OTHER ACTIVITIES

	FY 2004 Actual	FY 2005 Enacted [1/]	FY 2006 Estimate	Increase or Decrease
Program Level	**$114,296,000**	**$124,349,000**	**$126,944,000**	**+$2,595,000**
Total FTE	*709*	*769*	*763*	*-6*
Budget Authority	**$98,597,000**	**$94,528,000**	**$94,708,000**	**+$180,000**
Food Defense	*N/A*	*$1,488,000*	*$2,988,000*	*+$1,500,000*
GSA Rent & Rent Related	*$8,422,000*	*$7,296,000*	*$7,446,000*	*+$150,000*
Administrative Efficiencies	*N/A*	*N/A*	*N/A*	*-$120,000*
IT Reduction	*N/A*	*N/A*	*N/A*	*-$1,350,000*
Total FTE	*575*	*597*	*583*	*-14*
User Fees	**$15,699,000**	**$29,821,000**	**$32,236,000**	**+$2,415,000**
PDUFA	*$14,204,000*	*$24,978,000*	*$26,386,000*	*+$1,408,000*
MDUFMA	*$1,281,000*	*$4,394,000*	*$4,889,000*	*+$495,000*
ADUFA	*N/A*	*$247,000*	*$749,000*	*+$502,000*
MQSA	*$214,000*	*$202,000*	*$212,000*	*+$10,000*
Total FTE	*134*	*172*	*180*	*+8*

Includes structure changes to FDA's budget, which displays GSA and Other Rent and Rent Related Activities in the Program line, and the Office of Regulatory Affairs as its own program. ORA estimates are for information purposes only and are not included in the Center program level total.
[1/]Contains budget authority rescission of 0.8 percent.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fee	Program Level FTE
2002 Actual [1/]	$94,086,000	$82,003,000	$12,083,000	788
2003 Actual	$107,675,000	$84,685,000	$22,990,000	813
2004 Actual	$114,296,000	$98,597,000	$15,699,000	709
2005 Enacted	$124,349,000	$94,528,000	$29,821,000	769
2006 Estimate	$126,944,000	$94,708,000	$32,236,000	763

Does not contain GSA Rent or Other Rent and Rent Related Activities.
[1/]Includes FDA's FY 2002 Appropriation and the Counterterrorism Supplemental.

STATEMENT OF BUDGET

The Other Activities program is requesting $126,944,000 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; and,

- Providing direction in the management of financial, human and information systems resources, knowledge management and other critical infrastructure needs in support of our science-based work.

PROGRAM DESCRIPTION

Through the Office of the Commissioner and the Office of Management, Other Activities 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 (including the Office of Management described below) that provide policy making, program direction, coordination and liaison, and expert advice to agency leadership and programs. These offices address emergency preparedness and crisis management; external relations with the public and various constituencies; legislation and program support to FDA's congressional authorizing committees; science and health coordination; international collaboration with foreign government and multi-governmental organizations; legal guidance; equal employment opportunity and diversity management; and management services. See table below for office's description.

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, counter terrorism activities, interagency and intra-agency coordination of emergency and crisis planning and management, and internal and external security.
Office of Planning and Policy	Provides advice and assistance in policy development and oversees FDA rulemaking; serves as 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 Legislation	Coordinates FDA's response to authorizing committees' requests, reviews proposed legislation, prepare agency testimony and facilities clearance by the Department and OMB.
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 association, stakeholders, and governmental bodies.
Office of Science and Health Coordination	Advises key officials on scientific issues that impact policy, direction, and long-range goals; coordinates the responsibilities for women's health issues and good clinical practices program; and administers the combination products and orphan product development programs.
Office of International Affairs and Strategic Initiatives	Advises FDA leadership on international activities including the coordination of the international conference on harmonization and World Health Organization functions; and fosters the development of and administers mutual recognition agreements and other policy documents with foreign countries and multi-national governmental organizations.
Office of Equal Employment Opportunity and Diversity Management	Advises and assists key officials on equal employment opportunity (EEO) and Civil Rights activities; develops, implements, and monitors the FDA's Affirmative Employment Plan and directs the Affirmative Employment Program; develops labor-management partnerships on EEO matters; and develops and oversees diversity initiatives.

The Office of Management (OM) provides a variety of administrative and program support services. OM assures strategic and operational management of information technology, financial management expertise, and administrative support services to FDA employees.

OM manages FDA's budget development as well as provides overall financial management accountability – including the creation of the annual financial report (see picture). OM also supports the Department in establishing a Unified Financial Management System (UFMS), with the goals of reducing costs, mitigating security risks, and providing timely and accurate information across DHHS. OM leads FDA's charge to implement the President's Management Agenda.

OM improved FDA's information technology program by consolidating various functions into a newly re-invigorated office of the chief information officer (OCIO), which provides strategic direction for IT resources focused on accomplishing FDA's mission and strategic goals.

Several OM functions are now being managed by a shared services organization that provides customized administrative and information technology services on cost-reimbursable basis to FDA components. The Office of Shared Services (OSS) operates within a portfolio of services that is aligned with customer's needs for transactional services, products and information, and

specialized services to fit specific customer segments. OSS uses multiple measuring techniques to ensure FDA employees are well served.

 OM is working with the GSA in constructing FDA's headquarters consolidated campus at the Federal Research Center in White Oak, Maryland. In December 2003, the Life Science Building was dedicated. A picture of this building, which currently houses about 125 CDER review staff, is shown at the left. Construction of the CDER Office building is near completion. More than 1,700 employees are scheduled to occupy the building in the Spring / Summer 2005. Additionally, construction is underway on the Central Shared Use I building, which completed, this building will provide employees and visitors with a cafeteria, conference and training center, credit union, fitness center, health unit, central library, and recreation and welfare store, along with housing the agency security command center, center data center, and NTEU offices.

PERFORMANCE ANALYSIS

During the latest completed performance period, (FY 2004), the Other Activities Program met the targets for nine out of the ten performance goals, and expects to meet the last goal once actual data is available in March 2005. For more detailed explanation of these goals and results, please see their respective section contained in the Detail of Performance Analysis under the Supporting Information tab.

The FDA supports the Department in establishing a unified financial management system. The goal of UFMS project is to reduce costs, mitigate security risks, and provide timely and accurate information across DHHS. Implementing a new financial system will provide qualitative and quantitative benefits to FDA because it will achieve improved business processes and provide more accurate and timely information to better support FDA's and DHHS' mission.

Performance Highlight:

Goal Target Goal Target	Context	Results
FDA's implementation of HHS's Unified Financial Management System	FDA is complying with the department's goal to establish a unified financial management system. Specifically, the Department plans to use two financial systems covering CMS and its contractors and the other one covering the rest of the Department.	Major components of data cleanup have been completed. Travel manager implementation has been completed throughout the Agency in preparation for UFMS.

In addition to accomplishing this performance commitment, the Program achieved success in the following areas that are highlighted below:

FDA / Departmental Initiatives:

- *Reducing Obesity Strategy* – In March 2004, Secretary Thompson released a FDA report outlining another element in HHS' comprehensive strategy for combating the epidemic of obesity that threatens the health of millions of Americans with a focus on the message, "calories count." The report includes recommendations to strengthen food labeling, to educate consumers about maintaining a healthy diet and weight and to encourage restaurants to provide calorie and nutrition information;

- *Challenge and Opportunity on the Critical Path to New Medical Products* -- FDA issued a major report identifying both the problems and potential solutions foster medical product development. The critical path outlines the crucial steps that determine whether and how quickly a medical discovery becomes a reliable medical treatment for patients; and,
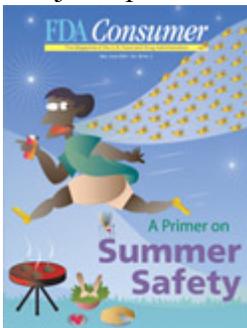
  - The May – June 2004 issue of the FDA Consumer Magazine reported on efforts of FDA and USDA to deal with the incident of mad cow disease that occurred in December 2003. The article entitled, "Agencies Work to Corral Mad Cow Disease," describes the government's reaction to the nation's first diagnosed case of BSE. This and other topical news are presented in the FDA Consumer several times a year to the public.

FDA Launches Web Sites on Heart Health and Drugs

Two new FDA Web sites offer valuable information for consumers about how to get heart-healthy and what drugs are approved for various medical conditions.

- FDA Heart Health Online contains reliable information about products used to prevent, diagnose, and treat heart disease; and

- Drugs@FDA is designed to help consumers and health professionals find information about approved drugs more quickly and efficiently. It is an exhaustive, searchable catalog of approved prescription and over-the-counter drugs and some discontinued drugs.

RATIONALE FOR BUDGET REQUEST

This request for Budget Authority and User Fees supports various activities that contribute to the accomplishment of program outputs and performance goals, and presents FDA's justification of base resources and selected FY 2004 accomplishments by strategic goal.

PROGRAM RESOURCE CHANGES

Program Account Restructuring

GSA Rent and Other Rent Activities Structure Change
To provide increased flexibility, eliminate the need for the many reprogramming requests to Congress, place accountability for rental costs within the operating program, and better reflect the total cost of each program, this budget changes the way the GSA Rent and Other Rent-Related Activities budget lines are displayed by incorporating these resources into Other Activities program level request.

Budget Authority

Food Defense: +$1,500,000 and +2 FTE
The increase continues funding for the Emergency Operations Network (EON) project, which plays a crucial role in strengthening FDA's capability to identify, prepare for, and respond to terrorist threats and incidents. The project's goals and objectives align with this strategy by facilitating the combination of multiple data streams from other electronic systems such as FERN, eLEXNET, EPI-X, and from FDA laboratories/investigators and external agencies to be presented in a coherent fashion during critical decision points. This will create a safety net that significantly reduces the probability that terrorist will achieve their aims and minimizes the impact of these threats if they occur; and improves the Agency's emergency preparedness and response time in the event of a terrorist attack. In FY 2006, a total of $1.5 million in new budget authority is requested for the EON.

GSA Rent: + $150,000
To help meet the rising costs of GSA rent, a total increase of $4,100,000 is requested, of which $150,000 is for Other Activities.

Management Savings: -$1,470,000 and -3 FTE
FDA will reduce spending on administrative and IT activities. Specifically, these reductions are:

- **Administrative Efficiencies: -$120,000**
  Administrative efficiency savings will total -$1,554,000 and -15 FTE, of which the Other Activities share is -$120,000.

- **Information Technology Reduction: -$1,350,000 and -3 FTE**
  IT reductions will total -$5,116,000 and -15 FTE, of which the Other Activities share is -$1,350,000 and -3 FTE.

User Fees

Prescription Drug User Fee Act (PDUFA): + $1,408,000 and +4 FTE
The PDUFA authorized the FDA to collect fees from the pharmaceutical industry to augment appropriations spent on drug review. The BT Act of 2002 reauthorized the collection of user fees to enhance the review process of new human drugs and biological products and established fees for applications, establishments, and approved products. These amendments are effective for five years and direct FDA to strengthen and improve the review and monitoring of drug safety; consider greater interaction with sponsors during the review of drugs and biologics intended to treat serious diseases and life-threatening diseases; and develop principles for improving first-cycle reviews. This increase will cover the inflationary costs of the Other Activities portion of the fees.

Medical Device User Fee and Modernization Act (MDUFMA): + $495,000
Sound, risk based review processes are imperative to ensure that medical devices on the market are safe and effective. To strengthen FDA's medical device review process MDUFMA was authorized in FY 2002 as multi-year effort to improve the quality and timeliness of the medical device review process. This legislation authorizes the collection of user fees for the review of medical device applications from those who submit premarket applications, certain supplements to those applications, and premarket notifications. This increase will cover the inflationary costs of the Other Activities portion of the user fees.

Animal Drug User Fee Act (ADUFA): + $502,000 and +4 FTE
Safe and effective animal drugs allow food animal producers to maintain healthy animals, and help ensure that resulting food products will be safe, wholesome, and free of drug residue, and that companion, service animals that assist the disabled, and other animals such as zoo animals will live healthier and longer lives.   The ADUFA program, under which new animal drug applicants, sponsors, and manufacturers incur a fee to expedite their applications, will help provide a cost-efficient, high-quality performance-driven review process. Modeled after PDUFA, this fee has strong industry support and provides a complementary set of incentives to all stakeholders. The increase will cover inflationary costs for staff associated with the implementation of ADUFA.

Mammography Quality Standards Act (MQSA): + $10,000
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 $10,000 will cover inflation.

JUSTIFICATION OF BASE

USING RISK-BASED MANAGEMENT PRACTICES
Base resources will be used to conduct science-based risk management in all agency regulatory activities; so that the agency's limited resources can provide the most health promotion and protection at the least cost for the public.

Bovine Spongiform Encephalopathy (BSE) and Other Transmissible Spongiform Encephalopathies (TSE)
FDA works closely with the USDA, Customs, in the Department of Homeland Security (DHS) and state agricultural and veterinary agencies on the implementation of BSE regulations and controlling imported products. FDA supports the department-wide action plan outlining new steps to improve scientific understanding of BSE, commonly known as "mad cow disease," and other TSE diseases, (e.g., CWD). These activities include:

- Upgrade equipment in the Office of Crisis Management's Emergency Operations Center (EOC) , including further integration of communications systems and purchasing additional software to better manage a potential or actual BSE incident;

- Implement a management system to ensure collaboration and development of geographic information, including geocoding of all firms being inspected for BSE; and,

- Provide equipment to facilitate operations during activation of the EOC, around the clock coverage.

International Activities
FDA provides leadership, management and coordination for all of its activities with foreign governments. These activities cover a wide variety of public health issues that pertain to all of the products FDA regulates, including human and animal food and drugs, human biologics, and human medical devices. These activities include:

- Direct the development and implementation of agency-wide strategies for FDA-supported international harmonization programs and managing FDA's submissions for U.S. policy development;

- Advance FDA's position on critical public health matters in international negotiations including the trade negotiations under the World Trade Organization and numerous free trade agreements under the auspices of the Office of the U.S. Trade Representative;

- Direct and manage the development of agency policy on critical international activities including the sharing of information with foreign governments that used to support FDA's import program and export policy. Activities in this area include work with foreign governments to facilitate the communication and cooperation in the event of emergencies, such as BSE, or acts of terrorism;

- Support the implementation of the Mutual Recognition Agreement and Veterinary Equivalence Agreement with the European Union, which will help FDA undertake a risk-based approach to leveraging our resources with those of competent counterpart agencies in other parts of the world so FDA can focus its resources on areas that are determined to present the greater risk to U.S. public health;

- Manage FDA risk management initiatives with foreign governments concerning compliance problems with foreign products, for example, violations of FDA requirements, and food and drug safety issues;

- Conduct cross-cutting agency technical assistance activities to leverage resources for training foreign regulatory scientists to improve the safety and quality of FDA-regulated products exported to the U.S., and,

- Supplement FDA's regulatory enforcement activities by directing and managing international agreements with foreign governments. This includes, assessing the efficacy of bilateral and multilateral agreements, and work with the Department of State, USTR, and other Federal agencies to negotiate additional agreements.

EMPOWERING CONSUMERS FOR BETTER HEALTH

Resources will be used to better enable consumers to make informed decisions weighing benefits and risks of FDA-regulated products. These activities include:

- Develop an FDA-wide consumer communication infrastructure and implement a consumer-media outreach strategy that is designed to help both consumers and patients understand how to live better, healthier lives;

- Create and leverage external collaborations with healthcare providers, and public and private healthcare organizations and institutions to increase both the reach and consistency of the FDA's "Better Informed Consumer" message; and,

- Seek out speaking opportunities for FDA to communicate directly with diverse consumer segments. This will be done in collaboration with the agency's Public Affairs Specialists as well as the Office of Special Health Issues, and the Office for Public Affairs.

Education and Outreach
FDA develops regulatory-based action plans across its different product centers in collaboration with other agencies in areas with great threat to public health, such as antimicrobial resistance and BSE, and ensures these actions are successfully implemented across the FDA.

PATIENT AND CONSUMER PROTECTION
FDA has a unique opportunity to develop more direct access to databases that will allow us to rapidly assess risks and improve the safety of medical products. Important information about FDA-regulated products also needs to be made readily available to health care professionals to facilitate the safe use of medical products.

- FDA will develop and foster collaborative efforts with private and public health care systems to create interactive data systems for identification of medical product risks in real-time and will work with other agencies in HHS and standards development organizations to develop standards for communication of safety information; and,

- FDA will work with the National Library of Medicine to set up a new way to distribute up-to-date and comprehensive medication information in a computerized format for use in health care information systems;

Pediatric Therapeutics
The Best Pharmaceuticals for Children Act directed HHS to establish an Office of Pediatric Therapeutics within FDA's Office of the Commissioner. The Pediatric Research Equity Act of 2003 gave FDA the authority to require pediatric studies and establish a Pediatric Advisory Committee. The Office of Pediatric Therapeutics has five areas of responsibility: pediatric ethics, safety oversight, agency-wide scientific coordination, external communications, and the Pediatric Advisory Committee. Office activities include:

- Enhancing the ethical conduct and quality of pediatric clinical trials by participating in, advising on, and developing procedures for the pediatric aspects of clinical trial oversight in conjunction with other relevant FDA entities;

- Assuring ethical pediatric research and child subject protection across all FDA centers by developing pediatric ethics guidance, educational materials and course design; educating FDA staff; providing pediatric ethics consultation; and overseeing ethical issues for studies requested by FDA for on-and off-patent drug products;

- Reviewing, evaluate and advise on Subpart D (additional protections for children) referrals from Institutional Review Boards. In collaboration with the HHS Office of Human Research Protection, coordinate the public discussion and development of a recommendation for these referrals by the Pediatric Ethics Working Group and the Pediatric Advisory Committee;

- Conducting an ethical review of all written requests developed for off-patent drugs which will then be contracted by the NIH and provide a focused ethical review of written requests for on-patent products eligible for pediatric exclusivity;

- Oversee the safety of all drugs granted pediatric exclusivity by tracking reported adverse events, informing the Pediatric Advisory Committee about them 2-3 times a year, and seeking Committee advice about management of newly identified pediatric safety issues;

- Develop cross-cutting pediatric scientific issues and coordinate activities pertaining to the pediatric population across all FDA product Centers;

- Enhance communication of pediatric issues and new pediatric information for FDA regulated products with consumers, advocacy groups, and healthcare providers (see Empowering Consumers); and,

- Serve as the pediatric liaison to organizations outside the agency, including the American Academy of Pediatrics, the Elizabeth Glazer Pediatric AIDS Foundation, the National Institutes of Health, the Office of Human Research Protection, the European Agency for the Evaluation of Medicinal Products, and others.

Office of Combination Products

The Office of Combination Products (OCP) has broad responsibilities that cover the regulatory life cycle of drug-device, drug-biologic, device-biologic and drug-device-biologic combination products, and include oversight of product jurisdiction decisions and specific premarket and postmarket processes. OCP will continue to:

- Conduct the FDA product jurisdiction program by determining the regulatory identity of a product as a drug, device, biologic or combination product; determining the agency component that will have jurisdiction for any drug, device or biologic product where such jurisdiction is unclear or in dispute; and, assigning review responsibility of combination products to the appropriate center;

- Facilitate the timely and effective premarket review of combination products presenting complex regulatory issues by consulting with both industry and agency review staff to clearly delineate regulatory paths for product approval;

- Actively monitor the intercenter consultation process to ensure the timely and effective premarket review of combination products involving more than one agency center;

- Ensure the consistency and appropriateness of postmarket regulation of combination products by providing guidance and consultation on the selection of appropriate postmarket regulatory authorities and reporting of adverse events involving combination products;

- Collaborate with FDA Centers to develop or update agreements, guidance documents or practices clarifying the regulation or assignment of combination products;

- Obtain external stakeholder input on guidance and policies concerning the regulation and assignment of combination products, as appropriate; and,

- Serve as the agency focal point on matters related to combination products for both internal and external stakeholders.

Human Subject Protection

FDA enhances the capacity and productivity of the Nation's health science research enterprise through strengthening the mechanisms for ensuring the protection of human subjects and the integrity of the research process. The Good Clinical Practice Program will continue to:

- Improve the human subject protection system and the integrity of the research process through the development of regulations that would, for example:

  o Establish a system to report fraud and scientific misconduct in clinical trials and build additional safeguards for children enrolled in clinical investigations;

  o Establish a registration process for Institutional Review Boards (IRBs) to allow better education of, and communication with, IRBs and to facilitate FDA inspections of IRBs; and,

  o Establish standards for the acceptance for the review of foreign clinical studies not conducted under an investigational new drug application that do not rely on now outdated versions of the World Medical Association's Declaration of Helsinki.

- Implement an improved quality assurance and quality improvement program for the agency's Good Clinical Practice (GCP) activities, FDA's GCP Bioresearch Monitoring Program and FDA's intramural and extramural research programs, that would provide for the systematic monitoring and evaluation of the various aspects of these programs and a process to allow program components to self-evaluate activities and identify those that can and should be improved; and,

- Develop and present education and training programs on good clinical practice and human subject protection to major Academic Medical Institutions.

PROTECTING THE HOMELAND -- COUNTERTERRORISM

FDA must have the capability to assess and effectively respond to risks associated with unexpected, and potentially widespread, terrorist-related health and safety threats to the U.S. public. The unpredictability and wide variety of ways that acts of terrorism can be launched complicate preparedness and the agency's ability to quickly and effectively respond to attacks. The challenges for FDA are to facilitate development of medical countermeasures and to effectively safeguard products and to respond at any point in the product pipeline – from farm/production through distribution to use/consumption – in both import and domestic arenas.

FDA has several major objectives that address these challenges:

- Facilitate the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian or military populations and enhance our emergency preparedness and response capabilities to be better able to respond in the event of a terrorist attack;

- Ensure the safety and security of FDA personnel, physical assets, and sensitive information;

- Enhance the safety and security of America's food supply in cooperation with other Federal agencies and with the States;

- Ensure adequate supplies of medicine and vaccines are available to the American public by working with sponsors in the development review and approval of important medical countermeasures to protect the American public and military personnel; and,

- Maintain FDA's Office of Crisis Management's Emergency Operations Center by doing the following:

  o Coordinate the investigation of incidents and emergencies using the Emergency Operations Network Incident Management System, consistent with HSPD-5, "Management of Domestic Incidents," and,

  o Work with FDA Centers and Offices to update the FDA hazard specific response plans, the FDA Crisis Management Plan, and the FDA Emergency Response Plan; coordinate the agency's participation in counterterrorism exercises; and coordinate with HHS on FDA participation in National Special Security Events.

  o For future iterations, the EON project will explore and evaluate FDA and other information systems and analytical solutions to bring surveillance data functionality to its emergency coordinators and participants. This data would provide an additional form of surveillance for the agency to quickly spot emerging issues. Ideally, such a data mart would include subsets of surveillance data from sources and/or reports and include a robust query, analysis, trending, and reporting capability. Linkages to FDA systems such as FACTS, OASIS, and eLEXNET, and other government systems such as NBIS and CDC biosurveillance systems have been identified as options to be considered. FDA has established an intra agency work group to address issues related to Agency inputs to NBIS and is coordinating with DHHS and other operating divisions on a Department-wide approach to NBIS submissions.

IMPROVING FDA'S BUSINESS PRACTICES
More effective regulation through a stronger workforce will help FDA recruit and retain a world-class professional workforce, and conduct effective and efficient operations to accomplish our mission, and meet the objectives of the President's Management Agenda. In support of these objectives, FDA will:

- Support the PMA and FDA's competitive sourcing effort by performing cost comparison studies for commercially identified functions to increase program efficiency and effectiveness;

- Ensure its IT resources support the accomplishment of FDA's mission activities;

- Improve agency financial management systems and integrate performance and budget information to support resource decisions; and,

- Continue support for facilities improvements. Construction of the CDER Office Building continues and completion by April 2005. The Central Shared Use Building and the CDRH Engineering/Physics Building at White Oak is under construction.

Shared Services Activities
In FY 2004, FDA implemented a shared services model for delivering its administrative services to its offices and centers. The OSS operates within a "portfolio of services" that is aligned with the needs of FDA's offices and centers. The "portfolio of services" includes communication, financial transactional functions, procurement, facilities, and equal employment opportunity and diversity management. A call center is used to monitor and analyze operational and customer satisfaction. The table shows the OSS provider office and functional responsibility.

OSS Office	Description
Employee Resource and Information Center	Serves as the central source of administrative and information technology services information for FDA employees.
Office of Acquisitions and Grants Services	Manages contracts, simplified acquisitions, technology transfers, assistance agreements and charge card administration.
Office of Equal Employment Opportunities and Diversity Management	Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity.
Office of Financial Services	Performs the day-to-day operations for financial services related to accounts payable, travel, payroll, fleet and claims management.
Office of Field Financial and Acquisition Services	Provides financial and acquisition services to the Office of Regulatory Affairs field offices and to National Center for Toxicological Research.
Office of Real Property Services	Oversees a wide variety of facility services, including portfolio planning, mail management, move management, and labor services.

These activities include:

- Maintain the Conflict Prevention & Resolution Program to provide FDA with effective dispute resolution processes;

- Process accounts payable, travel vouchers, and payroll for Headquarters and Field accounts;

- Continue to provide commercial payment digital imaging to speed invoice payments;

- Provide leadership and guidance to Headquarters and Field activities for all aspects of real property management and building operations functions for all FDA facilities nationwide;

- Direct the management of programs and systems leading to the acquisition, alteration, maintenance, and utilization of leased and owned facilities nationwide;

- Provide leadership and direction to assure the efficient and effective utilization of resources dedicated to engineering design, facility improvements, and new construction of FDA facilities nationwide, excluding the White Oak project;

- Ensure adherence to applicable legal and regulatory requirements governing Federal procurement; and,

- Provide ongoing administration of grants/cooperative agreements, memoranda of understanding, and interagency agreements including planning, review, and negotiations.

Financial Management

FDA financial systems support all of the agency's financial activities and are mission critical needs for our public health mission. Improved financial performance includes initiatives to reduce erroneous payments, reengineer business processes to include accounting operations in field offices, and a plan for a new core financial management system. These endeavors are vital to comply with changing Federal financial requirements, maintain a clean audit opinion, and integrate accounting and financial systems throughout DHHS. These activities include:

- Formulate budget submissions to the Department, OMB, and Congress, and provide support to Senior agency leadership by preparing testimony and documents used to defend these requests;

- Liaison with members and staff from congressional appropriations committees on FDA budget issues, and coordinate clear responses from FDA offices and centers;

- Prepare quarterly financial statements and annual financial reports, and liaison with the Office of Inspector General's independent auditor conducting the audit on FDA's financial statements, and perform necessary audit follow-up;

- Strengthen information systems security program controls by completing security plans for all major financial applications and upgrade current database system for legacy financial systems in order to strengthen access control;

- Ensure the integrity of major financial applications by reviewing and updating the financial management's software development and change control processes to facilitate year-end closeout, financial statement preparation, and CFO audit activities;

- Implement the UFMS General Ledger, and complete, plan, and implement the second and third phase of the Accounts Receivable, Accounts Payable and Purchasing modules of Oracle

Financials. These phases will also include planning for the interfaces for procurement, property and travel;

- Implement a reporting system that allows users to query and report on the financial system providing up-to-date information in order to make sound resource allocation decisions;

- Implement a standardized system for user fees within the agency that will allow one point of entry for industry and FDA centers integrating the system with each Centers' user fee application tracking systems; and,

- Complete planning for the Activity Based Costing (ABC) system by gathering requirements, selecting a vendor and integrating the system with UFMS.

User Fees

Prescription Drug User Fee Act (PDUFA)
Medical Devices User Fee and Modernization Act (MDUFMA)
Animal Drug User Fee Act (ADUFA)
Mammography Quality Standards Act (MQSA)

The Other Activities share of the user fee programs provides the financial management infrastructure for the collection, receipt, payment, accounting, and reporting of user fee revenues and expenses for PDUFA, MDUFMA, ADUFA, and MQSA. It also coordinates the acquisition and management of the additional space, and provides information technology support.

Other Activities also coordinates the preparation of the annual fiscal report to the Congress for PDUFA, MDUFMA, and ADUFA. Additionally, it is also responsible for the annual PDUFA performance report to Congress and for assisting with other management responsibilities including the PDUFA III goal for improved Performance Management and the various contracts associated with this goal.

Management Programs
FDA management programs support the agency by providing specialized workforce programs, administering the FDA ethics program, implementing programs on the Privacy Act, Freedom of Information Act, and Paperwork Reduction Act, and providing management analysis support to the Office of Commissioner. FDA management programs provide leadership and direction regarding all aspects of a variety of essential agency management programs. These activities include:

- Manage the agency Ethics program to ensure that all FDA employees are in compliance with regulations to maintain high standards of ethical conduct;

- Coordinate the implementation of the Federal Manager's Financial Integrity Act in the agency and prepare the annual assurance statement that internal controls are providing reasonable assurance against waste, fraud, and abuse;

- Liaison with the Department's Office of Inspector General regarding the conduct of audits and evaluations, and provides coordination of agency responses to audit reports and audit follow-up;

- Direct FDA's organizational management and delegations of authority program in conformance to government-wide regulations and departmental policies;

- Establish and oversee implementation of the FDA policy, procedures and processes to ensure agency conformance with the Paperwork Reduction Act;

- Provide leadership and direction to FDA's Freedom of Information (FOI), Privacy Act, and regulatory dockets and rule-making activities;

- Oversee the agency's competitive sourcing (A-76) program;

- Conduct specialized workforce planning and development programs including the Quality of Work Life, Reward & Recognition, Performance Management, Scientific and Regulatory Peer Review Program; and,

- Liaison with the Commissioned Corps and the Department's Human Resources Offices to ensure FDA personnel issues are addressed.

Information Technology
Support the 24 President's Management Agenda e-Gov initiatives and Departmental enterprise information technology strategic initiatives and an enterprise approach to investing in key IT initiatives such as the Federal Health Architecture, the Secure One HHS program, and Public Key Infrastructure. These investments will enable HHS programs to carry-out their missions more securely and at a lower cost. These activities include:

- Continue to align IT resources and investments in support of priority goals and objectives by maintaining an IT planning process synchronized with the business process planning effort;

- Manage the Office of Information Technology Shared Services to deliver efficient and effective services, including on-site desktop management, server and network management, help desk services, electronic mail administration, IT security and electronic trust infrastructure, IT asset and inventory management, training, requirements analysis, and software testing and evaluation;

- Further institutionalize the IT financial reporting process initiated in FY 2004, consisting of processes, tools to track and analyze IT spending in order to maximize the services, and products funded by the IT budget;

- Continue leveraging the Project Management Office and use of an IT Portfolio Management tool in order to facilitate the efficient and effective use of IT resources, including periodic review and measurement of initiatives towards their stated objectives and goals;

- Continue to mature the governance processes integrating Investment Management, Enterprise Architecture and strategic business planning in order to ensure the FDA rigorously selects, controls and evaluates its IT investments in a way that most effectively and efficiently supports agency's mission; and,

- Provide security and confidence to the electronic interchange of data through continued management of an effective IT security program.

Enterprise Information Technology Fund

This request includes funding to support the PMA expanding E-Gov initiatives and Departmental enterprise information technology initiatives. Agency funds will be combined with resources in the Information Technology Security and Innovation 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 goals such as secure and reliable communications and lower costs for the purchase and maintenance of hardware and software. Examples of HHS enterprise initiatives currently being funded are the Enterprise Architecture, Enterprise E-mail, Network Modernization, and Public Key Infrastructure.

SELECTED FY 2004 ACCOMPLISHMENTS

EMPOWERING CONSUMERS FOR BETTER HEALTH

Office of Women's Health
- Supported six intramural research projects on women's health issues related to counterterrorism, product safety, and cardiovascular disease;

- Monitored and evaluated ongoing research projects, jointly sponsored by CDER, that are designed to collect dosing, efficacy and safety information for subpopulations of the general public including pregnant women, fetuses, lactating women and the elderly;

- Conducted site visits at two institutions to ensure studies are consistent with contractual and human subjects protection obligations;

- Conducted extramural research program addressing issues related to FDA products and heart disease in women. Supported three research projects covering:
  - Use and Outcomes of Coronary Stents in Women: Use of a National Medicare Database;
  - Reduced Efficacy of Ace Inhibition in women with chronic heart failure; and,
  - Transmission Attenuation Correction for Female Patients undergoing Myocardial Perfusion Imaging: Correction for Confounding Breast Tissue Artifact.

- Implemented the Menopause and Hormones Information Campaign to bring clear and useful information to women about the use of hormones during menopause. Specific accomplishments include:
  - Distributed more than 650,000 pieces of campaign information throughout the country;
  - Participated in a radio and television station interviews that broadcast the menopause messages in top media markets across the United States;
  - Developed a radio, print and on-line advertising campaign that highlighted the English and Spanish versions of the menopause fact sheets and a public service announcement; and,
  - Conducted a radio tour during the month of September (National Menopause Month) under the campaign theme "Menopause and Hormones: What Can You Believe?"

- Developed a series of consumer information fact-sheets about FDA-regulated products for women and their families;

- Created a widely received educational campaign on promoting mammography in Puerto Rico with local government, organizations, and the press; and,

- Awarded a Consumer Choice Award from the GSA's Federal Citizen Information Center recognizing OWH for "extraordinary service for a decade as a clear voice, empowering millions of consumers by providing reliable health information".

PATIENT AND CONSUMER PROTECTION

Office of Pediatric Therapeutics
- Provided consultative advice on pediatric issues across the agency. In particular, the Pediatric Ethicist responded to 52 consult requests in FY 2004, involving difficult and complex pediatric topics, such as the conduct of appropriate clinical research in the pediatric population, informed consent, standards of therapy in international HIV trials, participation of healthy children in studies and the use of a placebo in clinical trials;

- Assisted the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee which conducted a public review of a referral from National Institutes of Mental Health regarding the use of Dextroamphetamine in healthy children and, through the Pediatric Advisory Committee, made a recommendation to the Commissioner regarding the study;

- Formed an agency-wide Pediatric Ethics Working Group. This committee meets quarterly and provides a forum to discuss cross-Center pediatric issues, policy, and the development of a consistent approach across all FDA product Centers;

- Developed guidance documents and made numerous presentations to agency and external groups regarding pediatric ethical issues related to clinical research and child subject protection;

- Tracked adverse event reports for 24 drugs (table below) and reported them to the Pediatric Advisory Committee. This committee met four times during FY 2004 to hear reports on these 24 drugs and advise FDA on pediatric drug safety management, and;

**PEDIATRIC ADVISORY COMMITTEE ADVERSE EVENT MEETINGS
AND DRUGS DISCUSSED**

October 2003	February 2004	June 2004	September 2004
Busulfex (busulfan)	Paxil (paroxetine)	Hycamtin (topotecan)	Pulmicort/Rhinocort (budesonide)
Zyrtec (certirizine)	Pravachol (pravastatin)	Temodar (temozolomide)	Clarinex (desloratadine)
Cozaar (losartan)	Celexa (citalopram)	Effexor (venlafaxine)	Cutivate/Flonase/Flovent (fluticasone), Advair (fluticasone and salmeterol)
Nolvadex (tamoxifen)	Navelbine (vinorelbine)	Vigamox (moxifloxacin)	Ocuflox (ofloxacin)
Accupril (quinapril)		Ciloxan (ciprolfloxacin)	Fludara (fludarabine)
Serzone (nefazodone)		Monopril (fosinopril) Allegra (fexofenadine) Duragesic (fentanyl)	Fosamax (alendronate)

- Coordinated review consults across FDA product Centers (see table below), developed specific pediatric topics for discussion with various Centers and promoted the communication of new pediatric information for FDA regulated products. Cross-cutting issues addressed in FY 2004 include the use of Probiotics in children, childhood obesity, safety issues for drugs excreted in breast milk, and legislative initiatives for pediatric devices.

**OPT Inter-Center Consult Tracking
FY 2004**

Total Number of Consult Requests	CFSAN	CBER	CDRH
13	3	3	7

Office of Combination Products
- Received and filed 55 formal Requests for Designation (RFD) under the agency's product jurisdiction program. The average RFD review time was 40 days of the 60 days provided by statute, and 100 percent of the decisions were issued on time;

- Published a proposed rule defining the primary mode of action of a combination product. The rule also described how FDA proposes to assign a lead Center when the primary mode of action is not readily determined;

- Published three draft guidance documents, covering Application User Fees for Combination Products, GMP's for Combination Products, and Dispute Resolution; and,

- Published capsular descriptions of ~70 jurisdictional determinations to improve the transparency of the assignment process, a longstanding concern of our stakeholders.

Good Clinical Practice Program

- Issued two proposed rules: IRB Registration in July 2004; and Acceptance of Data from Foreign Studies Not Conducted under an Investigational New Drug Application in June 2004 with the Department's Office of Human Research Protections to determine need for response to Advance Notice of Proposed Rule Making on Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews;

- Published three draft guidance documents on guidance for industry on Pharmacogenomic Data Submissions; Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions; and Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmaco-epidemiologic Assessment; and

- Conducted Good Clinical Practice and Human Subject Protection Education and Outreach Programs with various academic and governmental institutions from St. Louis, Philadelphia, Chicago, Buffalo, Detroit, Tuskegee, Alabama, and Montreal in Canada.

PROTECTING THE HOMELAND -- COUNTERTERRORISM

Office of Counterterrorism Policy and Planning

FDA's Office of Counter Terrorism Policy and Planning serves as FDA's focal point for the development and implementation of policies that safeguard food and medical products from intentional adulteration or disruption of supplies, and policies to facilitate the availability of safe and effective medical countermeasures. Specific accomplishments include:

- Developed and implemented an implementation plan and tracking system for FDA responsibilities under HSPD 9. This plan has been used by Homeland Security Council as a model for other agencies with HSPD 9 responsibilities; and,

- Led the development of Draft Guidance on Emergency Use Authorization of medical countermeasures. Consulted with DHHS, DOD, NIH, and CDC in the development of this guidance;

- 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; and,

- Led the development of FDA's portion of the Interagency Security Plan and the National Infrastructure Protection Plan.

IMPROVING FDA'S BUSINESS PRACTICES
Shared Services

- Stood up the final organizational units to achieve full implementation of the OSS covering over 10,000 headquarters and field employees nation-wide;

- Created a Office of Field Financial and Acquisitions Services that provides contract support and financial services to ORA and NCTR;

- Expanded the Employee and Resource Information Center to cover the Field and NCTR providing employees' access to an array of administrative and IT services;

- Met the FY 2004 administrative staff reduction targets by centralizing delivery of administrative services into a single organization using the shared services model that has incorporated customer service agreements and standards of performance;

- Established Service Provider Resource Center Web site as a centralized knowledge repository for use by OSS employees;

- Met 65 out of 67 service agreement metrics that OSS agreed to provide FDA components;

- Implemented the Most Efficient Organization for General Accounting and Real Property Management as a result of the recent sourcing competition determination;

- Executed a consolidated IT contract that reduced the number of companies providing IT support services from 15 to one; and,

- Incorporated workforce diversity program measure into FDA strategic action plan and Commissioner's Performance Contract.

Financial Management

- Transferred processing of financial transactions (commercial payments, travel, payroll, etc.) from the Office of Financial Management (OFM) to the OSS. OFM retained the functions related to policy, reporting, systems, application management, budgetary formulation, and budget execution;

- Created User Fees Team in OFM to better manage the execution, reporting and accountability of the FDA's user fee programs, in addition to the information provided for the budget formulation process;

- Received its seventh consecutive unqualified, or clean, audit opinion on its financial statements from the DHHS Office of Inspector General in December 2004;

- Entered the development phase of UFMS. This involves evaluating the software to see if it meets FDA-specific needs, testing the new system and determining training requirements for users. The agency continued its efforts on data clean-up, collect management reporting requirements, and support the upgrade of the legacy systems;

- Developed financial management applications to support user fees, travel, property, and procurement functions that would be integrated into UFMS;

- Created three performance budget submissions that integrated performance plan information into the traditional budget justification;

- Changed the budget structure by distributing FDA's total GSA rent expenditures to the respective programs, to help prevent the need for reprogramming request from Congress, to promote managerial efficiency and to better portray the full cost of each program's operations, and are now displaying FDA's field activities as a single line item, in order to provide ORA with increased flexibility to meet changing priorities and unforeseen emergencies.

Management Programs

- **Human Resources Consolidation - DHHS "40 to 4" Consolidation**. Assisted the Department's Rockville Human Resources Center with their stand-up on January 2004. This involved the coordination of the migration of staff and functions, including the coordination of physical space moves, establishing client contacts, review and approval of Service Level Agreements and coordination of service delivery. Along with the other OPDIVs, FDA started to use the Enterprise Human Resources and Payroll (EHRP) system and other automated personnel software. Other specialized workforce activities include the following:

  - Supporting the strategic goal of building a Strong FDA, redesigned the Leadership Development Program to ensure that high potential employees are developed as future agency leaders;

  - Expanded the FAME leadership training, created to assist supervisors, managers and team leaders in identifying and developing critical management and leadership skills necessary to communicate effectively, manage successfully and create and contribute to motivated high-performance teams. By adding of a fourth course, FDA widened its audience to include non-supervisory employees seeking the opportunity to explore supervision as a career. The newest course, the Supervisory Potential Course, was designed to address succession planning needs. It supports the agency's strategic workforce plan by identifying future supervisors early in their careers; and,

  - Participated in the HHS Career Mentoring program that was piloted this year targeting HHS employees who have at least one year of experience and less than five years. FDA has 40 mentoring pairs participating in the program.

Information Technology

- Revamped the organizational framework for managing IT in the agency by having all formal IT organizations report directly to the CIO;

- Awarded the IT Consolidated Infrastructure contract in August 2004;

- Completed establishment of the Office of IT Shared Services. which is already exhibiting performance metrics (e.g., abandoned call rate, calls answered within 30 seconds) better than industry standards;

- Brought the Prior Notice module on line, including account management capability;

- Achieved a performance level for the FDA web sites that regularly place it among the federal government's 10 best;

- Completed the "As Is" architecture, developed the target architecture for the gateway part of the e-submission initiative, and completed integration with the portfolio investment management tool;

- Developed the target architecture and awarded the contract to launch the FDA Submission Harmony and Reliable E-business project, which is intended to provide a single point of entry for electronic submission for the FDA;

- Established a governance framework to ensure the FDA's process for selecting, controlling and evaluating IT investments is rigorous enough to ensure mission needs are met, federal requirements for portfolio management are addressed, and integration also occurs with enterprise architecture and strategic planning programs;

- Broadened the effort to improve project management of IT initiatives through the active efforts of the Project Management Office to increase training, publish policies and guidance and sponsor mentoring;

- Finalized a Systems Development Life Cycle and associated investment and project management policies. End result will be a standardized and measurable process for deploying IT that allows continuous improvement, meaning lower costs and better service;

- Met federal and HHS targets for agency security programs in all areas: certification and accreditation, security awareness, self-assessments and privacy impact assessments; and,

- Continued leadership of the HHS-Net initiative, including authoring the design of the network and being the first Operating Division to switch to the new circuits.

PERFORMANCE GOALS AND FY 2006 TARGETS

The following table of performance goals and FY 2006 targets is presented to compliment the sequential display of this program's "outputs" by more closely linking the traditional budget presentation of base and increased activities and workload outputs contained in the Program Activity Data (PAD) charts. Activities discussed throughout this narrative support the accomplishment of outputs (PAD and performance goals) which in turn contribute to the accomplishment of long term outcome and strategic goals. Full cost information for these goals as well as other historical information has been provided in their respective sections in the Detail of Performance Analysis contained in the supporting information tab.

Performance Goals	Targets
Increase percentage of contract dollars allocated to performance based contracts. (19006)	FY 06: 50%
FDA's implementation of HHS's Unified Financial Management System. (19017)	FY 06: FDA will pilot an activity-based costing application integrated with HHS UFMS project as part of Prescription Drug User Fee Act III. The UFMS and its FDA modules will be operational in FY05 allowing FDA's legacy system core financial system to be decommissioned during the first quarter of FY 2006 configuration of UFMS. Begin development of FDA's unique interfaces and test global interfaces.
Enhance the Agency Emergency preparedness and response capabilities to be better able respond in the event of a terrorist attack. (19008)	FY 06: Enhance functionality and continue deployment of the National Incident Management System throughout the Agency (HQ, Centers, Field offices).

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