HEADQUARTERS AND OFFICE OF THE COMMISSIONER

The FY 2009 program level budget request for FDA's Headquarters and Office of the Commissioner program is a $139,227,000.

The following table provides a three-year funding history for FDA's Headquarters and Office of the Commissioner program.

FDA Program Resources Table

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Program Level	**$111,425,000**	**$133,436,000**	**$139,227,000**	**$5,791,000**
Program Level FTE	**671**	**696**	**701**	**5**
Budget Authority	**$91,813,000**	**$97,496,000**	**$99,398,000**	**$1,902,000**
Food Protection (non-add)	*$31,559,000*	*$33,526,000*	*$35,740,000*	*$2,214,000*
Admin. Savings & Man. Efficiencies (non-add)			*-$312,000*	-$312,000
Budget Authority FTE	**523**	**533**	**535**	**2**
User Fees	**$19,612,000**	**$35,940,000**	**$39,829,000**	**$3,889,000**
PDUFA	*$16,042,000*	*$29,531*	*$31,773,000*	*$2,242,000*
DTC			*$430,000*	*$430,000*
MDUFMA	*$2,808,000*	*$5,450,000*	*$5,914,000*	*$464,000*
ADUFA	*$522,000*	*$732,000*	*$732,000*	*$0*
MQSA	*$240,000*	*$227,000*	*$238,000*	*$11,000*
Proposed User Fees			***$742,000***	***$742,000***
Generic Human Drugs			*$549,000*	*$549,000*
Proposed Animal Generic Drugs			*$193,000*	*$193,000*
Total User Fee FTE	**148**	**163**	**166**	**3**
Mandatory User Fees			***$7,512,000***	***$7,512,000***
Reinspection (Non-Add)			*$7,512,000*	*$7,512,000*
Reinspection FTE			*16*	*16*

Following is a list of the Headquarters and Office of the Commissioner Statutory Authority:

The Federal Food Drug and Cosmetic Act* (21 U.S.C. 321-399)
Radiation Control for Health and Safety Act (21 U.S.C. 360hh-360ss)
The Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Foods Additives Amendments of 1958*

* Authorities under this act do not appear in sequence in the U.S. Code (codified as amended in scattered sections of 21 U.S.C.

Color Additives Amendments of 1960*
Animal Drug Amendments (21 U.S.C. 360b)
Controlled Substances Act (21 U.S.C. 801-830)
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Federal Anti-Tampering Act (18 U.S.C. 1365)
Medical Device Amendments of 1976*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Generic Animal Drug and Patent Term Restoration Act*
Prescription Drug Marketing Act of 1987*
Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201)
Prescription Drug Amendments of 1992*
Safe Medical Device Amendments of 1992*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Animal Medicinal Drug Use Clarification Act of 1994*
Animal Drug Availability Act of 1996*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Medical Device User Fee and Modernization Act of 2002*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12)
Project Bioshield Act of 2004(21 U.S.C. 360bbb-3)
Minor Use and Minor Species Animal Health Act of 2004*
Food Allergy Labeling and Consumer Protection Act of 2004*
Medical Device User Fee Stabilization Act of 2005*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug and Consumer Protection Act (21 U.S.C. 379aa-1)
Food and Drug Administration Amendments Act of 2007*

Allocation Method: Direct Federal/Intramural

Program Description and Accomplishments

The Headquarters and Office of the Commissioner Program provides FDA-wide program direction and administrative services to ensure that FDA's consumer protection efforts are managed effectively and efficiently. The Office of the Commissioner consists of six subordinate

* Authorities under this act do not appear in sequence in the U.S. Code (codified as amended in scattered sections of 21 U.S.C.

offices that provide policy making, program direction, coordination and liaison, and expert advice to FDA 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 the Chief of Staff	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 and Special Programs	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 Operations	Provides advice and direction for day-today operational activities and the interaction and execution of initiatives across all FDA Centers, Field Offices, Regions and Headquarters. Provides administrative and program support services, assures strategic and operational management of information technology, financial management, and administrative programs. Serves as FDA's focal point for coordinating emergency and crisis response activities, interagency and intra-agency coordination of emergency and crisis planning and management, and internal and external security.
Office of Policy, Planning and Preparedness	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 Scientific and Medical Programs	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 the Chief Counsel
The Office of the Chief Counsel (OCC) provides legal advice and policy guidance, acts as liaison to the Department of Justice and other Federal agencies for programs.

In FY 2007 OCC provided legal advice or review to FDA/HHS on draft and final regulations, draft and final guidance documents, responses to citizen petitions, draft legislation, congressional testimony, press materials, and correspondence. OCC provided key advice in numerous meetings on complex legal issues related to pending legislation such as the Food and Drug Administration Amendments Act of 2007, medical product approvals and safety issues, food

safety and nutrition issues, animal health issues, and public health emergencies. OCC reviewed more than 525 draft letters from FDA to firms that had violated the Federal Food, Drug, and Cosmetic Act.

In FY 2007 OCC also conducted defensive and enforcement litigation on behalf of FDA. OCC successfully defended the agency's drug approval standards in the Abigail Alliance, Provenge, and Genendo cases and played significant roles in the successful criminal prosecutions of at least four individuals for selling or administering imitation Botox (Poet, Berman, Van Wormer and Rothenberg). OCC defended the integrity of FDA's generic drug approval decisions in numerous cases such as Hill Dermaceuticals, Mylan, Biovail, and three separate challenges brought by Apotex. The office also gave substantial support to the agency's enforcement actions initiated to ensure the quality of the medical device manufacturing process.

Office of the Chief of Staff

The Office of the Chief of Staff (OCOS) is the principal liaison to the Department of Health and Human Services and advises and provides integrated policy analysis and strategic consultation to FDA officials on activities and issues that affect significant agency programs, projects and initiatives.

The Office of Public Affairs (OPA)

In FY 2007, OPA conducted numerous announcements on agency actions, including drug, biologics and device approvals and recalls. OPA conducted major rollouts of agency initiatives including the Food Protection Plan, China Partnerships and the Generic Initiative for Value and Efficiency (GIVE). In FY 2007, OPA conducted some of the largest crisis communications events in recent history, including the nationwide peanut butter and pet food recalls.

The Office of Legislation (OL)

In FY 2007, OL worked with Agency experts and Congressional staff to ensure prompt passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA). In addition to providing the Agency with new authority, FDAAA reauthorizes four critical FDA programs: the Prescription Drug User Fee Act, the Medical Device User Fee and Modernization Act, the Best Pharmaceuticals for Children Act, and the Pediatric Research Equity Act. In addition, OL provides Congress with information requested on FDA programs and policies. Last year, OL staffed 30 Congressional hearings and provided over 1,000 written responses to Members of Congress.

Office of International and Special Programs

The Office of International and Special Programs (OISP) serves as the FDA focal point for all international matters, pediatric matters, and combination product matters.

The Office of International Programs (OIP)

In FY 2007, OIP led FDA efforts as part of an intensive process with the Department of Health and Human Services to negotiate two binding agreements, one on food and feed safety, and one on drugs and medical devices, with China. These agreements contain specific commitments and performance metrics to help ensure the safety of FDA-regulated products exported from China to the U.S. This supports a key element of the President’s Import Safety Action Plan.

Under the President's Emergency Program for AIDS Relief, FDA "tentatively approved" 23 products. In August 2007, FDA tentatively approved the first fixed-dose anti-HIV product designed to treat children under the age of 12 years (pediatric triple-fixed-dose combination tablet of lamivudine, stavudine and nevirapine).

In FY 2007, OIP led the planning and conduct of two training workshops to support the HHS international strategy for pandemic influenza. A Good Clinical Practices (GCP) workshop was held in Vietnam Ministry of Health (MOH) staff and selected administrators from academic medical centers across Vietnam to provide a basic understanding of GCP and related processes. A Good Manufacturing Practices (GMP) workshop was held in the U.S. for fifteen foreign medical products regulatory agencies.

OIP organized and led two food safety workshops funded by a grant from the Department of State under the Middle East Partnership Initiative (MEPI). The workshops included over 200 food safety officials from middle-eastern countries and advanced discussions on the importance of food safety infrastructure using a regional approach.

Office of Combination Products (OCP)

OCP, in response to MDUFMA 2002, ensures the prompt assignment of combination products (drug-device, biologic-device, drug-biologic, or drug-device-biologic products) to FDA Centers, the timely and effective pre-market review of such combination products, and consistent and appropriate post-market regulation of these products.

In FY 2007, OCP published a jurisdictional update describing the assignment of devices used to process human cells, tissues, and cellular and tissue-based products. OCP also Published eleven Request for Designation (RFD) letters for approved or cleared products. Additionally, OCP issued 32 combination product RFD assignments in the last fiscal year. One hundred percent of these assignments met the 60-day decision time requirement.

The Office of Pediatric Therapeutics (OPT)

OPT supports FDA's Safety of Products Used in Children and the Ethical, International and Scientific Activities initiatives. Between 2004 and 2007, OPT coordinated the public safety reviews of over 70 products studied under the Best Pharmaceuticals for Children Act (BPCA). To accomplish this mandate, OPT annually convenes at least 3 Pediatric Advisory Committee (PAC) meetings, each lasting 2-3 days and involving 6-10 products and additional pediatric safety issues of concern.

In FY 2007, Europe initiated a new incentive program for pediatric studies. FDA and the European Medicines Agency (EMEA) have engaged in an extensive exchange of scientific information. Since September 2007, over 60 products proposed by sponsors for the European incentive program have been discussed at monthly meetings, often involving broad-ranging scientific and ethical topics of mutual concern.

The Office of Food Protection

In FY 2007, the Office of Food Protection developed, and publicly released, the *FDA Food Protection Plan - An Integrated Strategy for Protection the Nation's Food Supply*. The plan is premised on preventing harm before it can occur, intervening at key points in the food production system, and responding immediately when problems are identified. Within these three overarching areas of protection, the plan contains a number of action steps as well as a set of legislative proposals. Taken together, these efforts will provide a food protection framework that ensures that the U.S. food supply remains safe. The Office of Food Protection also developed an integrated Food Protection and Import Safety Action Plan operations plan as a foundation document for the implementation of the two major initiatives. Taken together, the two plans will improve efforts by the public and private sector to enhance the safety of a wide array of products used by American consumers.

Office of Operations

The Office of Operations (OO) provides executive direction, leadership, coordination, and guidance for the overall day-to-day operations of FDA, assuring the timely and effective implementation of operations and high quality delivery of services across FDA and its Centers.

Office of Management Programs

The FDA Competitive Sourcing goal in FY 2007 was to announce the study of at least 308 commercial positions. FDA exceeded this target by 15% by announcing thirteen individual studies of 354 commercial positions. These studies are critical to ensuring the FDA is using the most cost effective organization and staffing for accomplishing its myriad missions. By creating Most Efficient Organizations (MEO) within the administrative support structure, public health and safety professionals are better able to focus on their primary roles in protecting and advancing the public health.

Office of Crisis Management (OCM)

OCM provided coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g.; melamine contaminated pet food, peanut butter contaminated with salmonella, and botulism in chili sauce.

OCM is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents;" HSPD-8, "National Preparedness;" and HSPD-9, "Defense of United States Agriculture and Food."

In FY 2007, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.2 and plans to release version 3.3 in June 2008. OCM uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2007 hurricane

season, response activities related to outbreaks involving peanut butter, and illnesses caused by pet food. EON IMS supports preparedness exercises that have included international, federal, state and local partners. OCM completed the FDA emergency response plan for pandemic influenza in September 2007 and participated in the TOPOFF4 exercise in October 2007.

The Office of Financial Management (OFM)

OFM expanded its scope for OMB A-123 Appendix A- Internal Controls Over Financial Reporting by utilizing a methodology of Control Rationalization to bring about a more robust risk-based internal control assessment and to identify opportunities for improvement. It utilized this methodology across the entire Procure-to-Pay process and in our Revenue process which includes User Fees.

Unified Financial Management System (UFMS) has been fully implemented in FDA. As UFMS is an integrated system and all OPDIVs share it, FDA remains involved and participates in all future phased implementations of other OPDIVs in the Department. As such, in FY 2006, we participated in the Program Support Center's phased implementation of UFMS and did so again in FY 2007 for Indian Health Services (which went live on October 1, 2007). A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009, FDA will begin migration to the latest version of ORACLE Federal Financials. This version of Federal Financials will do away with multiple manual processes and will enhance reporting capabilities.

The Office of Information Management (OIM)

OIM enables FDA's strategic efforts to transform and improve the systems and infrastructure needed to support critical agency operations. The program maximizes 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. OIM works to align IT investments to business goals that fully support core mission and business priorities and reduce costs of existing legacy systems while providing the platform required for FDA to meet Agency-wide IT initiatives and to move towards the Bioinformatics era of science-based decisions in the 21st Century.

Office of Policy, Planning, and Preparedness

The Office of Policy, Planning, and Preparedness (OPPP) advises the Commissioner and other key FDA officials on matters relating to policy, development of regulations and guidance, legislative issues, planning and evaluation activities, and counter-terrorism and emerging threats.

The Office of Policy

In FY 2007, the Office of Policy led and successfully concluded the agency's negotiations with industry to reauthorize the Medical Device User Fee and Modernization Act of 2002. The Office of Policy co-led agency negotiations with Congress on reauthorization of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act as well as revisions to the clinical trials database provisions. The Office of Policy also coordinated development of the

plan and tracking system for implementation of the Food and Drug Administration Amendments Act of 2007.

The Office of Policy served as a full-time member of the interagency staff team that supported the Interagency Working Group on Import Safety established by President Bush in July 2007. The Working Group issued two documents – *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety* (September 10, 2007) and *Action Plan for Import Safety: A Roadmap for Continual Improvement* (November 6, 2007).

The Office of Policy oversaw the development of the regulatory policy section of the Nanotechnology Task Force report – *Nanotechnology: A Report of the Food and Drug Administration* (July 25, 2007). The report, in part, provided an assessment of the adequacy of current FDA regulatory frameworks and made recommendations to Commissioner von Eschenbach on the steps the agency should take to ensure that its regulatory pathways are optimally positioned for the oversight of nanotechnology-based FDA-regulated products.

The Office of Planning

The Office of planning completed the FDA Strategic Action Plan in FY 20007, which describes FDA's long-term strategic goals and objectives, and identifies specific actions the agency will undertake over the next eighteen months to deliver major progress toward these goals and objectives. The Office of planning led the effort to reauthorize and enhance the Prescription Drug User Fee Act (PDUFA), which broadens and upgrades the agency's drug safety program. In FY 2007, the Office of Planning established a new Risk Communication Advisory Committee, which will bring together national experts to advise FDA on the science and practice of improving the effectiveness of risk communications to the public, regulated industry, and health practitioners. In addition, the Office of Planning completed the final Regulatory Impact Analysis of Hepatitis C "Look Back" Final Rule which cost-benefit analysis indicates reduces the costs of the net annualized benefits..

The Office of Integrity and Accountability

The Office of Integrity and Accountability published Waivers Draft Guidance on procedures for determining eligibility and waivers for participation on an FDA advisory committee and completed publication of the draft guidance on public disclosure of waiver information.

The Office of Counter Terrorism and Emerging Threats (OCET)

OCET coordinated FDA's activities on Emergency Use Authorization (EUA) of medical countermeasures during declared emergencies involving a heightened risk of attack or significant potential to affect national security, and exercised important role this as part of the national TOPOFF 4 exercises. In FY 2007, under the leadership of OCET and through the efforts of the FDA EUA Working Group, FDA has finalized guidance on authorizations to use countermeasures for chemical, biological, radiological, and nuclear agents during declared emergencies.

OCET coordinated FDA's pandemic preparedness planning as co-lead of the Agency's Pandemic Influenza Preparedness Task Force. The Task Force released the FDA Pandemic Influenza Preparedness Strategic Plan in FY 2007. In addition, the Task Force has participated

in and provided input to significant interagency pandemic influenza efforts, such as the implementation of the President's National Strategy for Pandemic Influenza and the HHS Pandemic Influenza Plan.

In FY 2007, OCET coordinated the activities of the interdepartmental Shelf Life Extension Program (SLEP) Rapid Response Team (RRT) to assess current capacity and explore possible future expansion of SLEP. The RRT was charged with fulfilling a mandate from the White House Homeland Security Council's Implementation Plan for the National Strategy for Pandemic Influenza. With FDA serving as the chair, the SLEP RRT held numerous meetings to address documentation of compliance by current SLEP participants and to inform decision-making on potential SLEP expansion to include antiviral drug and vaccine stockpiles maintained by the States. The RRT provided a timely and comprehensive assessment of SLEP capacity to the HSC and thereby contributed to the successful implementation of the National Strategy for Pandemic Influenza.

Office of Scientific and Medical Programs

The Office of Scientific and Medical Programs (OSMP) serves as the focal point for scientific, medical, and related activities within the Office of the Commissioner.

The Science Board

The Science Board to the FDA (Science Board) is the only FDA advisory committee that provides advice directly to the Commissioner of Food and Drugs on specific technical issues, as well as emerging issues within the scientific community, industry, and academia. During the 2007 meeting, the Science Board discussed (1) a review of the agency's safety/risk assessment regarding consumption of meat from animals fed feed containing melamine and related compounds and (2) an in-depth review of the agency's science programs and infrastructure so that FDA can prepare for future changes in science, technology and population health needs. The peer-review of the agency's safety/risk assessment is an important science-based component of the federal joint investigation into imported wheat gluten and rice protein concentrate from China that contained melamine and melamine-related compounds. The in-depth review of the agency's scientific capacity is critical to assuring that FDA will continue to meet the regulatory challenges of the present and future developments in science and technology.

Office of Critical Path Programs

The Critical Path Initiative began in 2004 with a focus on modernizing medical product development. In 2006, as it developed its list of 76 possible opportunities (with extensive input from industry, other federal agencies, academia, etc), it became increasingly obvious that Critical Path touches on All FDA regulated products. During 2007, we have successfully expanded Critical Path into all FDA centers.

The Critical Path Initiative is viewed as the creation of a new, permanent program that will strive to harness all available resources in the development of cutting edge scientific processes and tools that will help ensure FDA can carry out its mission of protecting the public health commensurate with the scientific and technical knowledge at hand.

The Office of Women's Health (OWH)
OWH has funded 37 scientific projects relevant to women's health and an improved understanding sex/gender differences including projects specific to cardiovascular disease in women and the collection of demographic data on women in clinical trials. In FY 2007, OWH provided consumer health information, such as a Menopause and Hormones Education Campaign, Spanish translation materials, new medication booklets (that provide information about all FDA approved drugs for: elevated cholesterol, depression, high blood pressure, HIV/AIDS, smoking cessation, menopause), and online information about medication use in pregnancy. OWH participated in over 40 national medical, scientific, and health care conferences and distributed more than 5.4 million health information publications through FCIC.

Other Headquarters Offices

Office of Shared Services (OSS) and Office of Information Technology Shared Services (OITSS) provide a portfolio of administrative and information technology services FDA-wide.

The Office of Shared Services (OSS)
OSS led the Department of Health and Human Services in exceeding all socio-economic contracting goals, such as Small Business Awards and Small Disadvantaged Veteran Owned Small Business Awards and achieved "green" progress for Presidential Management Agenda real property management objectives.

The Office of IT Shared Services
In FY 2007, the Office of IT Shared Services consolidates and modernized the FDA's IT infrastructure and provided 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.

Five Year Funding Table

Fiscal Year *	Program Level	Budget Authority	User Fees	Program Level FTE
2005 Actuals	$104,504,000	$87,230,000	$17,274,000	652
2006 Actuals	$103,886,000	$85,676,000	$18,210,000	672
2007 Actuals	$111,425,000	$91,813,000	$19,612,000	671
2008 Enacted	$133,436,000	$97,496,000	$35,940,000	696
2009 Estimate	$139,227,000	$99,398,000	$39,829,000	701

** FY 2004 Actuals include a portion of GSA Rent and Rent Related Activities.*

Budget Request

The FY 2009 budget request includes $139,227,000 in program level funding for FDA Headquarters and the Office of the Commissioner. This includes an increase of +$1,902,000 in budget authority and +$3,889,000 in user fees above FY 2008 Enacted. The overall increase provides additional budget authority to cover a targeted increase to protect the food supply and a cost of living pay increase for the entire Headquarters and Office of the Commissioner; and provides the inflationary increases for current law user fees and two proposed user fees.

Protecting America's Food Supply Initiative

The FY 2009 budget requests $2,214,000 for the Protecting America's Food Supply Initiative. Of this amount, $550,000 is the Headquarters and the Office of the Commissioner (OC) portion of the initiative that will fund the Office of Crisis Management's Emergency Operations Network and support OC activities associated with implementing the memoranda of agreements with China. In addition, $1,664,000 is the amount is for the cost of living pay increase. The cost of living pay increase will allow FDA to maintain staff levels, including a national cadre of trained staff in order to achieve FDA's performance commitments and to anticipate and respond to public health emergencies.

The Protect America's Food Supply initiative will allow FDA to accomplish its mission of ensuring the safety of domestic and imported food by implementing priority components of the Food Protection Plan, The Headquarters and the Office of Commissioner requests $550,000 to support its Food Protection activity. These resources will be used to strengthening its Emergency Response Infrastructure. Recent food safety threats have demonstrated that the size and scope of recent emergencies have strained FDA's emergency response infrastructure. These resources would support the FDA's ability to coordinate Agency response to foodborne illness events, outbreaks and emergency situations by continuing to support the functionality of the Emergency Operations Network Incident Management System (EON IMS) to increase knowledge management.

FDA is implementing the December 11, 2007 agreements with China on food protection. The requested resources for the Headquarters and the Office of the Commissioner will also be used to support the FDA Office in China by carrying out the provisions of two Memoranda of Agreement (MOA) with China and to conduct site visits, which may include traditional inspections.

Administrative Savings and Management Efficiencies: -$312,000

The Administration has supported a reduction associated with Administrative Savings and Management Efficiencies. FDA has achieved increased efficiencies by enhancing its business processes, streamlining its organizational structure, improving the delivery of information technology and administrative services, and continuing to reap the benefits of its unified financial systems. The Headquarters and Office of Commissioner Program portion of this Administrative and Management Savings is a reduction of $312,000.

User Fees:

Prescription Drug User Fee Act (PDUFA IV): +$2,672,000
In the FY 2008 Consolidation Appropriations Act, the Prescription Drug User Fee Act (PDUFA IV) was reauthorized for FY 2008 to FY 2012. It includes an update in the workload adjuster to better reflect the Investigated New Drug (IND) workload, an adjustment for rent activities, and the addition of fees for reviewing direct-to-consumer advertising. Additionally, the reauthorization contains a change in the Consumer Price Index (CPI) factor to better correspond to our budgeting process, and the addition of an inflation factor to reflect the five-year average of FDA's salary and benefit costs. User fees revenues under this program are estimated at $511,108,000 in FY 2009, with $31,773,000 for Headquarters and Office of the Commissioner. Of this amount, $430,000 is proposed to be generated from the Direct-To-Consumer advertising review fees.

Medical Device User Fee and Modernization Act (MDUFMA II): $464,000
In the Food and Drug Administration Amendments Act of 2007, Medical Device User Fee and Modernization Act (MDUFMA II) was reauthorized for FY 2008 to FY 2012. MDUFMA II includes the addition of an establishment fee to ensure a more stable revenue base, a change in the CPI factor to better correspond to our budgeting process and the addition of an inflation factor to reflect the five-year average of FDA's salary and benefit costs. User fee revenues under this program are estimated at $52,547,000 in FY 2009, with $5,914,000 going to Headquarters and the Office of the Commissioner.

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 American women will contract breast cancer during their lifetime. The Mammography Quality Standards Act (MQSA), which was reauthorized in October 2004, addresses the public health need for safe and reliable mammography. The Act required that mammography facilities be certified by October 1994, and inspected annually to ensure compliance with national quality and safety standards. The reauthorization codified existing certification practices for mammography facilities and laid the groundwork for further study of key issues that include ways to improve physicians' ability to read mammograms and ways to recruit and retain skilled professionals to provide quality mammograms. The increase of $11,000 will cover inflationary costs.

Proposed User Fees:

Generic Drugs User Fee: +$549,000
Abbreviated New Drug Applications (ANDAs) to market generic drugs are critical to lowering Federal spending on pharmaceuticals. Since 2002, the number of ANDAs has more than doubled. The additional resources generated by the 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. User fee revenues under this program are estimated at $16,628,000 in FY 2009, with $549,000 going to Headquarters and the Office of the Commissioner.

Animal Generic Drugs User Fee: +$193,000

The proposal for the Generic Animal Drugs User Fees will generate resources that will allow FDA to improve product review performance and reduce review time. Increasing costs for the review of Abbreviated New Animal Drug Applications (ANADAs) along with inadequate resources has resulted in a significant increase in review times and a backlog of generic animal drug applications for review. Management initiatives that have been implemented to increase efficiency in the generic animal drug review process include dedicated review teams for evaluation of generic animal drugs, phased review of generic investigational new animal drug submissions, and establishment of periodic meetings with representatives of the generic animal drug industry to discuss issues and ideas for improvement. Despite these efforts, under-funding has led to a significant increase in review time for generic animal drug applications and submissions.

Adding additional staff and information technology through user fee revenues will shorten the time to approval, and decrease the delay in making lower cost medications available to the food animal production industry, veterinary practitioners, companion animal owners, and the general public. The user fee revenues generated under this program are estimated at $4,831,000, of which $193,000 will go to the Headquarters and Office of the Commissioner.

Headquarters and the Office of the Commissioner Outputs / Outcomes Table

#	Key Outcomes/ Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 1: Strengthen FDA's base of operations.									
1	The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". (291401) (Efficiency)	350 FTE Conduct Clerical Study	350 FTE (combined with FY 2004)	154 FTE	Study cancelled in February 2007 with the approval of the CSO.	308 by Sept 15	354 FTE by 9/15/07	154 FTE by Sept 15	154 FTE by Sept 15
2	FDA's implement-ation of HHS's Unified Financial Management System (UFMS). (291402) (Efficiency)	Began develop-ment of FDA's unique inter-faces and test global inter-faces	Imple-mented the General Ledger and the Payroll interface	Pilot activity-based costing appli-cation for PDUFA FDA's legacy core financial system decomm-issioned	Goal accom-plished through various activities discussed under Perform-ance text.	Finalize decision on an activity-based costing appli-cation and make it oper-ational for its user fee programs.	01/08	Stabilize UFMS environ-ment Explore/ analyze effects of moving to a later version of ORACLE Federal Financials[1]	Begin migration to the latest version of ORACLE Federal Financials

[1] This goal had originally been dropped in the FY 2008 CJ because FDA had implemented and was maintaining the UFMS system. However, FDA remains involved in the continued rollout of UFMS to other OPDIVs, and is planning to move to a later version of ORACLE Federal Financials.

Long-Term Objective 2: Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.									
3	Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (292201) (Output)	Developed Crisis Management Plan for CT and Agency Emergency Operations Network	EON IMS version 2.2 implemented in March 2005 and used during the April 2005 TOPOFF 3 Exercise	Enhance functionality and continue deployment of the EON IMS through out the Agency (HQ, Centers, Field offices)	EON IMS Version 2.4 August 06. deployed to OCM/ OEO located in FDA field offices and used to prep and respond to emergencies	Continue Enhancement EON IMS Coordinate FDA's participation in exercises, including TOPOFF 4 Develop an FDA emergency response plan for pandemic influenza.	EON IMS version 3.2.1 implemented December 2007 and used in the preparation and response to natural disasters and crises and emergencies. FDA emergency response plan for pandemic influenza developed Sept 2007.	Continued enhancement of EON IMS increased knowledge mgmt and GIS capabilities. Test FDA emergency response plan for pandemic flu and coordinate FDA's participation in other exercises and workgroup.	Continued enhancement of EON IMS and GIS capabilities. Coordinate FDA's participation in exercises and workgroups, including TOPOFF 5.

1. The number of Commercial Activities that will be reviewed for competitive sourcing per "Green Plan". (291401)

Context: FDA plans to study at least 154 FTE per year based on the FAIR Act Inventory of 2003. To accomplish this, FDA conducts an intensive annual review of its FAIR inventory data from functional, organizational, geographic, and business perspectives. Once the review is completed, FDA evaluates all commercial positions that have not undergone a competitive sourcing study in order to identify a sufficient number of positions that will satisfy FDA's requirement in meeting the OMB and DHHS established goals. The commercial positions are presented to FDA senior management in the form of logical business units to determine what will be reviewed that year. The selected commercial business units are publicly announced and subjected to A-76 competitive sourcing competition either as one or more standard and/or streamline cost comparisons. For FY 2007, the FDA announced 308 commercial FTE positions by September 15.

Performance: FDA exceeded its FY 2007 Competitive Sourcing goal by 15% by announcing 354 positions divided into thirteen individual streamlined studies. Eight of these studies have been completed, resulting in in-house wins. The remaining five studies are nearly complete with decisions expected by January 31, 2008. The eight studies completed in FY 2007 resulted in a total projected annual savings of $2,163,879. Combined with the seven in-house wins resulting from FY 2002-2005 studies, the total projected annual savings for the FDA now exceeds $7.6 million. FDA was also recently identified as a critical component to the DHHS receiving a Government wide Presidential Quality Award for Competitive Sourcing.

2. FDA's implementation of HHS's Unified Financial Management System (UFMS). (291402)

Context: The Department announced in FY 2001 that it intended to establish a unified financial management system to replace its operating division's individual financial management systems. The goal of the UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. FDA, CDC, NIH, and the Program Support Center (which covers the remaining components other than CMS and its contractors) began the design of the UFMS. Although this goal had originally been dropped after FDA had implemented UFMS, FDA has continued to be involved in the implementation of the UFMS system across the Department. A new FY 2008 target has been added based on FDA's efforts to stabilize the UFMS environment now that all OPDIVS have gone live, and to explore/analyze the effects of moving to a later version of ORACLE Federal Financials, bringing DHHS one step closer to FMFIA compliance. In FY 2009, FDA will begin migration to the latest version of ORACLE Federal Financials. This version of Federal Financials will do away with multiple manual processes and will enhance reporting capabilities.

Performance: UFMS has been fully implemented in FDA. Because UFMS is an integrated system and all OPDIVs must share it, FDA remains involved and participates in all future phased implementations of other OPDIVs in the Department. As such, in FY 2006, we participated in the Program Support Center's phased implementation of UFMS and did so again in FY 2007 for Indian Health Services (which went live on October 1, 2007).

3. Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (292201)

Context: FDA's Office of Crisis Management (OCM), which includes the Office of Emergency Operations and Office of Security Operations, is charged with meeting the DHHS goal to improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. OCM is responsible for ensuring that FDA's emergency preparedness and response capabilities are in accordance with the requirements of the National Response Plan, National Incident Management System and several Homeland Security Presidential Directives (HSPD), including HSPD-5, "Management of Domestic Incidents," HSPD-8, "National Preparedness," and HSPD-9, "Defense of United States Agriculture and Food."

Performance: In FY 2007, the Emergency Operations Network Incident Management System (EON IMS) designed, developed and implemented production system version 3.2.1 and plans to release version 3.3 in June 2008. The FDA Office of Crisis Management/Office of Emergency Operations uses the EON IMS to assist in the coordination and strategic management of FDA's response to numerous incidents regarding FDA regulated commodities, including outbreaks, natural disasters, and actual or potential product defects that pose a risk to human or animal health; e.g.; melamine contaminated pet food, peanut butter contaminated with salmonella, and botulism in chili sauce. OCM used the mapping capabilities of EON IMS to generate geo-coded maps to support preparedness efforts for the 2007 hurricane season, response activities related to outbreaks involving peanut butter, and illnesses caused by pet food manufactured with contaminated ingredients imported from foreign sources. EON IMS has also been used to support preparedness exercises that have included international, federal, state and local partners.

OCM completed the FDA emergency response plan for pandemic influenza in September 2007 and participated in the TOPOFF4 exercise in October 2007.