must ensure its resources are used for maximum public health impact. This requires FDA to make funding decisions based on risk-based prioritization of needs. FDA diligently assessed research and outreach activities under the Headquarters and Office of the Commissioner Program and proposes a reduction of $1,721,000 in FY 2008. This reduction contributes to the FDA's ability to fund cost of living pay increases, medical product and food safety initiatives, and rent increases in FY 2008.

User Fees

Current Law User Fees

Prescription Drug User Fee Act (PDUFA): +$1,150,000
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. . 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.

In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress renewed FDA's authority to the collect PDUFA user fees. This authority is effective for five years and directs FDA to strengthen and improve the process for the review of human drugs and to improve risk management for drugs approved under PDUFA. The authority to collect fees under PDUFA expires on September 30, 2007.

Proposals to reauthorize PDUFA are currently under discussion. The PDUFA user fee is expected to bring in $339,195,000 in FY 2008 collections, with the Headquarters and the Office of the Commissioner's increase being $1,150,000, for a total of $26,547,000.

These FY 2008 amounts assume that the current authorities in effect for PDUFA III continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes PDUFA IV and establishes new performance goals and fee levels.

PDUFA user fees help Headquarters and the Office of the Commissioner perform three activities:

- providing resources for the Office of Combination Products and Office of Pediatric Therapeutics for PDUFA activities

- supporting the financial, legislative, and administrative functions of user fee programs, including setting fees and collecting and managing user fee revenue

- preparing the annual PDUFA Performance and Financial Reports to Congress.

Medical Device User Fee and Modernization Act (MDUFMA): +$425,000 and +1 FTE
Enacted in 2002, MDUFMA improves the quality and timeliness of the medical device review. It authorizes FDA to collect user fees to supplement appropriations for the medical device review program. FDA collects fees from device manufacturers that submit premarket applications and premarket notifications. The authority to collect fees under MDUFMA expires on September 30, 2007.

Proposals to reauthorize MDUFMA are currently under discussion. The MDUFMA user fee is expected to bring in $47,500,000 in FY 2008 collections, with the Headquarters and Office of Commissioner's increase being $425,000, for a total of $5,346,000. These FY 2008 amounts assume that the current authorities in effect for MDUFMA continue in FY 2008. FDA may need to amend its budget request when Congress reauthorizes MDUFMA and establishes new performance goals and fee levels.

MDUFMA user fees help Headquarters and the Office of the Commissioner perform three activities:

- providing resources for the Office of Combination Products and Office of Pediatric Therapeutics for MDUFMA activities

- supporting the financial, legislative, and administrative functions of user fee programs, including setting fees and collecting and managing user fee revenue

- preparing the annual MDUFMA Performance and Financial Reports to Congress.

Animal Drug User Fee Act (ADUFA): + $36,000
Enacted in November 2003, ADUFA helps the FDA, through a strengthened animal drug premarket review program, to provide greater public health protection by ensuring that animal drug products that receive FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption. ADUFA will help provide a cost-efficient, high quality animal drug review process that is predictable and performance driven.

The ability to collect ADUFA user fees expires on September 30, 2008. The statute authorizes fee collection to include up to three months of operating costs to carry over into FY 2009. To achieve this carry over reserve and factor in the inflation levels allowed by statute, an increase of $2,092,000 in FY 2008 fee collections is required, for a total of $13,696,000. The Headquarters and the Office of the Commissioner portion of the ADUFA increase is $36,000, for a total of $732,000.

ADUFA user fees help Headquarters and the Office of the Commissioner perform three activities:

- supporting the financial, legislative, and administrative functions of user fee programs, including setting fees and collecting and managing user fee revenue

- allowing the program to operate if reauthorization is not completed by September 30, 2008

- preparing the annual ADUFA Performance and Financial Reports to Congress.

Mammography Quality Standards Act (MQSA): +$11,000
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 requires FDA to inspect facilities annually to ensure compliance with national quality and safety standards.

MQSA user fees help Headquarters and the Office of the Commissioner support the financial, legislative, and administrative functions for user fee programs, including setting fees and collecting and managing user fee revenue.

Proposed User Fees

Generic Drugs: +$518,000
Applications to market generic drugs, Abbreviated New Drug Applications (ANDAs), are critical to lowering federal spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled.

This proposal is to modify the Food, Drug, and Cosmetic Act to establish user fees for each new application and annually for approved generic products. The additional resources generated by the proposed generic drug user fees would allow FDA to reduce the time to conduct reviews of ANDAs and respond to the growing number of generic drug applications.

The Headquarters and the Office of the Commissioner component of this user fee is $518,000. These funds will be used will be used to develop a user fee tracking system. Based on FDA's past experience with user fees, such a system is necessary to ensure the smooth tracking and reporting of the user fees, a necessary requirement of the program.

Justification of Base

The Justification of Base describes the activities FDA plans to accomplish under the FY 2008 request. The Headquarters and Office of the Commissioner Program supports a wide variety of regulatory program management, policy development, and related support activities covering the entire agency. Several programs are housed in the Office of the Commissioner and were created by the Congress.

Unlike previous version of this budget that arrayed the justification by FDA strategic goals, for the FY 2008 submission, FDA is showcasing the justification in five broad areas:

- Regulatory Programs
- Policy, Outreach, and Response
- Scientific Coordination
- Program Enabling
- Administrative Supporting.

Within each of these categories are similar offices whose activities are described in the following justification. The chart below displays the five areas of the Headquarters and Office of the Commissioner Program, and shows their broad support for FDA's strategic goals.

	FDA Strategic Goals			
	Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products	Increase Access to Innovative Products and Technologies to Improve Health	Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight	Transform administrative systems and infrastructure to support FDA operations.
Program Area				
Regulatory Programs	X	X	X	
Policy, Outreach, and Response	X	X	X	
Scientific Coordination	X	X	X	
Program Enabling	X	X	X	
Administrative Supporting				X

The Headquarters and Office of the Commissioner areas support all of FDA's strategic goals:

- The program areas covering Regulatory Programs; Policy, Outreach, and Response; Scientific Coordination; and Program Enabling support FDA's strategic goals of increasing access to innovative products and technologies to improve health; improving product quality, safety and availability through better manufacturing and production oversight; and enhancing patient and consumer protection and empowering them with better information about regulated products

- The program area covering the Administrative Supporting supports FDA's strategic goal of transforming administrative systems and infrastructure to support FDA operations.

Regulatory Programs

Within the Office of the Commissioner, there are three regulatory programs that address orphan products development, combination products, and pediatric therapeutics. Two of these functional activities are described below. The justification of base activities of the Orphan Products Development program is provided in a separate stand-alone presentation after the Human Drugs budget narrative. Regulatory programs support FDA's strategic goals and Secretary's priority of transforming health through improved regulatory processes and enhanced communications to patients and health professionals. Under the Regulatory programs, the Headquarters and Office of the Commissioner plan to conduct activities in the following offices:

Office of Combination Products (OCP)
OCP is a statutorily mandated Office. OCP has five primary activities:

- conducting the FDA product jurisdiction program
- facilitating the timely and effective premarket review of combination products
- ensuring consistent and appropriate postmarket regulation of combination products
- developing cross-cutting regulations, guidance documents, procedures and processes to clarify the regulation and assignment of combination products
- serving as FDA's primary focal point on matters related to combination products for internal and external stakeholders.

Office of Pediatric Therapeutics (OPT)
OPT has five areas of primary Agency responsibility: pediatric ethics, safety review and reporting for certain pediatric products, agency-wide scientific coordination of all pediatric issues, external communications regarding pediatric products regulated by FDA, and managing and coordinating the use of the Pediatric Advisory Committee. Within these areas of responsibilities, OPT performs five activities:

- managing the safety review and public discussion of all drugs granted pediatric exclusivity and facilitating the dissemination of information to relevant external stakeholders
- enhancing the ethical conduct and quality of pediatric clinical trials, including evaluating and coordinating reviews of Subpart D (additional protections for children) referrals from Institutional Review Boards with HHS' Office of Human Research Protections
- assuring ethical pediatric research and child subject protection across all FDA centers
- developing cross-cutting pediatric scientific issues within FDA and leveraging external scientific expert resources to assess and analyze pediatric trial issues and data
- providing scientific and ethical information and coordinating activities pertaining to the pediatric population across all FDA product centers and with external pediatric stakeholders and international colleagues
- managing the scientific and ethical agendas for the Pediatric Advisory Committee and Pediatric Ethics Subcommittee public discussions.

Policy, Outreach, and Response

Within the Office of the Commissioner, there are four functional areas addressing policy development, counterterrorism policy and planning, external relations, and crisis management. Policy, Outreach, and Response support FDA's three program strategic goals and the Secretary's priorities of transforming health and securing the homeland. Under the Policy, Outreach, and Response area, the Headquarters and Office of the Commissioner plan to conduct activities in the following offices.

Office of Policy and Planning (OPP)
OPP is responsible for providing leadership and direction on matters relating to FDA policy, regulations development, legislative issues, planning and evaluation activities, and economic analyses. In support of these responsibilities, OPP performs five activities:

- developing and coordinating the review and analysis of broad FDA policy
- designing and developing strategic plans, performance management systems, and operational/business process plans as well as the FDA Strategic Plan, identifying long term measurable outcome goals and objectives, and other performance metrics
- overseeing, directing, and coordinating the agency's rulemaking activities and regulations development system
- analyzing cost and benefits of FDA regulations, and analyzing changes in the domestic health-care system and Office of Policy and Planning international and trade issues
- representing the FDA in user fee negotiations with industry and reauthorizations of legislation, and leading technical discussions with industry on performance goals and user fees.

Office of Counterterrorism Policy and Planning (OCTPP)
OCTPP serves as FDA's focal point for the development and implementation of policies on counterterrorism and other emerging threats. These include policies designed to safeguard food and medical products from intentional adulteration or disruption of supplies, and policies to facilitate the availability of safe and effective countermeasures against chemical, biological, radiological, and nuclear threat agents. OCTPP also is responsible for policies and plans that address emerging threats, such as strains of influenza with human pandemic potential. In addition to these, OCTPP performs five other key activities:

- leading, with the Office of Policy, the Pandemic Influenza Preparedness Task Force, in developing and implementing an action plan to accelerate the

development, production, and regulatory review of pandemic countermeasures and a strategy for food and feed security

- leading implementation of a program for the Emergency Use Authorization of medical countermeasures

- providing technical assistance to the HHS Public Health Emergency Medical Countermeasure Enterprise Governance Board and working groups

- providing scientific and policy expertise as an ex officio member of the National Scientific Advisory Board on Biosecurity

- coordinating the development and review of critical infrastructure plans.

The Office of External Relations (OER)

OER is responsible for conducting public participation, communication, and outreach programs designed to effectively reach and productively work with the agency's diverse stakeholder communities – including the news media, consumer, health professional, patient advocacy, academic, and scientific organizations, and the regulated industry.

Specific activities include building a stronger FDA-wide communication infrastructure, improving the agency's Web site and stakeholder outreach strategies, and enhancing collaborations and partnerships with stakeholder organizations to leverage FDA resources and expand the reach and consistency of the agency's health messages. OER serves as the FDA focal point in four areas:

- *Stakeholder Relations*, such as establishing and maintaining relationships with consumer, patient advocacy, academic, scientific, and health professional organizations to sustain a long-term dialogue on issues of high public health significance

- *Media Relations*, such as responding to requests from newspapers, magazines, journals, and reporters, producers, and researchers from network, affiliate, cable, radio, and syndicated programs

- *Communication*, such as developing public information programs and educational materials to communicate FDA's public health and consumer protection messages

- *Ombudsman Activities*, such as exploring complaints, resolving issues and problems and finding approaches that are acceptable to both the affected party and to the FDA.

Office of Crisis Management (OCM)

OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with Federal policies and programs. OCM performs five activities in support of those responsibilities:

- enhancing FDA's Emergency Operations Network Incident Management System (EON IMS), a web-based system that provides agency officials seamless and real time access to large volumes of data critical to the agency's management and response to emergency events

- creating and testing of a plan for FDA's emergency response to an influenza pandemic which will address operationally the accomplishments of FDA's critical regulatory and public health roles and responsibilities during a pandemic

- participating in international and national emergency response exercises

- developing and updating FDA-specific emergency response and crisis management plans

- conducting exercises to test the effectiveness of FDA-specific emergency response plans and agency-wide training

- facilitating agency wide training to meet the requirements of the National Incident Management System (NIMS)

- implementing systems to ensure collaboration and development of geographic information, including geo-coding of FDA-regulated firms in relationship to emergencies.

Scientific Coordination

Within the Office of the Commissioner, there are three functional areas addressing good clinical practice, women's health, and science coordination. Scientific Coordination supports FDA's three program strategic goals and the Secretary's priority of transforming health. Under the Scientific Coordination area, the Headquarters and Office of the Commissioner plan to conduct activities in the following offices:

Office of Science and Health Coordination (OSHC)
OSHC manages the activities of the FDA Research in Human Subjects Committee to ensure FDA sponsored clinical studies meet the standards of ethics and Human Subject Protection (HSP), oversees the FDA Good Clinical Practice (GCP) Program to ensure clinical studies conducted under FDA regulations meet standards of ethics and HSP, coordinates standards development for HHS, plans and conducts Office of the Commissioner advisory committees, and coordinates science initiatives across FDA.

Base resources support the FDA by monitoring the integrity of clinical research to ensure adequate human protection, ensuring that women's needs are considered in the review of FDA-regulated products, and providing avenues for the public and the

regulated industry for resolving compliance issues under the Mammography Quality Standards Act, Small Business Regulatory Enforcement, and Fairness Act, and the Information Quality Act.

OSHC performs three major activities relevant to these responsibilities:

- administering Science First, an FDA intranet designed to facilitate communication and collaboration among FDA scientists
- developing regulatory approaches on products using nanotechnology
- participating in the International Organization of Economic Cooperation and development working groups on nanotechnology in order to ensure effective international communication on risk assessment and management approaches for FDA-regulated products using nanotechnology

Good Clinical Practice (GCP) Program

This program is the focal point within FDA for GCP and HSP issues arising in human research trials regulated by FDA. GCP performs five activities focused on improving and enhancing protection for human subjects:

- coordinating FDA policies, developing guidance, and providing advice on HSP and GCP
- providing leadership and direction through the administration of FDA's HSP/GCP Steering Committee
- coordinating FDA's Bioresearch Monitoring program with respect to clinical trials
- contributing to international GCP harmonization activities
- serving as FDA's liaison with the HHS Office of Human Research Protection and other federal agencies and external stakeholders committed to the protection of human research participants.

Office of Women's Health (OWH)

OWH works to identify key agency priorities regarding women's health and sex/gender differences and to effectively deliver health messages to women around the nation via multiple languages. OWH also develops partnerships and collaborations with stakeholder organizations to best facilitate outreach and consumer information disseminations. These partnerships have resulted in unprecedented free publicity for, and duplication and dissemination of, millions of FDA/OWH materials using a variety of media venues (e.g., print, radio, television). OWH performs five activities to accomplish key agency priorities regarding women's health and sex/gender differences:

- developing and disseminating consumer health information about FDA-regulated products that will result in improved health for consumers, including women

- conducting outreach campaigns related to menopause and hormone therapy, cardiovascular disease, and safe medication use

- rolling out developing outreach campaigns on health fraud, drug medication charts, and Spanish language translations

- showcasing activites and consumer product information

- updating the OWH web site with current products and information, including the pregnancy drug exposure registry site.

Program Enabling

Within the Office of the Commissioner, there are four functional areas grouped as Program Enabling that provide cross-cutting support to Agency programs. These four areas include chief counsel, ombudsman, legislation, and international affairs. The Program Enabling functions support FDA's three program strategic goals and the Secretary's priorities of transforming health and securing the homeland. Under the Program Enabling area, the Headquarters and Office of the Commissioner plan to conduct activities in the following offices:

Office of the Chief Counsel (OCC)
OCC promotes the FDA public health mission by providing high quality legal services through the performance of five activities:

- representing the agency in court proceedings and administrative hearings related to criminal investigations and litigation, and civil enforcement, inspections, and civil (enforcement and defensive) litigation

- providing legal advice and policy guidance on FDA programs

- drafting or reviewing proposed and final regulations and Federal Register notices; performing legal research; providing legal opinions on regulatory issues, actions, and petitions; and reviewing proposed legislation affecting FDA

- serving as liaison to the Department of Justice and other Federal agencies

- providing legal advice and assistance to the Commissioner.

The Office of the Ombudsman (OO)
OO is responsible for investigating and resolving internally- and externally-generated complaints and disagreements regarding the administrative processing of various

applications for products regulated by the Agency, as well as regarding the fair and even-handed application of Agency policy and procedures in this process. In performance of these responsibilities, the Office performs four major activities:

- administering Part 16 Regulatory Hearings to determine whether compliance to FDA regulation has been met
- responding to comments and complaints from the U.S. Small Business Administration (SBA) and acting as liaison to small businesses in negotiating FDA regulations
- coordinating industry appeals to the Commissioner
- reviewing and determining compliance to the Information Quality Act, which permits consumers to challenge or request correction on scientific information disseminated by the Agency.

Office of Legislation (OL)

OL provides leadership for FDA's offices concerning legislative needs, pending legislation, and oversight activities affecting FDA. This leadership is supported by two broad activities:

- advising and assisting Congressional members and staff, in consultation with the Office of the Secretary, on FDA actions, policies, and issues related to legislation
- analyzing legislative needs of FDA and drafting or developing legislative proposals, position papers, and departmental reports on proposed legislation.

Office of International Programs (OIP)

OIP advances the mission of FDA through global public health diplomacy. OIP's mission is to lead, manage, and coordinate all of FDA's international activities, and to serve as the primary focal point within FDA for the Agency's entire international and public health diplomacy activities:

- negotiating and managing bilateral arrangements with key regulatory counterparts to further scientific and regulatory cooperation
- leading, coordinating, and managing FDA's participation in major international harmonization bodies
- directing and managing FDA's capacity building activities for improving the infrastructure in foreign countries; this ensures products we receive meet our standards and support U.S. pandemic influenza preparedness initiatives, while improving the public health of citizens in developing countries
- directing and supporting FDA's contributions to HHS multilateral work

- managing FDA's contributions to U.S. bilateral and multilateral trade negotiations, providing FDA-related trade capacity building, and providing technical expertise to trade agencies.

Administrative Supporting

Within the Office of the Commissioner, there are five functional areas grouped as administrative supporting that provide cross-cutting administrative support to Agency programs. These five areas include shared services, management programs, user fee programs, financial management, and information technology. The Administrative Supporting the Agency's strategic goal on FDA's transforming administrative systems and the HHS strategic goal on improving management practices. Under the Administrative Supporting, the Headquarters and Office of the Commissioner plan to conduct activities in the following offices:

Office of Shared Services (OSS)
OSS and Office of Information Technology Shared Services (OITSS) provide a portfolio of administrative and information technology services FDA-wide. The shared services concept employs innovative management techniques such as customer advocacy, negotiated service level agreements, engaged performance planning, active governance boards, and integrated strategic planning that leverages the best of centralized and decentralized organization structures. The list below of activities OSS performs is representational and not comprehensive:

- providing advisory services on the business and administrative aspects of the contracting program
- managing contracts, grants, technology transfers, purchase cards, and interagency agreement programs
- performing financial services related to accounts payable, travel payments, invoice payments, payroll, fleet, and claims management
- directing programs and systems leading to the acquisition, alteration, maintenance, and utilization of leased and owned facilities nationwide
- assuring effective building operations functions for all FDA facilities nationwide
- providing comprehensive Library services to all FDA employees, including the state-of-the-art facility at the FDA Headquarters White Oak Campus
- providing advice, assistance and oversight on equal opportunity issues, activities and programs
- operating a modern contact center (Employee Resource and Information Center) to enable FDA employees nationwide to obtain administrative and IT assistance.

OITSS performs two major functions:

- consolidating and modernizing the FDA's IT infrastructure
- providing FDA customers with a single point of contact for the identification, consolidation, testing, evaluation, integration, deployment, and decommissioning of all IT infrastructure services and equipment.

Financial Management

FDA's financial systems support all agency financial activities and mission-critical needs for FDA's public health mission. Improved financial performance includes initiatives to reduce erroneous payments and roll-out an activity based cost application for FDA's user fee programs. FDA moved into an environment that resolved outstanding audit findings, met modern Federal financial requirements, maintained a clean audit opinion, and provided timely financial information to support strategic and resource allocations. The list below of Financial Management activities is representational and not comprehensive:

- monitoring and ensuring that financial operating plans and budget execution reports meet Federal requirements, while providing timely financial information to Agency leadership
- formulating user fee projections, executing and monitoring user fee resources provided to FDA programs, and reporting annually on FDA expenditures to the Congress
- preparing quarterly financial statements and annual financial reports and liaising with the Office of Inspector General's independent auditor on FDA's financial statements.

User Fees Programs: Prescription Drug User Fee Act (PDUFA), Medical Devices User Fee and Modernization Act (MDUFMA), Animal Drug User Fee Act (ADUFA), Export Reform and Enhancement Act (EREA), and Mammography Quality Standards Act (MQSA)

The Headquarters and Office of the Commissioner Program's share of the user fee programs provides financial and management infrastructure for collection, receipt, payment, accounting, and reporting of user fee revenues and expenses for PDUFA, MDUFMA, ADUFA, EREA, and MQSA. It coordinates acquisition and management of additional space, budgeting, accounting, and resource acquisition support. It also provides information management and technology support, contracting and acquisition support. Furthermore, it prepares the annual PDUFA, MDUFMA, and ADUFA financial reports to Congress.

Management Programs

FDA management programs support the FDA by developing FDA policy; program requirements and evaluation standards for many mandated management programs including the FDA Ethics and Integrity Program, the Privacy Act, and Freedom of

Information Act; dockets management; delegations of authority; A-76 Competitive Sourcing; executive resources management; organizational management; and various internal control programs such as Office of the Inspector General liaison, Federal Manager's Financial Integrity Act, and providing management analysis support to the Office of Commissioner. The list below of Management Program activities is representational and not comprehensive:

- providing leadership in the development, implementation, and evaluation in areas of strategic human capital management, performance management, competitive sourcing, and consolidating management functions
- administering the FDA's ethics program
- providing administrative oversight, leadership, and direction to the FDA's Freedom of Information (FOI) and Privacy Act programs
- coordinating the implementation of the Federal Manager's Financial Integrity Act in the agency
- acting as liaison with the Department's Office of Inspector General with regards to audits and evaluations involving FDA.

Information Technology

FDA's Information Technology (IT) program enables FDA's strategic efforts by transforming and improving the systems and infrastructure needed to support critical agency operations. The program performs five major activities:

- enhancing the implementation of enterprise-wide management systems
- optimizing data and systems security measures
- providing support and tools for ongoing business process planning
- maximizing the availability and use of information technologies that increase or enhance electronic access for the public, as well as for the full span of FDA external and internal customer base, while maintaining effective security
- aligning IT investments to business goals in a manner that reduces costs of existing legacy systems and aligns and fully supports core mission and business priorities.

Enterprise Information Technology Fund

The FDA's request includes funding to support the President's Management Agenda Expanding E-Government and Departmental enterprise information technology initiatives. Operating Division funds will be combined to create an Enterprise Information Technology (EIT) Fund to finance specific information technology initiatives identified through the HHS strategic planning process and approved by the

HHS IT Investment Review Board. These enterprise information technology initiatives promote collaboration in planning and project management and achieve common HHS-wide goals. Examples of HHS enterprise initiatives funded by the EIT Fund are Enterprise Architecture, Capital Planning and Investment Control, Enterprise E-mail, Grants Management Consolidation, and Public Key Infrastructure.

The FDA will contribute $6,507,576 of its FY 2008 budget to support Department enterprise information technology initiatives as well as the President's Management Agenda (PMA) Expanding E-Government initiatives. Operating Division contributions are combined to create an Enterprise Information Technology (EIT) Fund that finances both the specific HHS information technology initiatives identified through the HHS Information Technology Capital Planning and Investment Control process and the PMA initiatives. These HHS enterprise initiatives meet cross-functional criteria and are approved by the HHS IT Investment Review Board based on funding availability and business case benefits. Development is collaborative in nature and achieves HHS enterprise-wide goals that produce common technology, promote common standards, and enable data and system interoperability. The HHS Department initiatives also position the Department to have a consolidated approach, ready to join in PMA initiatives.

Of the amount specified above, $1,724,084 is allocated to support the President's Management Agenda Expanding E-Government initiatives for FY 2008. This amount supports the PMA E-Government initiatives as follows:

PMA e-Gov Initiative	**FY 2007 Allocation**	**FY 2008 Allocation**
Business Gateway	$135,800	$81,958
E-Authentication	$0	$2,717
E-Rulemaking	$633,973	$544,995
E-Travel	$0	$50,244
Grants.Gov	$11,130	$11,464
Integrated Acquisition	$250,952	$258,612
Geospatial LOB	$0	$0
Federal Health Architecture LoB	$536,149	$694,454
Human Resources LoB	$20,477	$20,477
Grants Management LoB	$587	$1,159
Financial Management LoB	$15,701	$26,916
Budget Formulation & Execution LoB	$14,131	$16,015
IT Infrastructure LoB	$15,073	$15,073
TOTAL	$1,633,973	$1,724,084

Prospective benefits from these initiatives are:

Business Gateway: Provides cross-agency access to government information including: forms; compliance assistance resources; and, tools, in a single access point. The site offers businesses various capabilities including: "issues based" search and organized agency links to answer business questions; links to help resources regarding which regulations businesses need to comply with and how to comply; online single access to government forms; and, streamlined submission processes that reduce the regulatory paperwork burdens. HHS' participation in this initiative provides HHS with an effective communication means to provide its regulations, policies, and forms applicable to the business community in a business-facing, single access point.

E-Authentication: Provides standards-based authentication architecture to support Federal E-Government applications and initiatives. It provides a uniform process for establishing electronic identity and eliminates the need for redundant solutions for the verification of identity and electronic signatures. E-Authentication's federated architecture also enables citizens and businesses to use credentials issued by commercial entities, such as financial institutions, to conduct transactions with the government, eliminating the need for HHS to issue credentials for its systems.

E-Rulemaking: Provides citizens and organizations a single point of access to Federal rulemaking information. HHS posts all rulemaking notices on Regulations.gov. HHS and E-Rulemaking are in the requirements and planning process for migrating HHS docket-management process to the E-Rulemaking system.

E-Travel: The E-Travel Program provides a standard set of travel management services government-wide. These services leverage administrative, financial and information technology best practices. By the end of FY 2006, all but one HHS OPDIV has consolidated services to GovTrip and legacy systems retired. By May 2008, all HHS travel will be conducted through this single system and the last remaining legacy functions will be retired.

Grants.gov: Allows HHS to publish grant funding opportunities and application packages online while allowing the grant community (state, local and tribal governments, education and research organizations, non-profit organization, public housing agencies and individuals) to search for opportunities, download application forms, complete applications locally, and electronically submit applications using common forms, processes and systems. In FY 2006, HHS received over 56,000 electronic applications from the grants community via Grants.gov.

Integrated Acquisition Environment: Eliminated the need for agencies to build and maintain their own agency-specific databases, and enables all agencies to record vendor and contract information and to post procurement opportunities. Allows HHS vendor performance data to be shared across the Federal government.

Lines of Business – Human Resources Management: Provides standardized and interoperable HR solutions utilizing common core functionality to support the strategic management of Human Capital. HHS has been selected as a Center of Excellence and will be leveraging its HR investments to provide services to other Federal agencies.

Lines of Business – Federal Health Architecture: Creates a consistent Federal framework that improves coordination and collaboration on national Health Information Technology (HIT) Solutions; improves efficiency, standardization, reliability and availability to improve the exchange of comprehensive health information solutions, including health care delivery; and, to provide appropriate patient access to improved health data. HHS works closely with federal partners, state, local and tribal governments, including clients, consultants, collaborators and stakeholders who benefit directly from common vocabularies and technology standards through increased information sharing, increased efficiency, decreased technical support burdens and decreased costs.

Lines of Business – **Financial Management:** Supports efficient and improved business performance while ensuring integrity in accountability, financial controls and mission effectiveness by enhancing process improvements; achieving cost savings; standardizing business processes and data models; promoting seamless data exchanges between Federal agencies; and, strengthening internal controls.

Lines of Business – Grants Management: Supports end-to-end grants management activities promoting improved customer service; decision making; financial management processes; efficiency of reporting procedure; and, post-award closeout actions. NIH is an internally HHS-designated Center of Excellence and has applied to be a GMLOB consortia lead. This effort has allowed HHS agencies such as FDA using the NIH system to reduce grants management costs. Both efforts have allowed HHS to achieve economies of scale and efficiencies, as well as streamlining and standardization of grants processes, thus reducing overall HHS costs for grants management systems and processes.

Lines of Business – Budget Formulation and Execution: Allows sharing across the Federal government of common budget formulation and execution practices and processes resulting in improved practices within HHS.

Lines of Business IT Infrastructure: A recent effort, this initiative provides the potential to leverage spending on commodity IT infrastructure to gain savings; to promote and use common, interoperable architectures that enable data sharing and data standardization; secure data interchanges; and, to grow a Federal workforce with interchangeable skills and tool sets.

<u>Major Information Technology Investments</u>

Modern IT systems and applications provide FDA the ability to meet its critical mission sensitive activities in a timely and quality manner. FDA's IT portfolio of major IT systems is represented through the Office of Management and Budget's Capital Asset

Plan and Business Case process (Exhibit 300). The Department of Health and Human Services will post public versions of FDA's Exhibit 300s on the HHS Web Site. The URL for viewing the Exhibit 300 is www.hhs.gov/exhibit300.

Research, Development, and Evaluation (RD&E) Activities

The Office of Women's Health (OWH) Research and Development Program addresses gaps in current knowledge, uses novel approaches for conducting and funding research, and sets new standards of excellence for women's health research. The program funds research projects at FDA and academic facilities including an intramural research program, an extramural research program, and special funding initiatives. The program is also responsible for meeting Congressional mandates to track the inclusion of women in clinical studies. The list below of RD&E activities is representational and not comprehensive:

- aligning OWH research priorities with FDA's Critical Path Initiative and identifying key opportunities for the application of sex/gender based scientific advancement

- using a peer review process to select the highest quality research projects of regulatory significance to FDA

- implementing a process to identify the women's health research needs of highest priorities in the FDA Centers to advance a science program that integrates these priorities with the FDA Critical Path Initiative

- partnering with other HHS organizations to identify gaps in women's health and sex/gender differences research and leveraging current funding to address those gaps

- seeking out opportunities to present the OWH scientific programs and facilitate discussion in cross cutting women's health scientific issues and research needs.

Selected FY 2006 Accomplishments

Regulatory Programs

Office of Policy and Planning (OPP)
In the course of OPT performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- established FDA Bioinformatics Board to develop a business driven, strategic, affordable information infrastructure for FDA

- led FDA negotiations with pharmaceutical and biological industries for reauthorization of PDUFA, resulting in a requested increase of approximately $100 million in user fee reimbursement beginning in FY 2008

- co-chair of the FDA/NCI Interagency Oncology Task Force. Directed overall FDA effort to ensure effective management and communication across six senior scientific subcommittees

- led performance components in development and submission of a better integrated FY 2007 Performance Budget, complete and on time.

Office of Combination Products (OCP)
In the course of OCP performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- issued all product jurisdiction decisions in response to formal Requests for Designation (RFD) submitted by industry on time

- monitored and actively facilitated 335 inter-center consulting requests for combination products to ensure the requesting center received timely and effective feedback; this represents a 22% increase in the number of inter-center consultations from FY 2005 to FY 2006

- provided assistance to over 650 inquiries from internal and external stakeholders submitted to the Office in FY 2006

- published three Federal Register notices and two new guidance documents related to combination product regulation

- made significant progress developing new policies and regulations for combination products.

Office of Pediatric Therapeutics (OPT)
In the course of OPT performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- submitted four articles and published three concerning pediatric issues in peer reviewed journals; office members also authored two textbook chapters.

- presented at approximately 40 national and international pediatric conferences and workshops

- responded to over 70 scientific or informational external requests, published a guidance on Subpart D submissions, and responded to Congressional, GAO and press inquiries

- coordinated 2 Pediatric Advisory Committee (PAC) meetings involving the safety review of 19 products used in children including a safety update on Tamiflu

- coordinated a Part 15 open public hearing on Emergency Research.

Policy, Outreach, and Response

Office of Counterterrorism Policy and Planning (OCTPP)
In the course of OCTPP performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- coordinated FDA's activities on authorization of medical countermeasures during declared emergencies

- coordinated FDA's pandemic preparedness planning

- ensured that recommendations of the Weapons of Mass Destruction Medical Countermeasures Senior Steering Committee on purchases for the Strategic National Stockpile are based on sound information, reflect FDA professional judgment and expertise, and are consistent with FDA policies and regulations

- provided scientific and policy expertise for the National Scientific Advisory Board on Biosecurity

- led the development and implementation of crosscutting counterterrorism policies, such as the FDA Food/Agriculture Sector portion of the Department of Homeland Security's National Infrastructure Protection Plan.

Office of External Relations (OER)
In the course of OER performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- identified and addressed stakeholder issues using a variety of formal and informal discussion forums

- conducted telebriefings and roundtables to discuss stakeholder views on discrete FDA issues or actions such as Critical Path, Nanotechnology, Clinical Trial Registries, Unapproved Drugs, Obesity, PDUFA, the FDA budget and FDA's New Prescribing Information for Drugs

- managed patient representative and patient consultant progams to recruit and train patient representatives who serve as special government employees on FDA advisory committees and other FDA meetings to provide patient perspective on issues related to serious illnesses

- provided direct assistance to patients and families dealing with serious or life-threatening diseases or conditions

- established a Health Professional Liaison program

- developed more than 40 electronic list-serve notices of important HIV/AIDS related messages alerting patient and medical communities to important updates concerning treatment information and safety alerts/updates, upcoming meetings, and opportunities to comment on policy and regulatory proposals http://www.fda.gov/oashi/aids/email.html.

Office of Crisis Management

In the course of OCM performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- coordinated the agency's emergency public health response to the nationwide outbreak of E. coli O157:H7 associated with prepackaged spinach

- led FDA's participation in the HHS hurricane preparedness workgroups

- led FDA's involvement in the development of HHS Emergency Support Function #8 (Public Health and Medical Services Annex to the National Response Plan) Hurricane Playbook to improve coordination and management of Federal public health and medical assets needed prior to and in the aftermath of a hurricane or tropical storm

- led FDA's review and development of the Emergency Support Function #8 (Public Health and Medical Services Annex to the National Response Plan) Pandemic Influenza Operational Playbook

- ensured rapid and sustained FDA response to Centers for Disease Control and Prevention's (CDC) request for assistance in the investigation of a series of illnesses and deaths in Panama eventually linked to a contaminated medication.

Scientific Coordination

Office of Science and Health Coordination (OHSC)
In the course of OSHC performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- put together the 2006 Science Forum; there were over 1,200 attendees, including 200 from industry and academia; 450 posters (about 65 from non-FDA participants)

- attended four meetings of the Interagency Committee on Standards Policy, three meetings of the American National Standards Institute (ANSI) Board of Directors and three of the ANSI Government Members Council, four meetings of the FDA Standards Committee, coordinated six ballots on voluntary standards, and published the annual report to Congress on FDA utilization of voluntary standards in lieu of government unique standards

- established the Agency Research Quality Assurance Board which will provide agency-level leadership to implement and direct the quality assurance program to oversee the quality of all FDA-sponsored intra- and extramural human subject research

- submitted 70 protocols for initial review, about 200 protocols submitted for continuing review, 10 meetings of the FDA IRB Committee, development of an e-room to facilitate communication among members, several responses to the OIG, three preliminary investigations to determine if audits were needed, and approximately 250 information requests/consultations on various human subject protection issues by the Centers

- established the requirements for a quality systems program to oversee the quality of all FDA-sponsored intra- and extramural research involving human subjects.

Office of Good Clinical Practice Program (OGCP)
In the course of OGCP performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- published an interim final rule to amend the informed consent regulations to establish a new exception for use of investigational in vitro diagnostic devices in certain circumstances

- published the following guidances: five revised FDA Information Sheet Guidances for Institutional Review Boards, Clinical Investigators and Sponsors; final Guidance for Industry on Using a Centralized Institutional Review Board Process in MultiCenter Clinical Trials; final Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees; draft Guidance for Institutional Review Boards, Clinical

Investigators, and Sponsors: Exception form Informed Consent Requirements for Emergency Research.

Office of Women's Health (OWH)
In the course of OWH performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- monitored, tracked and funded approximately 30 research projects including 14 (eight new) intramural, nine extramural, and five demographic research projects
- aligned OWH research priorities with top Agency priorities, i.e., Critical Path Initiative, and provided funding support for four specific critical path projects pertinent to women's health, sex/gender differences, and demographic data collection
- participated in over 45 national medical, scientific, and health care conferences
- distributed more than 3.5 million health information publications and 165,000 kits. Materials highlighted nationally in "Hints from Heloise" and Parade magazine
- conducted three site visits to OWH funded academic institutions and respective principal investigators to ensure studies are consistent with contractual, human subjects protection, and Research Involving Human Subjects Committee (RIHSC) obligations.

Program Enabling

Office of the Ombudsman (OO)
In the course of OO performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- received an "A" rating from the U.S. Small Business Administration regarding our responsiveness to issues involving small businesses
- coordinated Agency response to three challenges under the Information Quality Act
- continued to review requests for Part 16 Regulatory Hearings enhanced capabilities and knowledge base to provide for quick response to industry requests for assistance involving import issues.

Office of International Programs (OIP)
In the course of OIP performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- FDA efforts were showcased as models of regulatory cooperation by other Federal Agencies in the following areas: FDA's Collaborations with the European Union (E.U.)/European Medicines Agency (EMEA) and FDA's work with Canada and Mexico under the Trilateral Cooperation

- launched an ambitious plan of outreach to Asia, during which FDA established structured bilateral meetings with our counterparts in China, Vietnam, and Korea

- sought and obtained grant funds from the Department of State to conduct capacity building activities in the Middle East

- concluded five new confidential information sharing commitments with agencies in Australia, France, Germany, Israel, and Sweden

- negotiated and concluded a Memorandum of Understanding (MOU) with the Servicio Nacional de Sanidad, Inocuidaty Calidat Agroalimentatria, and United States of Mexico, to establish and build confidence in a system that increases the likelihood that cantaloupes from Mexico offered for import into the U.S. comply with U.S. law.

Administrative Supporting

Office of Shared Services (OSS)
In the course of OSS performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- exceeded the Department goals and led other HHS Operating Divisions in the use of HHS Strategic Sourcing Blanket Purchase Agreements, with an average 85 percent usage rate

- negotiated an operations and maintenance contract for the Jefferson Lab facility, resulting in an approximate $3 million projected savings for the five-year contract period

- resolved over 85 percent of all reported workplace conflicts (both EEO and non-EEO).

Office of Financial Management (OFM)
In the course of OFM performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- participated in the implementation and successful Go-Live of the PSC on Unified Financial Management System (UFMS) and is doing the same for Indian Health Service (HIS) for their October 2007 implementation of UFMS

- used deployed tool for better control of status of funds by providing users the ability to drill down into the UFMS system; provided FDA the necessary visibility to meet its OMB requirement of cleaning up its reporting and balancing issues as identified in the FY 2005 audit report

- implemented the new OMB Circular A-123 Appendix A – Annual Assurance on Internal Controls over Financial Statements

- implemented the Departments' Gov.Trip travel management solutions across the FDA.

Office of Management Programs (OMP)
In the course of OMP performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- completed FY 2006 Competitive Sourcing Plan by announcing a study of 228 FTEs in the Office of Information Technology Shared Services

- implemented Performance Management Approval (PMA) initiative by rolling out PMA Program (PMAP), where FDA's individual and organizational performance goals align with FDA's Strategic Goals and the "One" HHS Top 20 Department Objectives

- implemented a "hybrid" Title 38 pay system that ensures FDA will be able to hire, train, and retain high caliber medical officers and dentists

- received a glowing endorsement following an audit conducted by the Office of Government Ethics that our Ethics Program was "strong and solid".

Office of the CIO (OCIO)
In the course of OCIO performing its day-to-day tasks, there were accomplishments worth noting. The list below is representational and not comprehensive:

- implemented the Document Archiving, Reporting and Regulatory Tracking System (DARRTS) release 1; the first drug submission type supported is therapeutic biologic Investigational New Drugs, to be followed by all other drug submission types

- implemented the Electronic Labeling Information Processing System for new drug submissions, efficacy supplements and labeling supplements – more than 1,700 electronic labels in the Structured Product Labeling format have been provided to the National Library of Medicine for public use

- deployed the initial portion of a new system to automate the tracking of 30-day notice supplements to premarket approvals for medical devices

- migrated 42% of FDA e-mail accounts to HHS Mail – nationwide upgrades will improve e-mail reliability for all FDA activities

- launched a downloadable, interactive learning computer program, Make your Calories Count, to assist consumers in their use of the Nutrition Facts Label to maintain a healthful diet while managing calorie intake

- implemented the Electronic Submissions Gateway , an FDA-wide solution that enables the secure submission of electronic regulatory submissions over the internet.

Performance Analysis

The FDA Competitive Sourcing (A-76) Program supports the President's Management Agenda's goal to promote competition between the federal government and the private sector for government functions that are also found in the commercial marketplace. The purpose of the Competitive Sourcing Program (sometimes referred to as the A-76 Program) is to implement OMB Circular A-76 http://www.whitehouse.gov/omb/circulars/a076/a076.html to create cost savings for FDA.

FDA annually searches its FAIR inventory for those commercial positions that have not undergone a competitive sourcing study. The objective of this search is to identify a sufficient number of positions that would fulfill FDA's requirement in meeting the OMB and DHHS established goal of reviewing all commercial positions by FY 2013. The selected commercial business unit is announced for review and is then subjected to A-76 competitive sourcing competition either as one or more standard and/or streamline cost comparisons.

FDA completed its FY 2006 Competitive Sourcing Plan by announcing a study of 228 FTEs in the Office of Information Technology Shared Services. The anticipated net savings for FY 2006, as a result of competitive sourcing, is approximately $1.88 million.

FDA has contributed strongly to DHHS' overall green rating. Recognized as a leader in competitive sourcing, FDA was invited to share its successes at several government audiences, including the OMB sponsored Joint Agency Competitive Sourcing meeting and the National Council for Public/Private Partnerships. FEDTECH magazine (May 2006) highlighted FDA's competitive sourcing program and its efforts to create Most Efficient Organizations, and conduct comprehensive post-award monitoring to ensure the best value for the American taxpayer.