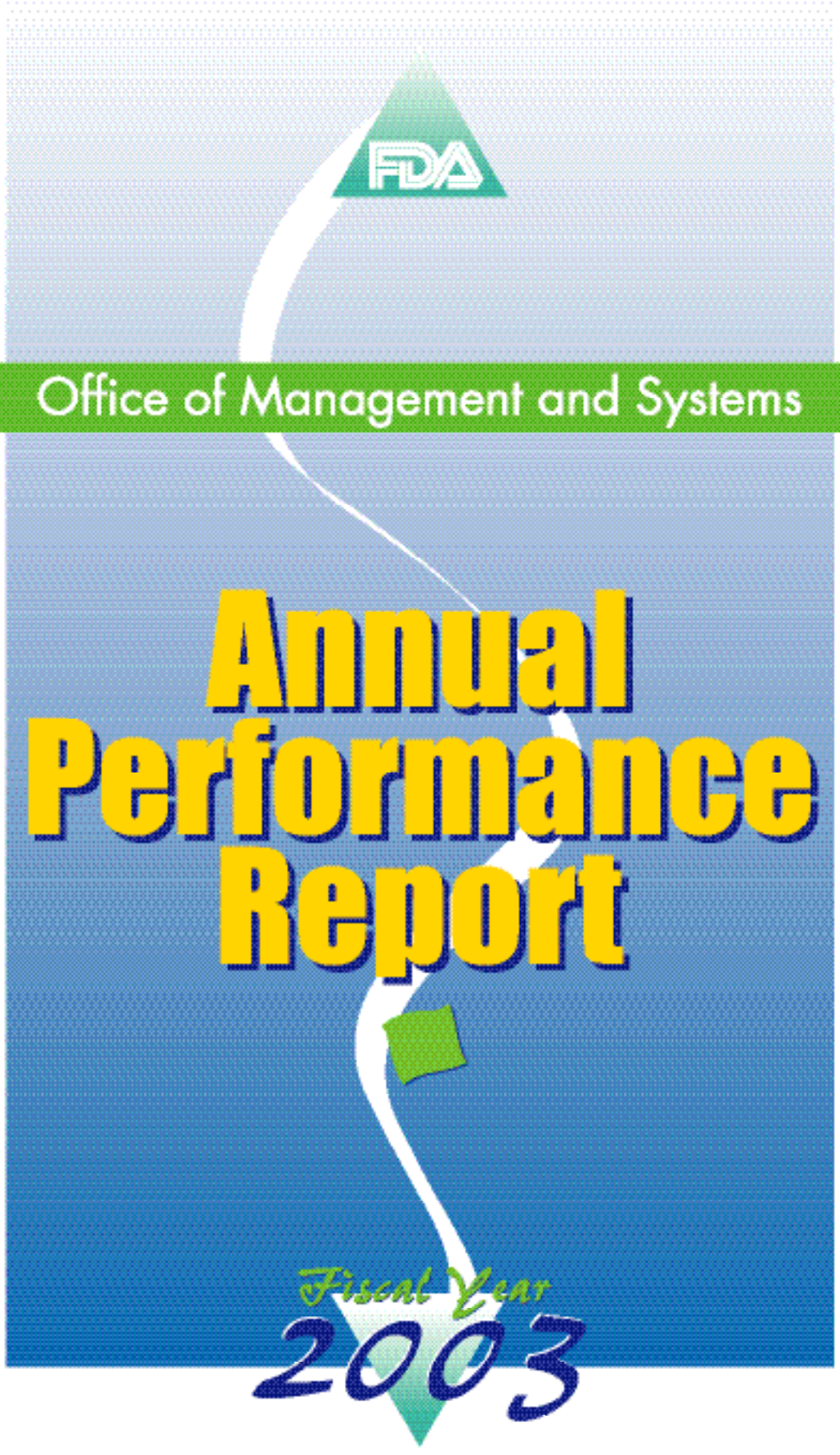
FDA
Office of Management and Systems
Annual Performance Report
Fiscal Year
2003

DEPARTMENT OF HEALTH & HUMAN SERVICES Food and Drug Administration

Rockville MD 20857

December 31, 2003

Dear Colleague:

I am pleased to share with you the Food and Drug Administration (FDA), Office of Management and Systems' (OMS') Annual Performance Report for FY 2003. As in previous years, this report highlights OMS/Agency accomplishments during the fiscal year and is intended to let our customers and partners know what we have done and are doing to help support the Agency's public health mission.

Fiscal Year 2003 was a year in which we continued to focus much of our effort toward the implementation of the President's Management Agenda (PMA). We are providing Agencywide leadership on all of the PMA-related initiatives, including the Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded Electronic Government, and Budget and Performance Integration. This report outlines many of our specific efforts and accomplishments during FY 2003 related to the PMA.

For the fifth year in a row, the Agency's financial statements received an unqualified or "clean" opinion from independent auditors with no material weaknesses. We worked with the Department and other HHS components on the development and implementation of the Unified Financial Management System (UFMS), which will help us meet federal financial management systems requirements. We spearheaded successful efforts resulting in a record appropriation for FY 2003, giving the Agency the necessary resources to support our responsibilities under the Food, Drug, and Cosmetic Act. We also provided leadership in both the development and implementation of the Medical Device User Fee and Modernization Act (MDUFMA), which was signed into law in October 2002.

We worked toward the development and implementation of the Shared Services model for the delivery of administrative services, and met our goal of starting up the new organization on October 1, 2003. For this effort, we led communications activities, conducted Center, ORA, and OC presentations, and held "all-hands" satellite broadcasts in order to keep FDA employees fully informed on the planned new organization and proposed administrative changes in the Agency. During this fiscal year we also continued our efforts on White Oak consolidation, worked to complete the Agency's Select Agent inventory, strengthened our Personnel Security systems, and completed Phase 1 of FDA Continuity of Operations Planning (COOP). Detailed descriptions of our accomplishments for each of these activities are included within this report.

It remains a privilege to work with the many talented and dedicated individuals who have contributed to FDA's accomplishments. I look forward to working together as we discover new opportunities in response to the challenges that lie before us. If you have any questions or comments about this report, you can contact me via e-mail at jeff.weber@fda.gov.

Sincerely,

Jeffrey M. Weber
Associate Commissioner for Management
Chief Financial Officer

* NOTE: In early FY 2004, extensive organizational changes took place, including the name change of the Office of Management and Systems to the Office of Management.

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Executive Summary

Last year, the Office of Management and Systems (OMS) identified several priority initiatives for Fiscal Year 2003 and beyond, including:

- *Working towards implementation of the shared services model for the delivery of administrative services, with the goal of starting up the organization on October 1, 2003.*
- *Providing leadership in the implementation of a number of PDUFA III initiatives, including working with the Centers to amend and improve their time reporting systems.*
- *Improving employee recruitment and retention processes.*
- *Implementing a Quality Step Increase (QSI) program in FDA.*
- *Conducting organizational studies of four additional FDA Centers as part of the Delayering effort which began in FY 2002.*
- *Maintaining a "clean", unqualified audit opinion for the FY 2002 audit of FDA financial statements, while at the same time meeting accelerated deadlines.*
- *Working with HHS and others toward the development of a new financial system.*
- *Building on the FY 2003 budget to seek additional programmatic budget increases and obtaining the necessary resources to continue providing the public with the high level of safety and security it expects.*
- *Purchasing and installing cameras, card readers, biometric devices, and other security equipment to enhance the security of select agent laboratories.*
- *Improving Personnel Security by making modifications to the EASE personnel system so that non-paid positions and contractors are included in the database.*
- *Providing planning, architectural, and engineering support to a nationwide initiative for adapting existing space as well as buildings under construction for containment of agents at Biosafety Level-3 (BSL-3).*
- *Providing intensive coordination and scheduling support while assisting CDER and CDRH in their relocation to the White Oak site.*
- *Expanding outreach and education efforts in order to increase the number of faith-based/community-based organizations receiving funding or serving in partnership with FDA.*
- *Awarding grants to states under the Bioterrorism and Response Act of 2002.*

- *Developing and implementing an information technology consolidation plan in order to meet Departmental consolidation goals.*

- *Completing the network design and infrastructure plan for the transition of voice, data, and video services to the White Oak campus.*

- *Updating the general IT Security user awareness training course and conducting Agencywide risk assessments/security reviews.*

As a result of Agencywide cooperation and the efforts of the entire FDA management team, we were able to achieve our FY 2003 goals in the areas listed above and in many others. We are pleased to share our major accomplishments with you in this report.

In FY 2004 and beyond, OMS must address additional challenges, particularly in our continued support of the President's Management Agenda and Departmental restructuring goals, and in the implementation of the shared services organization. We will continue to provide high quality services, utilizing many of the cost-saving and cost-avoidance initiatives currently underway, and will initiate further program improvements including:

- *Starting up the Employee Resource and Information Center within the Office of Shared Services (OSS). Developing the start-up plan for OSS support to ORA field organizations and beginning implementation.*

- *Continuing our White Oak consolidation efforts, including:*
  - *relocating CDER and CDRH programs to the Life Science Laboratory*
  - *completing core and shell construction and interior fit-out design, and beginning interior fit-out construction of the CDER office building*
  - *Completing the design of the Central Shared-Use building and beginning construction*
  - *Completing the design of the CDRH Engineering/Physics Laboratory and beginning construction*

- *Continuing to support the FDA Strategic Plan*

- *Continuing to support the President's Management Agenda and Agency goals by conducting cost comparison studies under OMB Circular A-76 and implementing six new MEO's, which resulted from previous competitions.*

- *Expanding FDA's outreach to further increase the number of faith-based/community-based organizations receiving funding from the Agency.*

- *Building on the FY 2004 budget to seek additional programmatic budget increases in critically underfunded areas in accordance with the FDA Strategic Plan.*

- *Maintaining an unqualified audit opinion for the FY 2003 audit with no material weaknesses.*

- *Continuing to coordinate with HHS in the implementation of the new financial system.*

- *Completing the HHS HR consolidation as soon as congressional approval is received.*
- *Developing and implementing FDA internship programs to foster the development of new leaders.*
- *Identifying efficiencies in order to meet the goal of $29M savings in Information Technology, which includes the Department consolidation goal of reducing infrastructure by 15% from the FY 2004 request.*
- *Developing an action plan to address areas of weakness in the IT Security program.*
- *Completing migration of Phase I of the White Oak Transition of CDER and CDRH Laboratory personnel and completing planning for IT services under Phase II of the White Oak migration.*
- *Continuing work on Bioterrorism Act-related Delegations of Authority.*
- *Completing the Agency's organizational delayering initiative and submitting an assessment report to the Department after the completion of the study.*
- *Implementing an Agencywide Freedom of Information Act (FOIA) tracking system module of AIMS.*
- *Continuing decommissioning efforts for FB-8, 1521 West Pico Blvd., Los Angeles, and 1560 East Jefferson Ave., Detroit.*
- *Providing planning, architectural and engineering support to ORA in support of Winchester Engineering and Analytic Center (WEAC) modernization.*

Program Summary

•• Who We Are ••

The Office of Management and Systems* provides administrative services to the various programmatic components of the Food and Drug Administration and consists of the following components:

- Office of Acquisitions and Grants Services
- Office of Executive Operations
- Office of Financial Management
- Office of Human Resources
- Office of Information Resources Management
- Office of Management Programs
- Office of Real Property Services
- White Oak Consolidation Program

We are an organization of approximately 420 employees, including a professional staff of accountants, engineers, personnelists, architects, administrators, and computer scientists who serve more than 10,800 Agency employees nationwide. We are an integral part of the FDA management team and provide leadership, guidance, and solutions to a wide and varied number of management and resource issues facing FDA. We are a customer-focused organization, supporting the management of the Agency's resources in a collaborative, coordinated, and cost effective fashion.

** NOTE: In early FY 04, extensive organizational changes occurred, including: 1) the name change of the Office of Management and Systems to the Office of Management, 2) the creation of the Office of Shared Services, 3) the title Change of the Office of Information Resources Management to the Office of the Chief Information Officer, and 4) the title change of the Office of Human Resources and Management Services to the Office of Human Resources.*

•• What We Do ••

Acquisitions and Grants Services: We provide high quality support to FDA programs by managing contracts and assistance agreements in a timely manner and at a reasonable cost, mindful of the vital role our Agency plays in consumer protection and the responsibility we ourselves bear for the stewardship of public funds. In FY 2003, the OAGS contracting program completed $ 216.9 million in contracts, $ 101 million in simplified acquisitions, $34.3 million in International Merchant Purchase Authorization Card (IMPAC) transactions, $97.4 million in Interagency Agreements, and $28.5 million in grants to support the activities of the Food and Drug Administration.

Executive Operations: We are a team of administrative and resource management specialists who ensure all Office of the Commissioner organizations effectively utilize the resources, information, and systems provided to them to accomplish their operational goals.

Financial Management: We provide resource management leadership and a full range of professional financial services throughout FDA. We serve as the focal point for Agencywide financial management including budget planning, preparation, formulation, presentation, execution and control; accounting, CFO Audit activities, payment processing, financial reporting, foreign and domestic travel management, employee relocation, and payroll liaison; and financial systems development, maintenance, coordination, and integration. We provide leadership during the development, monitoring, and tracking of an annual budget of $1.65 billion, which includes two direct appropriations and five separate and unique user fee activities. We manage FDA's annual budget hearings with DHHS, OMB, and the House and Senate Appropriation Subcommittees. We pay more than 38,000 invoices per year, and process vendor payments of more than $304 million, with more than $276 million made via wire transfer. We manage and provide oversight for the annual CFO audit, and we develop, operate, maintain, and continuously update FDA's financial systems including FDA's new financial system – Financial Enterprise Solutions (FES) - a component of the DHHS Unified Financial Management System.

Human Resources: We provide a full range of professional human resources and management services to FDA employees located in the Washington, D.C. metropolitan area and over 4,000 field employees throughout the United States, including San Juan, Puerto Rico, U.S. Virgin Islands, Hawaii, and Alaska. We provide HR services to a variety of scientific occupations including Medical Officers, Chemists, Microbiologists, Pharmacists, Consumer Safety Officers, Veterinarians, and Engineers. Our quality personnel services include staffing the Office of the Commissioner, and Agencywide programs for recruitment, position classification policy, quality of work life, training, compensation, awards, performance management, employee relations, and labor relations.

Information Resources Management: We coordinate Agencywide information technology and associated activities such as strategic business planning, enterprise architecture, and IT portfolio investment management that enable the FDA to anticipate and move seamlessly to future technologies. We are responsible for building and maintaining an information technology infrastructure and ensuring interoperability of FDA systems. We provide information technology services in support of

critical FDA program and administrative operations. These services include telecommunications support, Intranet and Internet management, systems development [e.g., Enterprise Administrative Support Environment], IT policy development, and information technology security. We also direct future IT investments and provide leadership for the FDA's IT planning in order to ensure the Agency's IT budget of nearly $200 million is used most effectively.

Management Programs: We are committed to providing leadership and direction to all FDA components through the most efficient use of resources and processes in order to achieve the best performances possible. As the focal point for many programs, this requires highly skilled experts who are dedicated to providing our customers with the best possible guidance, technical advice, and training that will enhance customers' professional performance while assuring compliance with Federal laws and regulations. We administer FDA's Delegations of Authority and Organizational programs, conduct special studies and projects for the Office of the Commissioner, oversee FDA's Internal Controls program, have responsibility for the FOI and Privacy Act programs, provide public access to FDA's regulatory dockets, provide Agency oversight for the Paperwork Reduction Act activities and records management, oversee the Agency's A-76 efforts, and manage the Agency Ethics program.

Real Property Services: We provide an efficient and effective program of nationwide logistical support for FDA in the areas of real property, engineering services, environmental, safety, and health and long range planning for the Agency's current and future facilities. This involves significant resources including annual lease costs of $120.4 million, and owned facilities valued at $188 million. We manage 354 government owned or leased buildings and facilities nationwide, totaling 3.4 million square feet (leased and owned).

White Oak Consolidation Program: We integrate the Agency's technical, programmatic and facilities requirements into the overall budget and development plan for the Agency's consolidation at White Oak. This requires project development expertise, to direct the process by which Center requirements are incorporated into architectural design and to coordinate the overall design and construction process for the new campus with the General Services Administration. We evaluate and implement strategies that enable the Agency to maximize efficiency through the consolidation of specific and shared functions. We monitor construction progress as individual projects proceed and coordinate necessary changes. We ensure meaningful and continuous communication with community leaders and associations, congressional representatives, other federal officials, State and local governments, and business leaders. In addition, we create and implement relocation plans needed to successfully transition the Agency into its new location by coordinating the various activities including the move, IT/telecom, security, safety and building operations.

Major Accomplishments in FY 2003

•• Initiatives Supporting ••
the President's Management Agenda

The President has expressed a desire to have an effective Federal government that is citizen centered and results-oriented. During FY 2003, the Office of Management and Systems continued to provide leadership in accomplishing the President's Management Agenda (PMA). The PMA includes five government-wide initiatives:

- Strategic Management of Human Capital
- Improved Financial Performance
- Expanding Electronic Government
- Competitive Sourcing
- Budget and Performance Integration

FDA is moving assertively to meet the goals of the President's Management Agenda in all five of these areas. During FY 2003, some of our major accomplishments on these initiatives included:

Initiative	Summary of Accomplishments
Strategic Management of Human Capital	• Put all mechanisms in place to provide for the start up of the shared services organization to achieve administrative consolidation • Completed delayering reviews of five FDA organizations • Tailored methods to improve workforce planning in organizations • Employed personnel flexibilities to retain FDA employees
Improved Financial Performance	• Achieved fifth clean audit opinion on FDA's financial statements • Improved communication with FDA components through various methods • Upgraded financial applications meeting regulations • Completed implementation of Travel Manager throughout the Agency • Began implementation of PRISM (procurement software), for Headquarters purchasing agents • Continued effort for data clean-up in preparation for the new financial system implementation, scheduled for October 2004

Expanding Electronic Government	• Created IT consolidation strategy and plan for FDA • Participated with DHHS and other OPDIVs on IT projects (human resources and financial management) • Collaborated on government-wide regulations web site • Partnered with other Federal agencies on E-projects (Federal Health Architecture Initiative, E-Grants, and E-Rulemaking)
Competitive Sourcing	• Completed six sourcing competitions covering graphics design, television studio, library services, facilities and property management, biological and physical science technician services, and accounting technicians which will result in over $16.3 million in savings during the next five years • Started a functional assessment of select clerical series • Submitted competition schedules for FY 2004 • Participated in DHHS wide initiatives
Budget and Performance Integration	• Reduced the number of plan performance goals • Created long term program outcomes goals, efficiency goals, and strengthened performance measures • Used PART 2004 review results for FY 2005 budget and planning processes • Completed FY 2005 PART review with OMB and significantly increased scores

•• OMS Accomplishments ••

Administrative Consolidation/Shared Services

Served as project manager for the shared services contract, providing day-to-day management and direction to FDA employees and contractors working on the implementation of the Office of Shared Services (OSS).

Led Change Management/Communications activities during the start-up of OSS. Developed logo and branding material. Developed and conducted Agencywide training on OSS for Headquarters employees. Conducted FDA-wide video broadcast on OSS implementation and other change initiatives.

Completed the organizational design of the Office of Shared Services, as well as the function organizations within OSS (Equal Employment Opportunity & Diversity Management, Financial Services, Acquisitions and Grants Services, Real Property Services, IT Shared Services, and the Employee Resource & Information Center (ERIC)).

Conducted workload survey to determine how and where administrative services are provided to FDA employees to ensure an accurately-sized organization and migrated pertinent administrative employees from the Centers, ORA HQ, and OC to staff the OSS organization.

White Oak Consolidation

- Life Science Laboratory: Building is completed and is being commissioned and prepared for occupancy. The upper two floors were re-designed into laboratory space for CDRH. Continued to work closely with the GSA construction team on technical design issues, building commissioning and coordination with the central utility plant.

- CDER Office Building: Core and shell construction reached the 45 percent complete level. To address structural issues, basements were added to four wings, providing needed though unanticipated space for document storage which satisfied a major requirement for CDER. Considerable effort was spent on designing the office layouts in a way that captures a new organizational interaction for the Office of Drug Evaluation. It is expected that the building will be ready for occupancy in April of 2005.

- Design of the CDRH Engineering/Physics Laboratory: Design has advanced to the 35% stage. Specific consideration has been given to vibration analysis, electro-magnetic interference, and the need to create interaction space in the transition area between laboratory and office. This facility will begin construction next year.

- Design of the Central Shared Use Facility: Design has progressed to the 75% level for the core and shell and to the schematic level for the interior space. Continued to identify and define the needs for the diverse groups that will occupy this building. Because of budgetary limitations, the interior space will be constructed in two phases, the first of which will be sufficient for the initial occupancy of the campus.

- Community, Employee and Official Presentations: Conducted briefings and tours for Administration and congressional staff. Secretary Thompson twice visited the site, once accompanied by Senators Frist and Hatch. Congressman Wynn was also provided a tour as were many congressional staff. Tours were regularly provided to FDA managers, employees and the members of the local community.

White Oak Animal Program

A major component of the first new facility at White Oak, the Life Sciences Laboratory, is a 16,000 square foot vivarium used for the purpose of supporting laboratory research. Through many discussions between CDRH and CDER, an innovative approach to the leadership and management of the Animal Program was defined which resulted in a Memorandum of Agreement between the two Centers, the Office of the Commissioner and CVM. This detailed agreement provided that an employee of CVM will serve as the Institutional Official for the facility. The agreement and the Animal Program will satisfy the functional needs of each program and the accreditation require-

ments of the American Association for Accreditation of Laboratory Animal Care (AAALAC), thereby creating an Animal Program at White Oak that will serve both CDER and CDRH occupants of the first building.

Relocation Planning and Coordination for White Oak Consolidation

Initiated the planning required to occupy the first building to be completed at the FDA consolidation site in White Oak. Through detailed scheduling of the multiple FDA components and needed vendors, the relocation is planned to start November 12. The preparation and coordination included the following:

- Tracking the relocation budget and expenditures.
- Establishing a laboratory office furniture standard for the site.
- Selecting and procuring furniture through a committee process involving the occupants, future occupants and the employee union.
- Identifying and selecting specialty vendors needed to move scientific equipment.
- Identifying and selecting a minority owned firm for the general move.
- Coordinating the information technology and telephone requirements with the occupancy schedule.
- Coordinated environmental health and safety concerns and security requirements with the occupancy schedule.
- Coordinated the commissioning of the fixed laboratory equipment and the employee training required.
- Coordinated the building operational needs with the building operations organizations.
- Developing a web site to provide employees information on the White Oak Consolidation and amenities.

Physical Security:

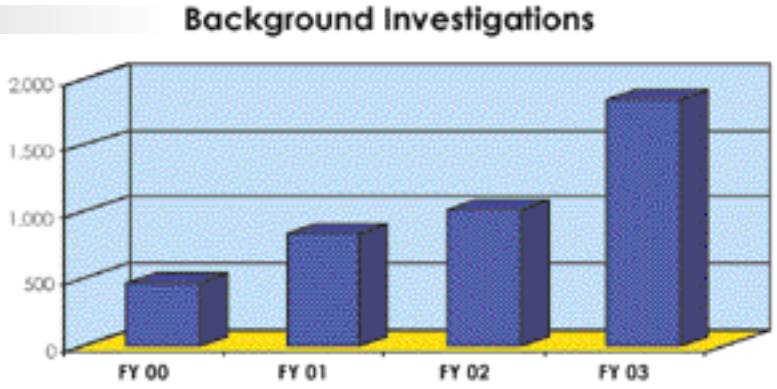
Working with the Centers we completed the consolidation of the Agency's Select Agent inventories. We have also begun installing cameras, card readers, biometric devices, and other security equipment to further enhance the security of the select agent laboratories.

Personnel Security:

The EASE system is being modified to accept all employee information for the use in tracking of FDA employees and non-employees to include a database on non-citizens working in FDA facilities. Once the modifications have been completed, the current Personnel Security tracking system, AIMS, will be incorporated into the newly created system to give FDA a precise accounting of who is working in all of the FDA buildings.

Under the new Select Agent Lab requirements approximately 300 FDA employees are currently undergoing upgraded backgrounds to allow them access into our labs. All Select Agent authorized

personnel have signed a Patriot Act notification letter. These two initiatives have ensured that effected personnel are in compliance with the requirements of the Patriot Act. Due to heightened awareness of our security responsibilities, every person granted an FDA badge is being required to undergo some level of investigation. This has resulted in over 1800 backgrounds being processed in FY 03. This is a yearly increase of more than 300% since FY 00.



Continuity of Operations Planning (COOP):

Completed Phase 1 of FDA COOP development by establishing viable plans for 29 headquarters offices in the metro area that are compliant with FPC 65 guidelines. Successfully exercised Phase 1 COOP plans and developed alternate locations for all COOP plans. Began Phase 2 to develop COOP for the ORA Regional/District Offices, NCTR and laboratories.

PDUFA:

Implemented the financial management aspects of the Prescription Drug User Fee Act (PDUFA) in FY 2003, including:

- Development and publication of the FY 2002 PDUFA Financial Report to Congress.
- Worked with the centers to assure that time reporting for FY 2003 takes into account the new PDUFA III definition of the process for the review of human drug applications, which now includes some post-approval risk management activities.
- Development and publication of the PDUFA III five-year Plan that provides a blueprint for the allocation of anticipated revenues in order to assure that performance goals are met.
- Met the PDUFA statutory requirement to publish FY 2004 PDUFA fees and procedures on August 1, 2003.

MDUFMA:

Provided leadership in both the development and implementation of the financial management aspects of the Medical Device User Fee and Modernization Act (MDUFMA) that was signed by the

President on October 26, 2002. Major accomplishments in FY 2003 include:

- Published a Federal Register Notice on November 21, less than a month after the President signed the legislation, providing the fee schedule for FY 2003 and interim procedures until the enactment of appropriations enabling the Agency to begin collection of medical device fee revenues.
- Developed an internal five-year allocation plan for anticipated MDUFMA fee revenues and appropriations to assure that MDUFMA performance goals will be met.
- Developed and published in the Federal Register a notice of detailed payment procedures and controls for medical device user fees on February 25, 2003, five days after the enactment of enabling appropriations.
- Published the FY 2004 medical device fee schedule on August 1, 2003, and met with trade association representatives the day before to explain the fees and the application of various revenue adjustments provided for in MDUFMA.
- In light of appropriations for FY 2003 and 2004 that fell short of criteria established in MDUFMA, developed a strategy for ensuring the continued viability of MDUFMA in FY 2005 and beyond. Marketed this strategy to the Office of Management and Budget (OMB), whose support for it was memorialized in a letter from the OMB Director to Congressional leadership.

•• Acquisitions and Grants Services ••

ACQUISITIONS

A-76 Cost Comparison Studies. Conducted six A-76 studies for the following functions: Graphic Arts/Visual Information Services; Television Studio Services at the Center for Devices and Radiological Health; Library Services; Facilities /Real Property Management; Biological and Physical Science Laboratory Technicians; General Accounting Services for the Office of Regulatory Affairs. These were the first full FAR Part 15 competitions to be completed by the Department. OAGS also completed one direct conversion for web publishing services. As a result of the studies, it is estimated that the FDA will recognize a savings of $16.3 million over five years, with no involuntary separations.

Purchase Request Information System (PRISM). PRISM was successfully rolled-out during the fourth quarter. All acquisition employees responsible for the award of simplified acquisitions, both in headquarters and at the Centers, were trained to use the new system. Since its implementation during the fourth quarter of FY 2003, more than 1,900 new awards were placed in the new system. Weekly training sessions given by both OAGS staff and Compusearch on the PRISM system have been conducted to address any issues or concerns that users may have.

Department Consolidation. OAGS participated in meetings with DHHS staff to discuss consolidation of certain acquisition functions within the Department. The proposed consolidation is to become effective in FY 2005. In conjunction with this initiative, OAGS made a presentation at a Department conference concerning FDA's efforts to streamline acquisition tasks to date. Accomplishments leading to more efficiency in the organization include: Moving to the new consolidated organization, i.e., the Office of Shared Services, which will provide a variety of administrative and information technology services to all FDA employees; Implementation of the PRISM system for simplified acquisitions; Being the first Agency in the Department to conduct cost comparison studies using FAR Part 15 procedures; and begun pre-award functions for consolidation of the IT infrastructure in accordance with the President's Management Agenda and the Secretary's initiative.

Awarded and Administered Contracts to Support the ORA Laboratory in Irvine. Awarded a contract to ensure the completion and acceptance of the ORA field laboratory consolidation, located in Irvine, California. OAGS also awarded all facility support contracts to support the Irvine facility.

Financial Enterprise Solutions/Unified Financial Management System Logistical Support. Awarded task orders and modifications to streamline, update and improve FDA's thirty-year old accounting system. Coordinated a modification with OFM and OGC to ensure that there is no conflict of interest with the DHHS UFMS contract with Bearing Point.

FB-8 Decommissioning. Awarded an order for decommissioning services at the FB-8 facility. During the course of the work, latent radioactive contamination was discovered and a supplemental order has been determined to be necessary.

Muirkirk Road Complex. Awarded a contract for mechanical and electrical operation and maintenance services for the Muirkirk Road Complex for a base period of seven months, with four one-year option periods.

Mod I Renovation Project. Awarded a contract for the completion of two major renovation projects at Mod I in support of the College Park transition.

Women's Health Studies. Awarded seven contracts for Women's Health Studies for the Office of Women's Health.

Small Business Goals. Continued to actively support the small business program. Exceeded goals for Small Business, 8(a), Small Disadvantaged Business, and Women-owned Small Businesses.

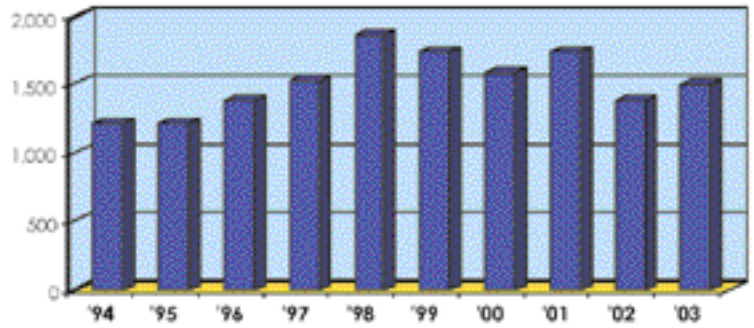
Business Category	Accomplishment*		DHHS Goals	
	%	$ in 000's	%	$ in 000's
Small Business	47.37	138,893	30.3	103,296
8(a) Awards	9.92	29,094	5.86	19,977
SDB	19.27	27,417	11.72	39,955
Women-Owned	8.41	24,670	5.05	17,216
HUBZone	1.79	5,238	3.03	10,330
Service Disabled Veteran	0	14	3.00	10,227

* Data current through 10/29/03

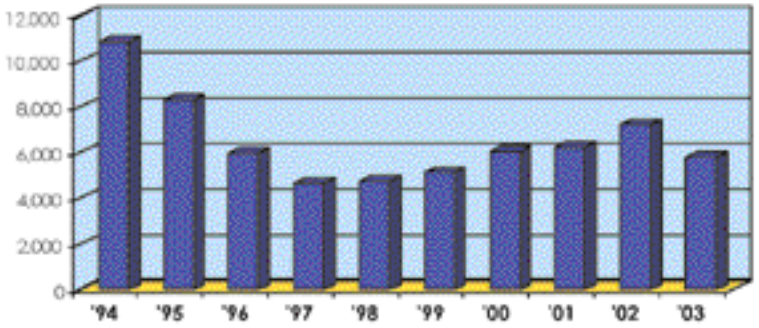
Acquisition Planning. OAGS implemented an acquisition-planning tool to improve acquisition planning throughout the Agency. Prior to the OFACS Council being abolished, the acquisition planning charts were discussed at each Council meeting. Moreover, procurement managers provide continuous communication with Center liaisons to discuss acquisition planning. OAGS continues to maintain the information on the Acquisitions Intranet website.

FY 2003 AWARDS

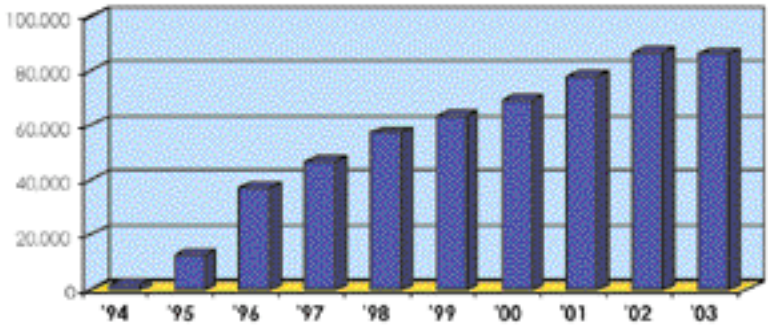
Contract Actions FY 94-FY 03



Simplified Acquisitions FY 94-FY 03



BankCard Actions FY 94-FY 03



GRANTS

Grants Advance Planning. Collaborated early with the Office of Orphan Products Development (OPD) and developed a Request for Applications (RFA) that was published in FY 2003 for FY 2004 and FY 2005 funding, with receipt dates of October 13, 2003, April 7, 2004 and October 6, 2004. This arrangement will help to provide for a more equitable distribution of new grant awards in fiscal years 2004 and 2005 that will help to alleviate the end of fiscal year crunch during the 4th quarters.

Grants Awarded. OAGS awarded 121 discretionary grants totaling $28.5M. Grant awards were made to many programs including: Clinical Studies of Safety and Effectiveness of Orphan Products Development; Small Business Innovation Research (SBIR); Innovative Food Safety Project; Small Scientific Conference; State Food Safety Task Force Meetings Conference; Food Safety and Security Research in support of the bio-terrorism effort; World Health Organization; Food Safety Research; Shellfish and Seafood Safety Assistance Project; and the Adverse Effects of Marketed Drugs Program.

Interagency Agreements. Fully executed 443 Interagency Agreements (IAG) totaling $97.4M, of which $21.1M represents reimbursable interagency agreements (income support from other Federal agencies). Of the 443 IAG actions, 226 or 51 percent represents over $35.1M processed and fully executed during the last quarter of the fiscal year.

E-Grant Initiative. Established an informal agreement with NIH to have FDA grants integrated into the NIH IMPAC II system. OAGS anticipates entering into an interagency agreement with NIH in FY 2004 to comply with the Secretary's challenge to develop "One DHHS" as well as P.L. 106-107. As part of the initiative, OAGS is entering 100% of FDA's grant program announcements into FedBizOpps. Additionally, OAGS educated Program and Regulatory Editorial Staff on the new standard format for program announcements that will go into effect October 1, 2003 in compliance with P.L 106-107. Furthermore, OAGS is involved in a myriad of outside activities to meet the President and the Secretary's challenge to develop one Agency such as: a member of the Awarding Agency Grants Administration Manual (AAGAM) workgroup, Referral Liaison Workgroup, National Grants Management Association (NGMA), FDA Focus Group, Electronic Grants Committee (EGC), and the Grants Streamlining Committee (SGC). Interaction with internal and external customers has enabled staff to stay abreast of changes in existing laws and regulations and enabled the sharing of information to support the Agency's mission.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002. As part of FDA's bioterrorism efforts and in conjunction with the scientific nature of the proposed research, FDA requested a policy deviation from the Department that the Food Safety and Security Research RFA grants be awarded in fiscal year 2003 with the budget period to coincide with the project period. The Department approved the deviation and we awarded a total of $2,829,119 to five high quality research projects for a one-time amount per award with budget/project period end dates up to 3 years.

In support of FDA's bioterrorism efforts to enhance the nation's food security, FDA anticipates issuing an URGENT single source Program Expansion Supplement to Illinois Institute of Technology (IIT) in FY 2004. No-year funds of $1.1 million have been made available. This cooperative agreement provides support for the National Center for Food Safety and Technology (NCFST), which is located on IIT's Moffett Campus in Summit-Argo, IL. This supplemental funding will enable IIT to undertake two new food contaminant mitigation projects and to continue with the build out of the Biosafety Level 2 (BSL-3) laboratory that was started in FY 2002.

Faith-Based/Community Based Initiatives. Initiated and expanded FDA's outreach to increase the number of faith-based/community-based organizations receiving funding from FDA. Produced a one-page flyer on FDA's Small Scientific Conference Grant Program Announcement. FDA staff members distributed the flyer while attending or participating in conferences, meetings, and workshops throughout the year. OAGS had anticipated that this action would stimulate an increase in community-based participation in FDA's small scientific conference grant program. Currently, we are only supporting one community-based organization.

FDA's Community-Based (CB) Workgroup is working diligently to foster cooperation and awareness of this important initiative within FDA centers and offices by sharing information on grant-related issues at meetings/conferences/workshops regionally. Also working with the Office of Regulatory Affairs to develop communication with State and local governments to increase participation of community-based organizations in the grants program. Developing and drafting a web page devoted to CB organization activities within FDA anticipated to be available in FY 2004. It is envisioned that this site will provide links to the HHS Partner Gateway, DHHS Faith-based web site, White House web site and others.

Finally, OAGS continues to focus on working with the Office of Regulatory Affairs (ORA) to encourage State and local governments to assure faith-based/community-based participation as sub-contractors.

•• Executive Operations ••

Special Projects. Performed coordination and implementation of special projects for the Agency and OC including:

- Transition planning for the Office of Shared Services:
  - Development and processing of personnel actions
  - Development of organizational package
  - Collaboration with OFM on financial resources
  - Providing executive leadership for the Training SIT
  - Providing the Lead Management Analyst for the ERIC FIT
- Coordinated 3 Commissioner's all hands and 1 Change Management Integration Team (CMIT) broadcasts. Included in the project was purchasing satellite time, arranging for the TV studio, and arranging for speakers.
- Upgraded Conference Room 14-68 with video/audio wall plate and additional phone lines with remote location capability for Dr. McClellan to deliver speeches via satellite from Parklawn.
- Worked with the Agency A-76 Coordinator on the Competitive Sourcing (A-76) from an OC perspective. Served as the Executive Sponsor for the implementation of the Graphics Arts and Visual Information Services MEO. Prepared and presented briefings for supervisors and affected employees regarding the clerical study and workload data.
- As the Rule of 5 Coordinator for OC, processed 42 Rule of 5 Travel requests.
- In partnership with the Office of Human Resources, worked with the Gallup Organization to facilitate the Q12 survey for OC. Following completion and analysis of the survey, supervisors will receive a 'scorecard', and will be trained on implementing improvements in their organizations.
- Administered the performance contract cascading policy to the SES, SES equivalent and GS-15 employees for OC as directed by the Department.
- Coordinated with OHRMS and administered the semi-annual call for pay adjustments, SES bonuses and Presidential cash awards for the OC Executives.
- Transferred the OC Property Officer function to the Office of Executive Operations (OEO). Worked with OIRM to develop a system to scan the property-related documentation and eliminate the need for large amounts of paper files and storage.
- Participated on Agency Correspondence Users Group to develop a tracking application that will meet the basic requirements of managing both internal and external correspondence throughout FDA.
- Participated on plans for development of Meridian as an Agency management learning system.

Financial:

- Analyzed the payroll and operating resources to reflect organizational changes:
  - The breakout of the Office of Legislation from the Office of Policy, Planning and Legislation

- The establishment of the Office of Acquisitions and Grants Services and the Office of Real Property Services
- The establishment of the Office of Crisis Management

- Participated as the OC Budget contact on:
  - The submission of data for the FY04 Congressional Justification and the FY05 OMB Budget
  - The Financial Enterprise Solutions Reporting Requirements team
- Managed an expanded OC Central Funds account to include Cell phones and Skytel pagers.
- Prepared various Budget Allocation scenarios for approval by the Associate Commissioner of Management and Systems that calculated the distribution of payroll and operating funds to the OC Non-OMS offices.
- Performed Travel Manager audits for various OC Components. Conducted workshops as requested. Worked with each OC component to resolve necessary routing and proxy lists concerns. Provided consultation to users throughout OC.

Procurement: Provided analysis and coordination for the FY 04 OC Copier Maintenance Contracts (Canon, Canon Color, OCE, Xerox, and Sharp) resulting in an overall savings of $29,000 to the Agency over the cost of last year's contracts. Also, negotiated two more toner inclusive contracts for additional savings to the Agency.

Facilities/Renovations:

- Coordinated the renovations and moves for the following components: Office of Human Resources, Office of Management Programs, Office of Management and Systems (IO), Office of the Ombudsman, Office of Information Resources Management, Office of Executive Operations, Office of Commissioner (IO), Office of Policy and Planning, Office of Combination Products, and Office of Crisis Management. Provided the required notification to NTEU of planned moves.
- Negotiated space to support contractors engaged in Agency initiatives, Shared Services and A-76.

Information Technology:

- Coordinated the purchases for refreshment of personal computers across the Office of the Commissioner.
- Initiated and negotiated an agreement between the OC and the CDER Receiving and Distribution Center (RDC) for a shared personal computer purchase, receipt, configuration, and distribution program for OC PCs. This program resulted in substantial cost savings for OC and improved delivery of equipment.

•• Financial Management ••

IMPROVED FINANCIAL PERFORMANCE

Since FY 1997, financial performance has steadily improved due to FDA taking many corrective actions, including establishing a branch organization in the Division of Accounting to prepare financial statements and to interact with the auditors. As a result, FDA went from not having an unqualified opinion (with three material weaknesses and five reportable conditions) in FY 1997 to having an unqualified opinion with no material weakness and one reportable condition in FY 2002. To achieve compliance with FFMIA and the Secretary's directive, FDA is working with HHS and other HHS components in the implementation and development of the Unified Financial Management System (UFMS), which will meet federal financial management systems requirements. The Agency has improved its performance and it is anticipated that the UFMS implementation will lead to further improvements.

The audit reports for the last three years have not included any material weaknesses or reportable conditions for internal control deficiencies related to financial reporting. FDA has strong internal controls over financial reporting and continues to reconcile data to ensure the correct balances are reported to Treasury and OMB. FDA prepares monthly and quarterly reconciliations as required by the Department to ensure the balances reported in financial reports are accurate.

We achieved a fifth consecutive unqualified audit opinion of annual financial statements for the FY 2001 reporting period. The audit disclosed one reportable condition with FDA's information systems controls and repeated the finding of non-compliance to the Federal Financial Management Improvement Act (FFMIA), a financial management law emphasizing electronic systems integration of financial transactions and reporting. With the implementation of the Department's new financial system, FDA will resolve these findings. We also produced the CFO Annual Financial Report that documented the account of prior year results and expenditures. Financial statements were required quarterly, instead of annually, which increased the amount of preparation time needed. The new procedure for preparing financial statements was implemented in FY 2003.

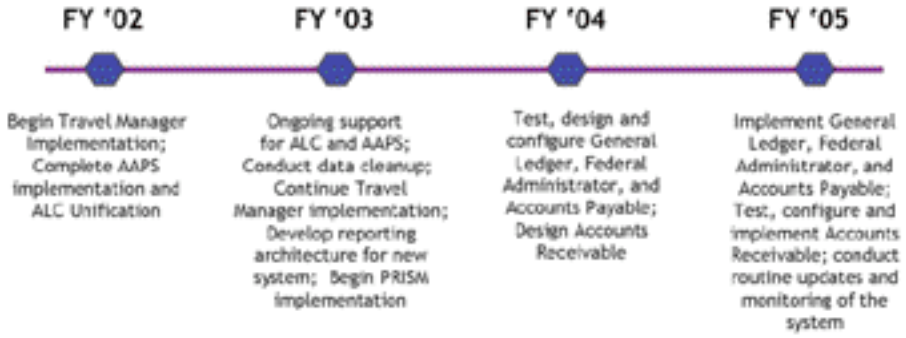
As part of our financial systems upgrade, project management was instituted across the office in preparation for the large number of projects to be integrated in FY03 – FY04. We are working to implement the United Financial Management System (UFMS) project, as initiated by Secretary Thompson to replace five legacy accounting systems currently used across the Operating Divisions. The UFMS will integrate the Department's financial management structure and provide HHS leaders with more timely and consistent financial management information, and in accordance with the President's Management Agenda, seek to improve performance throughout HHS by integrating budget and performance. It will also promote the consolidation of accounting operations and, thereby help to substantially reduce the cost of providing accounting services throughout HHS

FINANCIAL SYSTEMS

New Financial System. The Financial Enterprise Solutions (FES) comprises a set of distinct and separate FDA financial systems that are integrated with HHS's Unified Financial Management System (UFMS). FDA responsibility for implementation of UFMS is led by OFM. Ultimately the team, made of resources from across FDA, will perform Business Analysis, Technology Analysis and Change Management activities to determine and carry forward FDA's business requirements. This effort (including contractors) will require more than 50 staff members to implement. The goal of HHS and FDA is to provide real-time reporting and allow for easier development of the DHHS/FDA financial statements. This past year, HHS and FDA have continued working together with the Center for Disease Control (CDC) and the Program Support Center (PSC) to develop an initial set of baseline requirements for UFMS. CDC has been designated as the pilot Agency for UFMS with a complete implementation of the Oracle Financials in October 2004. In preparation for the FDA implementation, OFM reorganized, forming a separate division dedicating more than fifteen personnel to this important effort. In addition, FDA, with the other HHS agencies, participated in a conference room pilot where the HHS Global team, FDA, CDC and PSC validated the configurations and ensured that the baseline requirements were met. FDA staff continued to work with the UFMS system integrators, BearingPoint, on developing a detailed project plan as well as documenting the current FDA business processes.

The UFMS and FES financial efforts involve four phases beginning in FY02 and conclude in FY05. This phased implementation allows FDA to process approximately 60% of its accounting transactions with little impact to Headquarters staff and demonstrates success to FDA's Agriculture Appropriation Committees who provide funds for this effort. Funding for the UFMS multi-year effort beginning in FY02 is estimated at over $290 million, with FDA's portion being approximately $37 million. The majority of these funds support HHS Global efforts and integration contractor costs for UFMS.

FDA's implementation and schedule involve the following activities:



Travel Manager. OFM began the last phase of the Travel Manager project in preparation for UFMS. This involves upgrading to version 8.2 and extending the implementation to all FDA components with the exception of ORA's Central Region. In an effort to improve services, OFM began automating Sponsored Travel (or 348s) by modifying NIH's 348 Travel Manager module for FDA's accounting interface. In recognition of this successful collaboration with NIH for improving travel management, FDA and the National Institutes of Health received a travel management award from Government Executive Magazine in June 2003. The Travel Manager team will begin piloting the automated Sponsored Travel module with CDRH in October 2003.

PRISM. The Purchase Request Information System (PRISM) involves developing a system to automate FDA's procurement functions. The system automates FDA's requisitions and award processes within the simplified acquisitions and contract functions. PRISM began its implementation in June 2002 to over 30 users in FDA Headquarters. Ultimately, the system will integrate with UFMS via the Oracle Compusearch Interface

Financial Management Reporting System. This new reporting system will work to enhance and replace FDA's current reporting system and work seamlessly with UFMS and FES systems. The new system will enhance current reporting by:

- Developing a "one-stop shop" or central repository for all financial reports;
- Providing functionality, such as: on-line viewing and processing capabilities, analytical capabilities through query tools, supplemental ad hoc reporting; and
- Providing pertinent, timely, and accurate information to the system users.

A team has been formed with representatives from the Centers to send out a survey and conduct personal interviews with key Center staff on their individual reporting requirements. From these requirements, a design for a new reporting system will take place.

Medical Device User Fee and Modernization Act (MDUFMA). FDA is required to implement a system to administer user fee transactions in accordance with the MDUFMA. This required OFM to design and implement an interface to: obtain applicant data, track MDUFMA billing and collection, and provide financial reports of MDUFMA activities. The MDUFMA implementation effort involves modifying the Accounts Receivable System by capturing initial MDUFMA receipts and transitioning MDUFMA to the Accounts Receivable module of the new financial system. In partnership with CDRH, OFM with OMS leadership participated in several workgroups with a multitude of subject matter experts and consultants to develop policy, procedures and a computerized system of billing and collecting for MDUFMA.

The state-of-the-art MDUFMA User Fee System will also serve as the basis of additional user fee based systems for Prescription Drug and Animal Drug User Fees and other accounts receivable.

Freedom of Information Act (FOIA). As part of FDA's efforts to streamline and integrate its financial systems, OFM performed an assessment of the Division of Freedom of Information's (DFOI) billing and collection processes. During this analysis, staff and stakeholders were interviewed and

requirements gathered. Based on the requirements, OFM and the DFOI staff determined that a new Oracle based system will be needed to meet DFOI's needs. In addition to the new system, some business process improvements will need to be implemented to ensure success.

Property. To upgrade and improve the efficiency of the Agency's Property system, a pilot project for a Wireless Property Inventory System was begun. This system will employ Blackberry devices with barcode readers attached. The Agency property personnel will be able to wirelessly transmit inventory data to and from the device, and use stored data to conduct their inventory thus automating the annual inventory process. The system application will be enhanced to support Agency's property inventory personnel. OFM is now developing plans to expand the pilot to other FDA Headquarters' components.

Rule of Five. We continued to implement policies and procedures to collect, manage, and gain DHHS approval of travel for FDA staff. Over 372 requests were processed. We also worked to gain approval for exemptions from the process.

Data Cleanup. FDA is currently preparing accounting and financial data for migration to the new financial enterprise system. The purpose of this effort is to improve the integrity of financial data to support favorable audit opinions, as well as to clean the data in FDA's financial systems and the General Ledger prior to data migration to UFMS. From August to October 2002, FDA conducted a data clean-up assessment where we evaluated the state of the financial data in our current systems, developed a recommended approach to "clean" existing data and identified process improvements.

BUDGET AND PERFORMANCE INTEGRATION

Strategies. The first strategy is to more effectively integrate FDA's performance plan and budget, building organizational cultures that focus on outcomes and results. Integration increases the transparency between the performance plan and budget to allow for better understanding of the outputs produced by FDA's resource investment. This is accomplished through estimating costs and incremental improvements in performance goals; reducing the number of performance goals to a manageable level; improving the linkage between the performance plan and budget by using strategic planning teams to develop multi-year plans for top Agency priorities, including resource needs and performance levels; identifying high quality outcome measures; and incorporating performance measures and accountability into the management of the Agency. In FY 2003, the Agency conducted an extensive planning process by which it created a strategic plan with strategic goals, objectives, and an action plan. Strategic planning workgroups, composed of representatives from the Centers, ORA, and OC developed long-term outcome goals for each strategic goal area. The work groups also developed an action plan that provides specific milestones for each strategy area.

The second strategy is to improve the accountability of FDA managers for achieving performance and management goals by linking them to individual performance contracts. The contract requires the highest to lowest senior level manager to commit to a level of performance as articulated in specific performance goals.

The third strategy is to implement a new financial system to allow FDA to measure the various costs of its programs and performance outcomes. FDA, in conjunction with other DHHS OPDIVS, has been planning to implement a new financial system to better track the specific costs of particular programs. The Agency will continue to look at new ways of developing performance outcomes and results, linking cost data to performance outcomes and results, and using those data in management decision-making.

Budget and Planning Integration. The development of the outcome goals by the Office of Planning began during the fall of 2002 in response to the corrective actions promised by FDA for OMB's FY 2004 Program Assessment Rating Tool (PART) evaluation. The FY 2004 PART also shaped FDA's planning and budgeting processes by focusing on improving program performance and accountability, and by identifying potential outcome goals and funding strategies. The FY 2005 Performance Plan is linked to the FY 2005 budget request, which describes the use of the funding but leaves the specific performance implications to the annual performance plan. The request includes examples of specific performance goals throughout the document to illustrate the request's description with a specific performance measure.

FINANCIAL MANAGEMENT

OFM completed work with CDER, CDRH, and Agency facilities staff to utilize the $4 million appropriated in FY 2002 and other sources of funds to complete preparations for the movement of the first group of FDA employees to the new White Oak campus in the Fall of 2003. In addition, we completed work with these two Centers and with CVM on an agreement for funding procedures for consolidated animal management services at the new facility.

We developed and provided funding estimates to Congress for resources to be transferred from CBER to CDER under the reorganization of drug review functions, as well as a number of reorganizations within the Office of the Commissioner, which have now been approved by the Appropriations Committees for implementation in FY 2004.

OFM coordinated emergency food security budget requests with CFSAN, ORA, DHHS, and OMB staff which resulted in the transfer of an additional $5 million from the President's Emergency Response Fund to FDA for essential food security research.

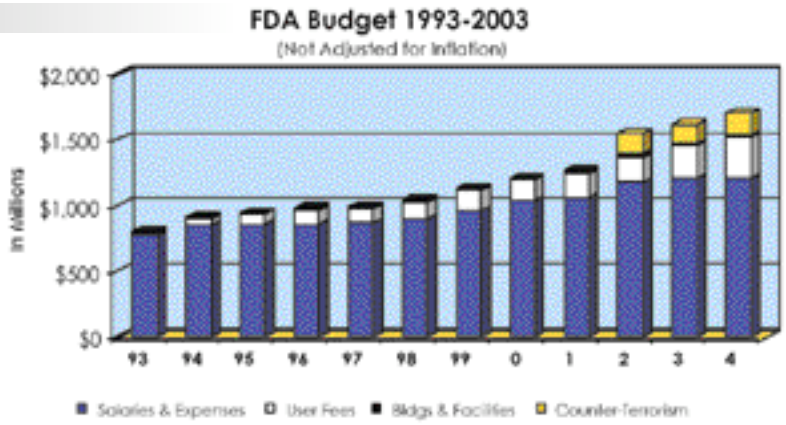
OFM also developed initial budget estimates for the new Office of Shared Services and developed proposed fund allocation and cost allocation procedures for this new office to be established in FY 2004, to assure effective funding of that Office as well as equitable cost allocation to the FDA components.

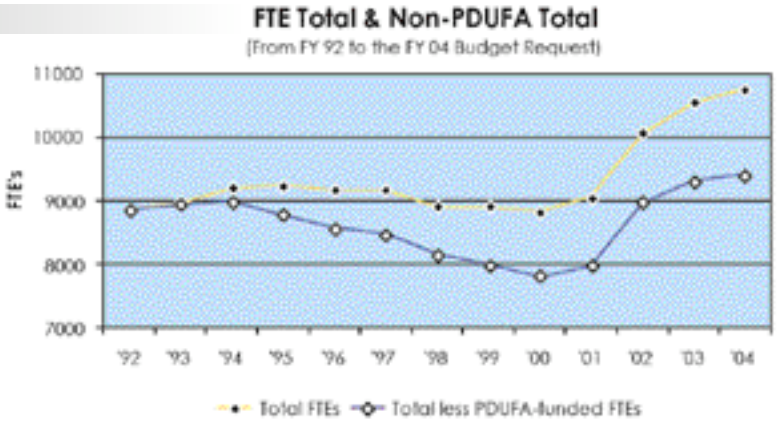
Appropriation Increases. On February 19, 2003, the President signed the FY 2003 Omnibus Appropriation Bill which provides FDA with a program level budget of $1.65 billion, giving the Agency the necessary resources to continue providing the American public with the high level of safety and security it expects. These resources will support our responsibilities under the Federal Food, Drug, and Cosmetic Act to ensure that new products are safe and effective for consumers.

This legislation allows for $271 million for user fees, including $223 million, or a $61 million increase, for Prescription Drug User Fees and $25.1 million in newly appropriated user fees authorized by the Medical Device User Fee and Modernization Act.

The appropriation also provides $5 million for improvement of patient protection against medical errors involving the use of FDA regulated drugs, biological products, and medical devices. An additional $5.3 million was provided for the expansion of FDA's generic drugs program. By hiring additional product reviewers, plant inspectors, and more closely monitoring the quality of imported generic drugs and bulk drug substances, FDA will be better able to provide consumers with access to safe and affordable medications.

The greatest increase, which comes from the incorporation of the FY 2002 counter-terrorism supplemental budget of over $150 million dollars into FDA's base budget, reflects the Agency's central role in the Nation's defense against the threat of terrorism. FDA's budget also includes the across-the-board rescission of 0.65% ($8.9 million), as well as cost savings of $2.6 million that will be achieved by the streamlining of operations, new management efficiencies, and the consolidation of administrative functions and facilities.





PDUFA. We continued to closely monitor the current Prescription Drug User Fee Act (PDUFA) funds to assure availability; developed draft language; and- assisted in the reauthorization of PDUFA III.

FINANCIAL MANAGEMENT OUTREACH AND COMMUNICATIONS

Stakeholder Communications. We improved communication of resource issues and mission priorities with Departmental, OMB, and Congressional staff. We facilitated informational briefings and visits to FDA facilities to improve understanding of FDA's mission and increased responsibilities. We have also provided more internal briefing to the staff, including the new Senate Agriculture Appropriations Subcommittee Clerk, and arranged for more site visits of our facilities.

OFM Council. Last year, we established the OFM Council as part of an initiative to improve administrative services, processes and systems delivery in the Agency and improve communication throughout OMS. The Council meets on a monthly basis to act as an advisory group to the Center Executive Officers for the coordination of business processes and their related topics within OMS and across FDA, to support new initiatives and charter workgroups to focus on specific topics or issues on an as-needed basis, and to review financial issues as well as changes to policy and/or procedures and recommend changes.

In another outreach effort in FY 2003, OFM supported a number of detailees in the Agency's Leadership Development Program and in personal development assignments. These details facilitated the exchange of information between OFM and the Centers, providing participants with first hand exposure to the budget process and financial management issues, while also providing OFM staff with an increasing awareness of the roles, responsibilities and processes in FDA's centers.

•• Human Resources and Management Services ••

HUMAN RESOURCES (HR) CONSOLIDATION

DHHS "40 to 4" HR Consolidation. Assisted the Departmental steering committee of high-level representatives from all DHHS Operating Divisions (OPDIVs) and the Office of the Secretary in planning for the proposed consolidation of 40 HR offices into 4, is scheduled to begin in FY 2004. The four offices will be located in Bethesda, Atlanta, Baltimore and Rockville. In preparation for this we have streamlined automated systems, all OPDIVs will be using the Enterprise Human Resources and Payroll (EHRP) system, QuickHire, and QuickClass and are moving to the desired service ratio of 1:82.

STRATEGIC WORKFORCE PLANNING

Coordinated and implemented the DHHS Emerging Leaders Program within FDA. The FDA hired five Emerging Leader interns in various scientific and public health related occupations.

Coordinated and implemented the Hispanic Association of Colleges & Universities (HACU) Intern Program. FDA placed approximately 30 interns for the spring, fall and summer semester programs.

Coordinated and implemented the Presidential Management Intern (PMI) Program within FDA. FDA hired two PMI's this year.

Retention. Explored ways to improve the quality of work life for our employees. Over 20% of FDA employees participated in our Flexi-Place Program and all employees worked some type of alternate work schedule, many of whom participated in our innovative "Any 80" Program. Using these flexibilities helped us reach candidates we might not have attracted in the past and improved retention of those onboard.

QUALITY OF WORK LIFE (QWL) INITIATIVES

Continued to institutionalize the concept of strengthening the quality of employee work life during this eighth year of FDA's QWL Program. Our QWL survey had a 43% response rate and continued the overall positive trend of the past few years. The QWL Survey is an indication of employee satisfaction. Initiatives under the QWL program have helped with recruitment and retention of the highly skilled, quality workforce in FDA.

Significant accomplishments include:

- Wrote a charter to provide guidance to Center/Office/Field representatives. Include participation from field representatives in monthly meetings.
- Provided a monthly Elder Care Support Group – offered in three locations.
- As part of the Elder Care Program, each employee received a copy of Five Wishes. Five

Wishes lets adults of all ages plan how they want to be cared for in case they become seriously ill. Five Wishes is an easy to use living will and is considered a legal document in most states.

- Continued the Smoking Cessation Initiative.
- Offered wellness programs such as testing for resting metabolic rate, and osteoporosis screening.
- Encouraged "Any 80", flexi-place arrangements, and alternate work schedules. Current flexi-place arrangements are up to 25% participation of eligible positions.
- Continued to offer a training class for potential supervisors "Supervisory Potential Program".
- Published the monthly OHRMS Newsletter and posted it on the FDA intranet home page.

EMPLOYEE AND LABOR RELATIONS PROGRAM

Provided advice and assistance to the Agency's A-76 initiative, including working with management officials to assure proper union participation and satisfied bargaining obligation with NTEU concerning procedures for placing employees affected by commercial activities (A-76) studies.

Provided advice, assistance and coordination to the Agency's White Oak move initiative, including coordinating with various union stewards, serving notices, and negotiated a revised Memorandum of Understanding concerning relocation of Phase 1 employees to White Oak, MD, necessitated by changes in occupancy plans.

Provided advice and guidance on FDA-wide implementation of the Office of Shared Services, to include evaluation of the union's proposals, providing counterproposals, and developing bargaining strategy.

Developed and presented supervisory training on the changes in the Collective Bargaining Agreement resulting from 30-month negotiations.

Participated in, and made presentations for, the U.S. Office of Personnel Management Symposium on Employee and Labor Relations.

Assisted in the establishment of Regional labor relations councils, and negotiated FDA-wide Mandatory Foreign Inspections policy.

The Agency Cooperation Council and Cooperation Office:

- The FDA Labor Management Cooperation Council received the HHS National Cooperation Council Award.
- Hosted a meeting of the HHS Department-wide Cooperation Council.
- Established the FDA Agency Cooperation Council Web Page.

EMPLOYEE AND ORGANIZATIONAL DEVELOPMENT

- Delivered 16 leadership training courses attended by 253 participants from all of the FDA Centers and ORA.
- Sponsored 14 organization development interventions including strategic planning, team building retreats, and executive coaching.
- Designed and implemented the FDA Supervisory Potential Program.
- Implemented e-learning in the Office of the Commissioner.
- Developed a proposal for the FDA "Cyber-Science" Training Academy.

AWARDS PROGRAM

Designed and implemented the FDA Quality Step Increase (QSI) program, which allows managers to give an employee, who is consistently performing above the "meets performance measures" level, an increase from one step of the grade to another. In FY03, 193 employees received a QSI.

EMPLOYEE BENEFITS AND SERVICES

- Conducted six employee benefit seminars, covering retirement, life and health benefits and related topics. Each seminar averaged between 50 and 80 attendees.
- Implemented the Thrift Savings Program (TSP) catch up contribution program.

•• Information Resources Management ••

IT Consolidation. Developed and executed an IT Consolidation Plan that enables the FDA to meet Department consolidation goals. We facilitated the design and implementation of a consolidated infrastructure service organization under a shared services framework. We hired the Director of the Office of IT Shared Services (OITSS). We reorganized the Office of the CIO to emphasize both the Agency's direction towards a more cohesive management of IT and the CIO's leadership role in developing IT strategy. In addition, we assigned an IT Program Director for all ongoing consolidation efforts, who will ensure the integration of all consolidation initiatives and also will identify cost reduction opportunities.

Investment Management. Implemented a pilot portfolio management tool (ProSight) to capture critical IT investment data, greatly easing the burden of responding to OMB and DHHS level data calls for IT budget information. It also supports the strategic decision-making needs of the FDA CIO and other senior leaders and has helped drive the FDA towards a more formal governance structure for FDA's IT program. We also documented formal governance structure through a series of weekly integration meetings between leads from project management, portfolio management, enterprise architecture, security and a representative Center.

Project Management (PM). Performed assessment to measure how well the FDA oversees its IT investments. Assessment evaluated 16 investments (two from each Center, ORA and OC) against a three pronged criteria based on the Capability Maturity Model (CMM), GAO's IT Investment Management (ITIM), and Project Management Body of Knowledge (PMBOK). Results were used to develop an Enterprise Implementation Plan (EIP) facilitating establishment of a project management office (PMO) under the CIO. Since inception in 2003, the PMO has established a steering committee to coordinate PM implementation at the "grass roots" level, established a 9 course PM certification program sanctioned through George Washington University, provided mentoring and coaching services to individual project managers, and provided change management training to PM champions at the Center/Office levels.

CIO Communications Program. Established a communications role to facilitate timely and consistent communications across the FDA IT community. We coordinated series of IT talks addressing topics such as IT consolidation, security, portfolio management and enterprise architecture. We also developed a strategy for "getting the word out" to all IT stakeholders using various medium based on the targeted audience.

PDUFA III IT Program. Under OMS leadership, progress was achieved towards each of the PDUFA III IT goals. PDUFA requires FDA to "centralize the accountability and funding for all PDUFA Information Technology initiatives/activities for CBER, CDER, ORA and OC under the leadership of the FDA CIO" and also makes the CIO "responsible for ensuring that all PDUFA III IT infrastructure and IT investments support the FDA's common IT goals, fit into a common computing environment, and follow good IT management practices." We established a program that fostered collaboration and allowed us to work with each of the PDUFA Centers/Offices in establishing a governance process for reviewing, prioritizing and funding new and existing PDUFA investments. We also par-

ticipated in quarterly meetings with industry to review and evaluate the status of PDUFA IT initiatives. We led the effort to develop and publish the PDUFA III Information Technology Five-Year Plan. We also worked with the PDUFA governance groups to explain and discuss the concept of a trusted repository and provider of regulatory data and content management services supporting the secure exchange of information between Bio-Pharmaceutical Sponsors, their partners, investigators and Regulatory Agencies.

IT Security. Updated and enhanced the general IT security user awareness training course, UserAware. As a result, FDA attained a 91% completion rate for FY03. We conducted an FDA-wide IT security review, which included a program-level review of compliance with appropriate government security requirements, as well as testing the effectiveness of information security controls within each Center/Office. The assessments, performed annually, will provide FDA's senior management and others with the needed information to determine the effectiveness of overall security programs and to develop strategies and best practices for improving information security. We developed a computer incident response plan to assist in ensuring a consistent approach to computer incident handling activities. We identified the requirements, and initiated the procurement process, for an FDA wide Intrusion Detection System deployment, which will monitor key network components for unauthorized access attempts. We also completed the NIST Self-Assessment Guide for Information Technology Systems (NIST Special Publication 800-26, published November, 2001) for all IT systems identified as major.

Enterprise Architecture(EA). Created the Enterprise Architecture Program and hired enterprise architect and procured contract support. We developed a plan for implementing enterprise architecture in FDA and produced first version of the "as-is" FDA enterprise architecture. This included an EA repository providing a view of the enterprise architecture and its relationships. We ensured EA was integrated into the overall governance process and that EA currently supports the FDA technical review board. We initiated business process documenting and modeling across the FDA, creating an EA working group comprised of a representative from each center. As a result, 5 centers have initiated EA activities. We formalized the working relationship with the FDA data council and documented and modeled the "as-is" current PDUFA submissions process for CDER and CBER. We have started to address the requirement gathering and target architecture for a totally electronic point of entry, which will have the capability to extend to all PDUFA centers.

IT COOP. Created an information technology COOP team comprised of representatives from each FDA center. Concluded requirement gathering and pricing for IT support of COOP level 4 operations and COOP level 1,2 and 3 operations.

Enterprise Administrative Support Environment (EASE). Completed modifications to EASE to address data differences and process issues to implement the interface from PeopleSoft HR to EASE production. We expanded the use of the EASE FDA Enterprise data to include interfaces to Peregrine for Shared Services Help Desk and CVM's Staff College and Activity Time Reporting (ATR) System. We utilized and enhanced the EASE Administrative Portal and EASE Roles management capabilities to allow for internal single sign-on access to FDA Unified Registration and Listing System. We added EASE Time and Attendance data to the Reporting and Analysis Module (RAM) to provide timely

reporting for all tour hours and leave categories. We also completed preparation and testing for the upgrade to Oracle 9i and the shared Business Objects Environment.

FDA Unified Registration and Listing System. Implemented an on-line Food Facility Registration Module that is capable of handling 5,000 on-line registrations simultaneously via the Internet and is a valued tool in the Federal Government's counter terrorism strategy. We provided a unified account management and single on-line entry point to be used for all FDA Registration and Listing systems. We also coordinated with the Prior Notice system development effort to ensure system interfaces were in place.

FDA Information Management Systems. Implemented new FDA wide database applications for the Docket Management Branch (DBM) documents lifecycle tracking. These applications include Dockets, Advisory Committee, NADA FOI Summaries and OTC Volumes. We enhanced the existing Ethics application, allowing Center liaisons access to the application. We also completed the correspondence application baseline design; development is underway. As an active partner in the e-Gov e-Rulemaking initiative, we provided the baseline application for Phase I of the initiative. The FDA e-comment application was implemented in January 2003 and can be viewed at www.regulations.gov. We continue to be an active partner as the lead for the Department.

Internet/Intranet Services and Support. Provided critical health information to the public through the FDA Public website. This site offers information of interest to health professionals, patients, consumers, industry, state and local officials, and many others. The Internet web infrastructure provides rich functionality, responds to changing needs, and provides high performance scalability and reliability. We supported a substantial increase in content on the FDA Internet website and traffic to this infrastructure, while continuing to remain within budget. We negotiated a new web hosting data center services contract and successfully migrated the entire web site to the new infrastructure in May, 2003. The new site provides technology, storage and security enhancements over the previous site. We also implemented Akamai's EdgeSuite web caching services, which will increase web site performance, reliability, and provide additional disaster recovery and security mechanisms for the site.

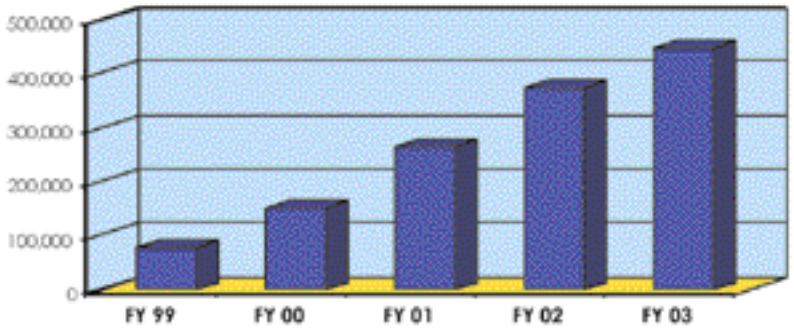
Telecommunications. Completed the network design and infrastructure plan for White Oak. We developed the migration plan for the transition of voice, data and video services to the White Oak campus (Phase I is scheduled for early to mid-November.) We completed Voice over IP (VoIP) testing, determined the viability of VoIP for White Oak and awarded a contract for implementation. We initiated management planning for the transition from the Telecommunications Improvement Project (TIP) to the Washington InterFDA Telecommunications System (WITS.) We also coordinated nationwide telephone installations with ORA and Facilities in conjunction with expansion as a result of Counter-Terrorism hires.

HHS-NET. Led the design and implementation team for HHS-Net. HHS-Net is a network modernization effort that supports HHS-wide, applications, provides a robust network that is secure and reliable, and provides interoperability among the OPDIVs. Our leadership facilitated agreement on a high-level and conceptual design. We placed all circuit orders in preparation for the cutover in FY04

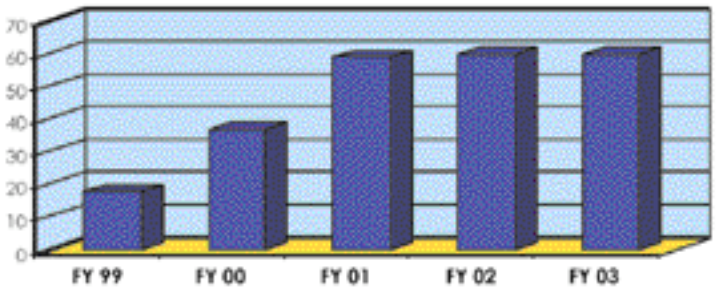
Internet/Intranet Data:

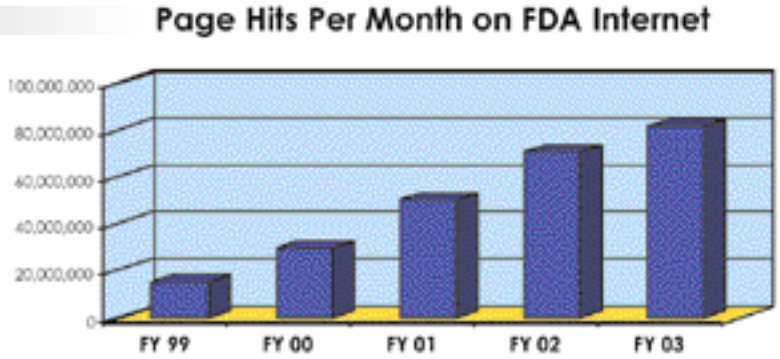
Year	# of files	# of web databases	# of Hits/Month
FY 1999	80,000	18	15,500,000
FY 2000	151,000	37	30,000,000
FY 2001	264,200	59	50,600,000
FY 2002	374,766	60	71,000,000
FY 2003	450,082	60	82,000,000

Files on Main Production Internet Servers



Internet/Intranet
Web-Enabled Databases Supported





•• Management Programs ••

Federal Managers' Financial Integrity Act. Met accelerated reporting requirements for the Preliminary Letter of Assurance/Annual Report for mid-July and the Final Letter of Assurance/Annual Report for mid-October.

Delegations of Authority:

- Updated the regulatory delegations to reflect the biologic therapeutic products review functional transfer from CBER to CDER
- Updated the former OFACS administrative delegations to reflect the reorganization under the Office of Shared Services, the establishment of the Office of Acquisitions and Grants Services and Office of Real Property Services, and the transfer of certain functions to OFM
- Prepared MDFUMA-related delegation for CBER, CDRH, and OMS
- Updated MQSA-related delegations for CDRH

Office of Inspector General (OIG) Program. Initiated and co-sponsored, with the Office of Policy and Planning, a joint forum to bring all parties together to share information, identify common issues and concerns, and recognize best practices during the audits and reviews. The meeting resulted in very positive exchanges between the groups, sharing of lessons learned, and agreement to continue the forum on an annual basis.

The OIG conducted audits of 11 FDA laboratories, assessing physical security and security controls on the labs containing select agents. During six Exit Conferences, OIG officials discussed working draft reports, and Agency officials presented comments on the recommendations addressed in the reports. FDA submitted comments on 10 OIG draft reports, and forwarded implementation plans and management decisions on seven OIG final reports, containing over 300 recommendations. Responding to an OIG request in July 2003, the Agency provided updated information regarding

steps taken to strengthen the security of 13 labs working with select agents, including updated status reports on three labs that were not included in the OIG audits. At the request of the Deputy Secretary, HHS, the OIG developed a "task order" for KPMG auditors to assess the steps undertaken by FDA, NIH, and CDC to strengthen the security of 15 labs working with select agents. KPMG officials issued a draft report, for which FDA submitted comments in September 2003.

Organization Program

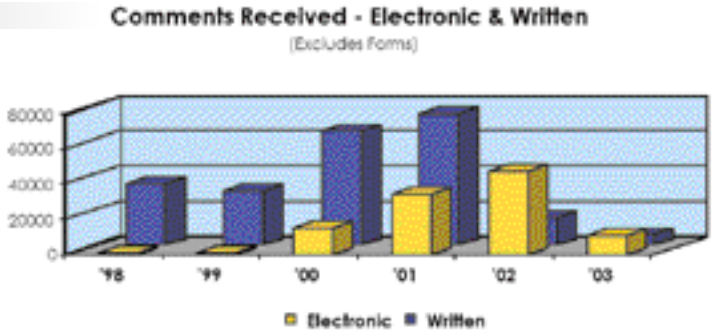
- Worked with CBER and CDER to complete the organizational transfer of the Office of Therapeutics Research and Review. This reorganization is an Agency effort to consolidate similar review functions, and further develop and coordinate scientific and regulatory activities between Agency Center/Office components;
- Worked with the Office of the Commissioner in establishing the Office of Combination Products in accordance with the Medical Device User Fee and Modernization Act of 2002; and
- Worked with the Office of Executive Operations in establishing the Office of Shared Services and its respective substructure. The implementation of this organizational component is an Agency initiative to comply with the President's Management Agenda goals and the Department's management of human capital and administrative reforms.

Delayering. Initiated by the Agency in FY02 and carried over into FY03. This initiative is an Agency effort to comply with the President's Management Agenda to improve efficiencies through delayering. The Secretary believes flat, streamlined organizations result in faster decision-making and better communication. FDA in FY03 conducted organizational studies and provided the Department with assessment reports for the following organizational components:

- Center for Devices and Radiological Health;
- Center for Drug Evaluation and Research;
- Center for Biologics Evaluation and Research; and
- Center for Food Safety and Applied Nutrition.

Expanding Electronic Government. Provided leadership and support to the HHS E-Rulemaking Team, chaired by the Department. E-Rulemaking is one of the 24 E-Government Initiatives on the President's Management Agenda. In 2003, the FDA team provided the base application and technical support for the implementation of the 1st phase of the E-Rulemaking initiative, www.regulations.gov. A FDA representative is the lead for HHS in this initiative and serves on the Advisory Board. Other FDA representatives serve on the legal, business process and technical workgroups. FDA will continue to provide leadership and support to the E-Rulemaking initiative for Phase 2, which is in the development stage and is scheduled for implementation in October 2004.

In 1998, OMS implemented its first online electronic submissions form that provided an easy way for the public to submit both general comments on specific issues and specific comments on proposed rules, guidances, and notices of meetings, workshops, and other activities. Electronic rulemaking at FDA reduces the processing time needed to make, receive, and review comments and increases the number of comments received.



Freedom of Information Act (FOIA) Activities. The Division of FOI (DFOI) received, reviewed, logged, referred, and monitored the processing of 18,094 FOIA requests, including 132 denials and 17 appeals. DFOI also continued the Document Repository pilot for all major Agency components. FOIA requests and responses are being distributed electronically via the FOI Document Repository.

DFOI planned, developed, and presented several FOIA/Privacy Act training sessions for headquarters and field employees and hosted an Agencywide observance of National FOI Day to heighten awareness of the importance of FOIA.

DFOI posted 710 warning letters on the Internet in the Agency's Electronic FOIA Reading Room and modified its database of warning letters to implement the Agency's Warning Letters Response Pilot Program.

DFOI issued a draft revision to FOIA Staff Manual Guide and published the Final Rule implementing requirements of the Electronic Freedom of Information Act (EFOIA). In addition, established the FOI Council that consists of the Director, Deputy Director, and Supervisors of DFOI, FOI Officers/Information Disclosure personnel from each Center and ORA, and disclosure attorneys from the Office of Chief Counsel. The Council will meet on a regular basis to discuss and disseminate information disclosure policies, issues, and procedures and to ensure Agencywide consistency in interpreting and applying disclosure policies and procedures.

Ethics Program Activities. The Ethics and Integrity Staff focused on improving communications across the Agency. The New Employee Orientation briefing was revised and won a Plain English award with the training module. Responsibility for briefing political appointees, a function previously performed by the Department, was assumed by the Staff. The FDA Ethics website moved to the FDA Internet, making it available to prospective hires and the public. In addition, FDA was invited to make a presentation on its waiver process for Advisory Committee members at the Annual Office of Government Ethics (OGE) Conference. Finally, the Agency requested and received a determination from the Director of the Office of Government Ethics that 29 positions in FDA, including some positions under Title 42, identified as confidential filer positions, were in fact SES equivalent. Based on this determination, the 29 employees are now required to file the Public Financial Disclosure report in lieu of the less stringent Confidential Financial Disclosure report.

Paperwork Reduction Act/OMB Team (PRAT). Continued efforts in 2003 to reduce the paperwork burden upon the public without compromising program integrity. Also, obtained approvals for 14 new information collections and extensions for 35 existing information collections and compiled FDA's FY 2003 Information Collection Budget.

Played an integral role in the publication of high profile regulations including four proposed Bioterrorism rules which included Prior Notice of Imported Food Shipments, Registration of Food Facilities, Administrative Detention of Food for Human or Animal Consumption, and Recordkeeping and Records Access Requirements for Food Facilities. These were all under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

PRAT also worked to get the information collections contained the Medical Device User Fee and Modernization Act program and its regulations, the Bar Code Label Requirements for Human Drug Products and Blood and Current Good Manufacturing, Packing, or Holding of Dietary Ingredients and Dietary Supplements. Provided advice and guidance in publication of the Interim Final Rule for Control of Communicable Diseases; Requests for Exemptions from Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals (Monkey Pox) approved by OMB.

Records Management and Information Dissemination (RID) Team. Led Records Management Renovation Projects, which included an OC-wide records inventory and scheduling project. When complete in December 2003, this project will produce an updated Records Control Schedule that is legally compliant and organizationally accountable. An adjunct to the updating of this schedule is an electronic records filing structure that is being developed to logically classify records groups that provides a comprehensive electronic records filing scheme for the future implementation of an electronic record-keeping system. The completed schema will be a milestone of the Agency's records data architecture. In addition, an automated records control schedule is being developed, which will provide a vehicle to electronically input information to be scheduled, reviewed, and approved through appropriate individuals.

The migration of the Records Disposition Tracking System into AIMS includes the development of a plan to migrate the current database in Microsoft Access to a relational database with protected access, that will allow FDA centers/offices to share and track records disposition information. The RID team scanned and imported Standard Form 135's (Records Transmittal and Receipt) covering 1995-1999 and 2003 into AIMS as part of the project.

•• Real Property Services ••

FACILITIES ACQUISITIONS, RENOVATIONS AND CONSTRUCTION

MOD I and BRF Renovations. The laboratory renovations of the BRF and MOD I were completed. A new roof was also installed on MOD I. The laboratory programs for CDER and CFSAN were relocated into the newly renovated space in MOD I and BRF.

Bio-Safety Level-3 Laboratories:

- ***MOD I and Moffett Center for CFSAN.*** Provided planning, architectural and engineering support in developing the statement of work and contract for design services for BSL-3 suites at MOD I and at the Moffett Center. Coordinated construction documents for MOD I BSL 3 suite with program representatives and begun renovation of existing laboratory into the BSL-3 suite. Began design and construction documents for BSL-3 suite at Moffett Center.

- ***Jamaica, Queens, New York; Irvine California; Cincinnati; and Atlanta for ORA.*** Provided planning, architectural and engineering support in developing the statement of work and contract for design services for BSL-3 suites at Jamaica, Irvine, Cincinnati and Atlanta. Jamaica construction is complete and final certification is pending completion of security work. Irvine BSL-3 suite is in the construction phase and nearing completion. Both locations have undergone a pre-certification inspection and report. The BSL-3 suites in Cincinnati and Atlanta are in the design phase.

Arkansas Regional Laboratory (ARL). Provided technical assistance to NCTR during the construction of the first stage of Phase III that includes landscape work and the renovation of the shower and locker rooms on the first floor of Building 50. The construction of the first stage of Phase III has been completed. Supported NCTR's solicitation, evaluation, negotiations, and value engineering and selection of a contractor for the construction of the next stage of Phase III. This stage includes the fit-out of the seventh floor of Building 50. The fit-out of floors five and six were options that if funding is included in the FY04 budget will be exercised.

Los Angeles (Irvine) Laboratory. Coordinated the installation of the telecommunication and security systems by OIRM's and Security's contractors. Completed construction of the facility, including incorporating the new counter-terrorism security measures, on time and on budget. Worked with ORA's Pacific Regional Laboratory and Los Angeles District Office staffs to organize a dedication ceremony on June 24, 2003. Coordinated a pre-certification inspection and report of the BSL-3. Met with local program representatives and provided support, coordination and management for the procurement of furniture and move services. Provided assistance to local program in coordinating the relocation from their existing facilities into the new facility.

Winchester Engineering and Analytic Center (WEAC) Modernization. Provided planning, architectural and engineering support in coordinating with local ORA program personnel in beginning to develop a Program of Requirements (POR) for a new laboratory facility on the existing FDA owned

land. The POR also includes office space to consolidate the New England District office personnel, located in leased space, into an FDA owned facility. The POR studies a two phased construction with the laboratory being constructed first. Relocation of laboratory personnel from the existing facility into the new facility, demolition of the existing laboratory, construction of the office portion, and relocation of office personnel from leased space. A project-planning estimate was developed and funds to begin the pre-planning and design phase were included in the FY 2005 budget request.

San Juan Office Building. Coordinated with local ORA program personnel on the finalization of the construction documents and acquiring the necessary permits from the Commonwealth. Awarded the construction, A/E post-design, and construction management services contracts and conducted a pre-construction meeting.

ORA Baltimore District Office and Laboratory. FDA took occupancy of the previous Baltimore District Office and Laboratory building in 1962, and relocated in October 2001. Once FDA vacated the building, the building owner filed a claim with GSA for $1,253, 000 for restoration of the building and as compensation for loss of rental income since the building was not tenantable. The Government's final offer of $208,000 for restoration costs was accepted by the building owner, saving FDA over $1 million.

ORA District Office Relocations. Three District Offices were relocated to new space.

ORA Resident Posts. Space was acquired for eight new Resident Posts, five Resident Posts were relocated, and expansion space was acquired for seven Resident Posts.

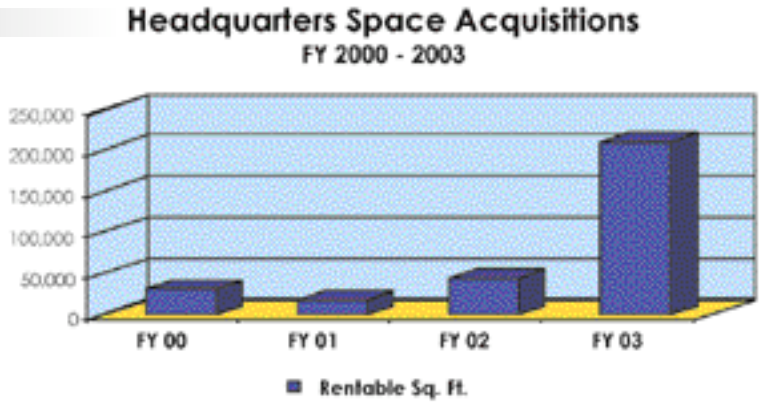
OCI Offices. OCI in Lenexa, KS was relocated and space was acquired for new OCI offices in Phoenix, AZ and Abingdon, VA.

GSA Rent Reviews. During the monthly GSA rent reviews, erroneous charges of $906,000 due to over-billing, double-billing, and other errors were discovered and subsequently recovered from GSA.

Headquarters Space Acquisitions.

- 5,504 square feet of new laboratory space for CBER to accommodate bio-terrorism program.
- 12,873 square feet of new space for CBER to accommodate PDUFA and bio-terrorism hires.
- 2,500 square feet of new space for CDRH to accommodate MDUFMA hires.
- 132,049 square feet of new space for CDER to accommodate increases in PDUFA and other programs.
- 30,332 square feet of new space for ORA for a new national training center.
- 1,935 square feet of new space for the OC, Office of Combination Products.
- 6,234 square feet of new space for the OC consolidation of Human Resources in North Montgomery County.

- 19,465 square feet of new space for CFSAN for a document room and new glass washing facility.
- Provided 6,522 square feet of space previously occupied by CDER to CVM.
- Provided 30,166 square feet of temporary laboratory space for CFSAN until their new permanent space is completed in College Park in November 2004.



ENVIRONMENT, SAFETY AND HEALTH (ESH)

ESH Information System (ESHIS). Continued designing the ESHIS with Information Resource Management staff. Several challenges were addressed regarding the acquisition of a worker's compensation system that would be tied to the ESHIS to allow for electronic processing of worker's compensation claims. This involved interacting with the Department and the fiscal year concluded with the Department again taking the lead, in the interest of "One HHS," to examine and ultimately select a worker's compensation reporting system. ORPS is moving ahead with the front-end hazardous condition reporting system. The relationship with the pending Employee Information Resource Center in terms of reporting facility-related hazardous conditions will need to be addressed.

ESH Planning for White Oak. Actively participated in the construction of the new Life Sciences Building (LSB), including ongoing collaboration with CDER and CDRH ESH Managers. Led and coordinated planning activities associated with short-term ESH needs for the Life Sciences Building (e.g., move planning, hazardous materials handling, laboratory signage, waste management, health unit services, etc.) as well as long-term ESH needs for the entire site.

Shelter-in-Place Procedures. Developed draft Shelter-in-Place (SIP) Procedures to be used in the event of a chemical, biological and/or radiological event when it would be safer for employees to remain in a facility rather than evacuate. Collaborated with Center/Office ESH Managers to finalize the procedures, and received National ESH Committee and FDA Safety Advisory Board approval for issuing the procedures for Agencywide use. The Associate Commissioner for Management and Systems issued the procedures indicating they should be used to develop building-specific SIP procedures as part of facility Occupant Emergency Plans.

Planned Initiatives for FY 2004

The OMS team is proud of FDA's FY 2003 managerial accomplishments and looks forward to the challenges ahead. In FY 2004, OMS will continue to work with all organizational components of the FDA management team to position the Agency to meet Departmental goals and objectives with state-of-the-art technology, re-designed cost management systems, streamlined business processes, and innovative approaches to meeting our customer needs. A discussion of some of the high priorities on which OMS plans to focus in FY 2004 follows.

Administrative Consolidation/Shared Services

Start-up the Employee Resource and Information Center (ERIC) to provide services in the areas of Information Technology, Equal Employment Opportunity and Diversity Management, Buildings and Facilities, Acquisitions and Grants, and Travel and Finance.

Finalize and publish service level agreements for each functional office.

Develop the start-up plan for OSS support to ORA field organizations and begin implementation.

Establish OSS operations budgets.

White Oak Consolidation Program

- Relocate CDER and CDRH programs to the Life Science Laboratory.
- Complete core and shell construction of the CDER Office Building.
- Complete the interior fit-out design of the CDER Office Building.
- Complete the design of the Central Shared Use building and begin construction.
- Complete the design of the CDRH Engineering/Physics Laboratory and begin construction.
- Initiate the move coordination for the CDER Office Building.

•• Acquisitions and Grants Services ••

Competitive Sourcing. Continue to support the President's Management Agenda and Agency goals by beginning cost comparison study for clerical staff under OMB Circular A-76. OAGS will support the initiative by conducting competitions and contract functions for the Agency's designated A-76 activities.

IT Consolidation. In support of the President's Management Agenda and the Secretary's initiative for the consolidation of Information Technology Infrastructure, OAGS will issue a solicitation to consolidate all IT infrastructures in FDA. It is anticipated that this will promote collaboration in planning and project management throughout the Agency with reduced expenditures.

Strategic Sourcing Pilot. OAGS is participating in the Department's pilot program for strategically sourcing general office supplies. The strategic sourcing pilot is part of the on-going "One Department" initiative within HHS to reduce operating costs and consolidate administrative functions. The goal of the pilot is to improve efficiency and reduce operating costs by leveraging the office supplies spent across HHS OPDIVs/STAFFDIVs.

Department Consolidation. OAGS will continue to participate in the Acquisition Consolidation Work Group sponsored by the Office of the Secretary, DHHS.

IMPAC Program. Continue the development of a web-based training module for cardholders, approving officials and central control points. A pilot training module was tested within the OAGS community and found to be a viable tool. OAGS intends to hire a contractor to develop certain enhancements and set up the training on the OAGS web site. It is the goal of the IMPAC team to have the web-based training available during the second quarter of FY 2004.

E-Grant Initiative. Establish an informal agreement with NIH to have FDA grants integrated into the NIH IMPAC II system. OAGS anticipates entering into an interagency agreement with NIH in FY 2004 to comply with the President and the Secretary's challenge to develop "One DHHS" as well as P.L. 106-107.

Faith-Based/Community Based Initiatives. Initiate and expand FDA's outreach to increase the number of faith-based/community-based organizations receiving funding from FDA. OAGS is currently supporting one community-based organization. OAGS plans to continue to work with the Office of Regulatory Affairs to develop communication with State and local governments to increase participation of community-based organizations in the grants program. Developing and drafting a web page devoted to CB organization activities within FDA anticipated to be available in FY 2004. It is envisioned that this site will provide links to the HHS Partner Gateway, DHHS Faith-based web site, White House web site and others.

•• Executive Operations ••

Special Projects:

- Provide administrative services in support of the start-up of the Office of Shared Services Organization:
  - Developing and processing personnel actions
  - Collaborating with OFM on financial resources
  - Establishing property oversight
  - Establishing OC Liaisons to interface with functional offices of OSS
- Continue and expand OC-wide coordinated Information Technology equipment purchases for greater savings and efficiencies through standardization.
- Develop an Information Technology Communication Tool for OC offices. Continue to provide a forum for OC programs through the OC Information Technology Governance Council to provide priorities and business needs to Information Technology support personnel.

•• Financial Management ••

Congressional Outreach. Continue the long-term process of strengthening communications with the appropriations subcommittees, as well as OMB and DHHS staff to increase their knowledge of the Agency's mission, goals, and public health initiatives: 1) through ongoing improvements to the budget submissions; 2) by conducting program briefings and facilities tours; 3) by providing timely and accurate background information; 4) through further integration of IT resources and planning into the process; and 5) coordination with the Office of Legislation to ensure appropriations and authorizations committees receive consistent information.

Budget. Build on the FY 2004 budget to seek additional programmatic budget increases in critically underfunded areas in accordance with the FDA Strategic Plan.

Continue work with CFSAN and ORPS for use of accumulated Color Certification funds, or other sources of funds, to meet special needs for providing new laboratories for that function in College Park. In addition, develop cost projections and develop proposal for an increase in the fees charged under this program, which will likely be necessary during FY 2004 or FY 2005.

Continue to address further budget and performance integration across FDA in accordance with the President's Management Agenda.

Continue with the annual PDUFA Financial Reports to Congress and managing the fee-exceeds-the costs waiver provisions while at the same time issuing Federal Register notices for new fees every August rather than every December. Also, we will need to work with the Centers to amend their

time reporting systems for FY 2003 to be sure that they capture new activities allowed under PDUFA III but not previously captured under PDUFA II, harmonize the PDUFA time reporting systems for CBER and CDER, and develop and refine the data we will have to use to apply and explain the workload adjuster provisions of PDUFA III for the first time next August.

Continue work to assure that funds are provided in FY 2004 and FY 2005 for the costs of occupying additional facilities at the new White Oak, Maryland, campus—specifically for the CDER office buildings to be occupied during 2005.

Continue work with all Centers, ORA, and the Office of Shared Services, to complete and implement budget allocations for that Office for the full fiscal year, and implement new procedures for monitoring the costs of that Office and the allocation of costs to the supported FDA components.

Develop cost estimates for the Agency costs of employee buy-outs, if those buy-outs are approved, and assist all FDA components in analyzing payroll costs for the fiscal year to determine the levels of staffing that can be supported with available funds.

Accounting. Maintain an unqualified audit opinion for the FY 2003 audit while at the same time meeting the accelerated deadlines. This will be accomplished by preparing monthly reconciliations throughout the year and by closing the General Ledger sooner using the new procedure for preparing financial statements. This new procedure will save time and allow us to meet the increased reporting requirements, as well as the accelerated dues dates

Produce the CFO Annual Financial Report within the designated time frames by ensuring advanced coordination and communication with all of the component contributors.

Resolve the reportable condition with FDA's information systems controls and the finding of noncompliance to the Federal Financial Management Improvement Act (FFMIA) by completing the planned implementation of the personal property information system's electronic interface and the accounts receivable system, and by working with the CFO Auditors to address remaining issues and developing reasonable performance targets and time frames.

Improve the close-out process for open obligations by closely monitoring monthly reports and working with components on timely deobligations.

Optimize the debt management function by improving internal processes and customer service.

Financial Systems. Continue to coordinate with HHS and the integrators in the implementation of the new financial system, UFMS. FDA will conduct its own Conference Room Pilot and participate in HHS's Conference Room Pilot 2 in February 2004. FDA will also be configuring and testing the General Ledger module of Oracle Financials with an interface to payroll which will account for almost 60% of FDA's accounting transactions. The General Ledger module is expected to be implemented October 2004.

A sponsored travel module will be implemented throughout each of the Centers along with a travel reporting module using Oracle and Business Objects. Beginning in the new calendar year, the approval process for travel will be streamlined by requiring only signatures of the travelers.

The PRISM implementation will be completed throughout the Agency for all simplified acquisitions and contracts and the E-Government initiative for Central Contractor Registry (CCR) will be integrated with the PRISM implementation.

A pilot reporting system will be completed demonstrating the new capabilities that will be integrated with the new financial system that is being implemented October 2004.

OFM with the assistance from the CVM will implement a billing and collection system for the new Animal Drug User Fee Act (ADUFA). In addition, OFM will begin to upgrade the Prescription Drug User Fee billing and collection system having three user fee systems (MDUFMA, PDUFA and ADUFA) using the same billing and collection system.

•• Human Resources ••

Complete HHS HR consolidation.

Support the "Strong FDA" goal by continuing to accelerate the hiring decision-making process by implementing QuickHire and use of OPM Direct-Hire authorities.

Use partnerships with Academia to help FDA acquire needed competencies.

Develop and implement FDA internship programs to foster the development of new leaders.

•• Information Resources Management ••

FDA Strategic Plan – Strong FDA. Support the "Strong FDA" goal by improving the IT planning and investment decision processes. In addition, look for opportunities to improve IT support for our scientific community.

IT Consolidation. Continue transitioning to OITSS. Implement new processes and performance measures. Continue effort to identify efficiencies in order to meet goal of $29M savings in IT, which includes Department consolidation goal of reducing infrastructure by 15% from FY 2004 request. Implement direct reporting relationship of all FDA IT Directors to the FDA CIO.

Investment Management. Implement the governance process to include select/evaluate/control criteria required by OMB and manage IT costs. Integrate ProSight with Invest Review Board, EA,

Project Management and Security processes. Implement FDA Systems Development Lifecycle (SDLC).

Project Management. Continue PM training and certification program, including mentoring. Establish formal policies. Implement Process Asset Library version 1. Improve PM of all IT initiatives across the Agency by establishing PM standards and measurements.

PDUFA III IT Program. Continue to meet the requirements of the PDUFA III legislation in the oversight and coordination of PDUFA IT investments. Continue to address the overall PDUFA Program needs and to address the PDUFA III Electronic Submission Goals, including the development of a common electronic submission solution and establishment of a cross FDA team to develop a target electronic submission architecture. Focus on integration of the CBER and CDER systems due to the biologic therapeutic product transfer effective October 1, 2003. As part of the integration an analysis will be done to determine the feasibility of using a single tracking and document management system to meet the business needs of both CBER and CDER.

IT Security. Develop an action plan to address areas of weakness in the IT security program, as identified in the FY03 Federal Information Security Management Act audit (FISMA; Title III of E-Gov Act of 2002). Establish a more proactive IT risk management capability, driven by business requirements, to support the confidentiality, integrity, and availability needs of the FDA business units. Develop policy and procedures for completing Certification and Accreditation (C&A) of major applications, with the FY04 goal of obtaining full C&A's for one third of the FDA's critical major applications (Exhibit 300 and Critical Infrastructure Protection systems). Complete the phase 1 deployment of an Intrusion Detection System and monitoring capability covering the FDA core network segments. Update and enhance the general IT security user awareness-training course, UserAware: FY04 goal will be a 95% completion rate. Establish IT security function within OITSS to implement policies and coordinate response to attacks and intrusions.

Enterprise Architecture. Develop FDA "target architecture". Refine the "as-is" architecture and provide proposed migration plan to the "target" architecture. Continue to develop and implement EA projects in each center with specific focus on architecture for a totally electronic gateway shared by CDER and CBER, which will be extendable to the other centers.

IT COOP. Identify a backup and disaster recovery site. Formalize IT operating procedures for COOP level 2,3 and 4 activities. Provide a business case for an investment into backup/disaster recovery and support for COOP level 2,3 and 4 activities.

Enterprise Administrative Support Environment (EASE). Complete the Oracle 9i upgrade. Complete the Business Objects upgrade and incorporate the suite of Business Objects tools into the FDA Business Objects Shared Environment. Complete the migration to and integration within the FDA Enterprise Portal. Incorporate enhancements to EASE to allow for the maintenance of non-employee data for background checks, FDA badges and other security-related requirement. Explore developing a pilot for self-certification and possibly activity-based time reporting capabilities. Support Shared Services needs with respect to FDA Enterprise data for persons, organizations, and locations.

FDA Unified Registration and Listing System. Continue to operate the Food Facility Registration Module under the peak loads expected from October through December 2003 and beyond. Expand the FDA Unified Registration and Listing System to include Drug Registration and Listing to encourage electronic registration and listing by Pharmaceutical firms. Provide access to the Prior Notice System mandated by the Bioterrorism Act of 2002 through the FDA Unified Registration and Listing System Account Management Module.

FDA Information Management Systems. Develop and implement correspondence application. Redesign and develop FOI upon completion of the correspondence module. Projected completion of the implementation of the FOI module is by end of calendar year 2004. Pilot Records Management capability through use of the Documentum tool set.

Telecommunications. Complete the migration of Phase I of the White Oak transition of CDER and CDRH Lab personnel. Complete planning for all Information Technology services for Phase II of the White Oak migration. Complete planning for the "Shared Use" building on the White Oak campus. Begin cabling installation for Phase II (CDER Office) at White Oak. Manage the transition of local telecommunications services from the Telecommunications Improvement Project (TIP) to the Washington InterFDA Telecommunications System (WITS.)

HHS-Net. Complete detailed designs and present for approval. Switch to new circuits by March 2004.

•• Management Programs ••

Modernize the Agency's Staff Manual Guide system

Enhance Office of Management outreach and communications by revamping the OM web-page, establishing internal web pages for OM organizations, and, in partnership with the Office of Shared Services, creating a vehicle to communicate Agencywide about services and programs administered by OM.

Federal Managers' Financial Integrity Act. Update policy and procedures and training presentation to reflect recent reorganizations and areas of responsibility.

Delegations of Authority

- Continue updating administrative delegations affected by the establishment of the Office of Shared Services and other consolidation initiatives
- Coordinate with CDER for further redelegation of authorities resulting from the CBER/CDER biologic therapeutic products review functional transfer and the newly established Office of Drug Evaluation VI and Office of Biotechnology Products
- Continue work on Bioterrorism Act-related delegations

- Finalize and publish the Federal Register notice to remove the delegations from the Code of Federal Regulations
- Conduct a comprehensive review/validation of administrative and regulatory delegations
- Enhance the delegations website with a training presentation and updated policy guidance

Organizational Delayering. The organizational study of the Office of Regulatory Affairs during the first quarter of the fiscal year will finalize the Agency's initiative. An assessment report will be submitted to the Department after completion of the study.

FOIA

- Agency Information Management Systems – Implement Agencywide FOIA Tracking module of AIMS which will include a rewrite of Division of FOI's existing FOIA tracking system and integration of FOI Document Repository and Electronic FOI Request Form.
- Jointly with Office of Chief Counsel, publish rule amending the Agency's public information regulations to incorporate exemptions one, two, and three of FOIA into FDA's public information regulations.
- Implement new Accounts Receivable System for billing and collecting FOIA fees.
- Plan, develop, and present FOI/Privacy Act training sessions for Agency employees and host National FOI Day Observance.

Ethics

- Formulate the FY 2004 Yellowbook based on North American Classification Coding System.
- Evaluate the definition of significantly regulated and present proposal to the Ethics and Integrity Administrative Advisory Board for discussion and possible revisions.
- Provide all Regional/District Offices and NCTR with updated and revised guidance for New Employee Orientation Guidance and guidance for employees separating from FDA.

Paperwork Reduction Act/OMB Team. Revise SMG 3270.1, Obtaining Clearance Under the Paperwork Reduction Act of 1995. Continue efforts in FY 2004 to reduce the paperwork burden upon the public without compromising program integrity while getting new information collections approved that are implemented in new FDA regulations and guidance. Continue consolidation of related information collections in single encompassing justification package. Provide timely responses to the FDA, Department and the Office of Management and Budget and the Public and Regulated Industries regarding FDA information collections.

Records Management. Expand the Records Management Renovation Project to FDA centers and offices. Develop a comprehensive framework for records management policies. Implement a plan developed in FY 2003 and migrate the Records Disposition Tracking System to a relational database using a prototype. Continue the scanning project for SF 135s and import-scanned copies to AIMS. Establish and implement an IAG with the National Archives for records storage and services in FY 2004. Design and Review a prototype electronic record keeping system. Implement an on-line Records Management Tracking system.

•• Real Property Services ••

Decommissioning of Federal Building 8. Complete decommissioning activities with a focus on radiological decommissioning required by the Nuclear Regulatory Commission (NRC), which must be completed prior to initiating many of the chemical decommissioning activities. Intensive collaboration between the Safety Staffs of CFSAN and ORPS as well as GSA has been ongoing. Several discoveries, logistical issues and other unanticipated events have resulted in adding time and significant costs to the project. Work will continue in FY 2004 to complete the project as quickly as possible so the building can be released to GSA.

Decommissioning of 1521 West Pico Blvd, Los Angeles. The Phase I Environmental Site Assessment (ESA), which initiates the decommissioning project, has been conducted. Since ORA has vacated the laboratory, Phase II of the decommissioning is scheduled to begin in October 2003. This facility will pose new challenges to the decommissioning process due to the presence of a considerable amount of asbestos in the building. Efforts will be made to accomplish the decommissioning of this facility in a time frame similar to other field laboratories in an effort to avoid additional rent charges.

Decommissioning of 1560 E. Jefferson Ave, Detroit. All phases of the decommissioning process, including Phase III remediation, have been completed at the facility. Samples were taken during Phase III to determine if the soil surrounding the acid dilution tank is contaminated. Laboratory analyses will determine if the soil is contaminated and if additional remediation activities are required at the facility. The project will be completed with a final decommissioning report that will be submitted to GSA and the building owner.

Winchester Engineering and Analytic Center (WEAC) Modernization. Provide planning, architectural, and engineering support to ORA management in review and finalization of the POR. Evaluate, refine and finalize the various alternatives and project-planning estimates and make a selection.

San Juan Office Building. Begin construction on an office building to be completed in the Spring 2005. Provide architectural and engineering oversight of the construction, A/E post design and construction management services contracts. Monitor and track the construction, schedule, and budget. Coordinate with ORA's local program personnel on all construction activities, such as utility shut downs and construction access.

Southeast Regional Complex, Atlanta, Georgia. Provide architectural and engineering oversight in the preparation of construction documents for the HVAC system improvements for Annex II and the BSL3 suite. Provide planning, architectural and engineering support to ORA management in preparation, review and finalization of the POR for the lease renewal of the Crawford Building and Annex I. Coordinate with GSA and ORA's local program personnel on the HVAC system improvements and the finalization of the POR.

Headquarters Space Acquisitions

- 46,000 square feet of new office space to facilitate the transfer of Therapeutics from CBER to CDER.
- 57,000 square feet of laboratory and office space for CFSAN's Color Certification and Cosmetic programs.
- 15,000 square feet of office space for CVM's user fee program hires.
- 15,000 square feet of office space for the Office of Shared Services.
- 14,000 square feet of office space to collocate the OCI Metro Field Office and OCI Metro Task Force in Prince Georges County.

Field Space Acquisitions

- 20,000 square feet of office space to relocate the Minneapolis District Office from its temporary location.
- 4,000 square feet of laboratory and office expansion space for CFSAN in the Moffett Tech Center.
- 4,500 square feet of office space to relocate the OCI San Francisco Field Office as a result of a forced move from the Oakland Federal Building.
- Office space will be acquired for expansion of OCI's New York, Chicago, and Los Angeles Field Offices.
- Office space will be acquired to accommodate 10 new ORA Resident Posts, to relocate 23 Resident Posts, and to expand 15 Resident Posts in their current locations.

OMS Honor Award Recipients

During FY 2003, OMS employees contributed greatly to the accomplishment of the Agency mission through their continued commitment, dedication, and hard work. The efforts of many of these employees were recognized at the Agency's Honor Awards Ceremony, with the presentation of numerous individual and group awards. The following is a listing of OMS Honor Award recipients for FY 2003.

•• Group Recognition Award ••

Office of Financial Management and Office of Legislation

Maria B. Boyreau
Charlene C. Cherry
Lori B. Henry
Richard H. Kodl
Stacey L. McHatton
Tom B. O'Brien
Karen T. Yates
Valencia Y. Camp
Jim C. Dillon
Helen S. Horn
Robert R. MacLeod
Jackie McNeil
Gail F. Vaskis
Jeff Weber

For exceptional performance in communicating the budget and policy goals of the Food and Drug Administration to congressional committees and staff in an efficient, coordinated manner.

Delegated Examining Unit Staff

Jacqueline W. Bennett
Dorothy A. Dwyer
Denise C. Harris
Olivia A. Rodriguez
Thomas E. Bowles
Jock J. Garcia
Jan P. Montoya

For exemplary commitment and achievement in performing external recruitment activities nationwide for FDA.

•• Outstanding Service Award ••

Delores M. Hughes

For continuous outstanding support in a challenging and dynamic personnel environment.

Dianne Taylor

For extraordinary customer service in dealing with a variety of FDA payroll issues.

Linda G. Gorenstein

For outstanding performance as Program Assistant in the Division of HR Policy and Programs, Office of Human Resources and Management Services, Food and Drug Administration.

Shannon L. Cole

For advancing and supporting team building within the division

Tammy L. Street

For outstanding troubleshooting and ingenuity in resolving complex human resource system problems.

Loretta M. Logan

For outstanding dedication and contributions to the Agency's management of Emergency Supplemental funds for Counterterrorism programs.

Patricia G. Calhoun
Clyde L. Messerly

For dedicated service to the Agency through oversight and direction in managing the construction of the FDA Irvine District Office & Laboratory Facility.

Pamela E. Pisner

For outstanding administrative support to the Office of the Commissioner distinguishing herself as a model of customer service and commitment to FDA's mission.

•• Plain Language Award ••

Jenny S. Slaughter
Vincent R. Tolino

For revising the ethics training program used at New Employee Orientation and creating a website to clarify FDA's ethics rules.

•• Quality Work Life Award ••

Sharon M. Chartos

For her initiative and enthusiasm in pursuing the Quality of Work Life for all FDA employees.

•• Leveraging/Collaboration Award ••

FDA CRADA Review Board

Beatrice A. Droke
James L. Tidmore

For exceptional leadership and support of the FDA's partnering activities under the Federal Technology Transfer Act and effective use of Cooperative Research and Development Agreements.

•• Commissioner's Award of Excellence ••

Nancy P. Nacev

For continuous innovative human resource support to the Office of the Commissioner.

Irene I. Diehl

For exemplary performance in providing personnel staffing policy advice, guidance and direction

David E. Dwyer

For outstanding leadership that led to meeting critical space needs relating to dramatic staff increases for Counterterrorism and other FDA initiatives.

Electronic Rulemaking Team

Jennie C. Butler
Gail L. Kohlhorst

For outstanding service to FDA and the Department by providing leadership for the Electronic Government Initiative entitled, E-Rulemaking.

•• Commissioner's Special Recognition Award ••

Grants Management Staff

Peggy L. Jones
Cynthia M. Polit
Maura C. Stephanos
Tya Mark
Rosemary T. Springer

For exceeding expectations and continually meeting the demand that sets an unusual record of achievement in view of increasing workload.

Security Operations Group

Glenda F. Barfell
Shannon L. Cole
Thomas L. Eckes
Michelle Frieze
Deborah K. Hammond
Pearl F. Lancaster
Christina S. Marrow
Marta Perlman
James J. Sawyer
Vicky L. Vandevander
Laurie A. Whalen
Michelle N. Caraffa
Patty R. Delotch
Danielle M. Fannings
Adam J. Gaudreau
Janice E. Kelsh
Loretta M. Logan
Kimberly McNutt
Janice E. Perry
Barry P. Smith
Nancy L. Webber

For superior performance for meeting the Agency's unprecedented personnel security and physical security requirements.

Central Account Management Group

Shonda E. Anderson **Mary Campas**
Sharon F. Heavey **Lisa M. McGee**

For outstanding management of and improvements to the FDA Central account and excellent customer support to its many users.

FDA Technical Working Group

Michael L. Buster, OC **Billy R. Earles, OC**
Michael B. Fullem, OC **John D. Gugliotti, OC**
Bradford K. Joyce, OC **Maria Meredith, OC**
Laura M. Samford, OC

For providing outstanding technical expertise in the development and implementation of the Information Systems Architecture Program and other critical cross-cutting IT initiatives.

•• Commissioner's Administrative Management Award ••

Paul E. Nugent

For outstanding performance and dedication in implementing Travel Manager for the Office of the Commissioner.

Frances Jo Graybill

For excellence in facilitating and managing administrative responsibilities in the Office of Financial Management.

•• Commissioner's Community Service Award ••

School Reading Volunteers

Pamela E. Pisner

For exceptional efforts to promote reading and literacy skills for students at local elementary schools.

Elwood J. Thornton

For continuing leadership and contribution to community service in supporting people with disabilities.

For More Information

The OMS team is pleased to work with all FDA personnel as we strive to protect, promote, and enhance the health of the American people. For more information about OMS services and systems, please contact:

- Associate Commissioner for Management and Systems, (301)-255-6762
- Director, Office of Acquisitions and Grants Services, (301)-827-7041
- Director, Office of Executive Operations, (301)-827-3440
- Director, Office of Financial Management, (301)-827-5001
- Director, Office of Human Resources, (301)-827-4120
- Acting Chief Information Officer, (301)-255-6763
- Acting Director, Office of Management Programs, (301)-827-4801
- Director, Office of Real Property Services, (301)-827-7052
- Director, White Oak Consolidation Program, (301)-827-1013

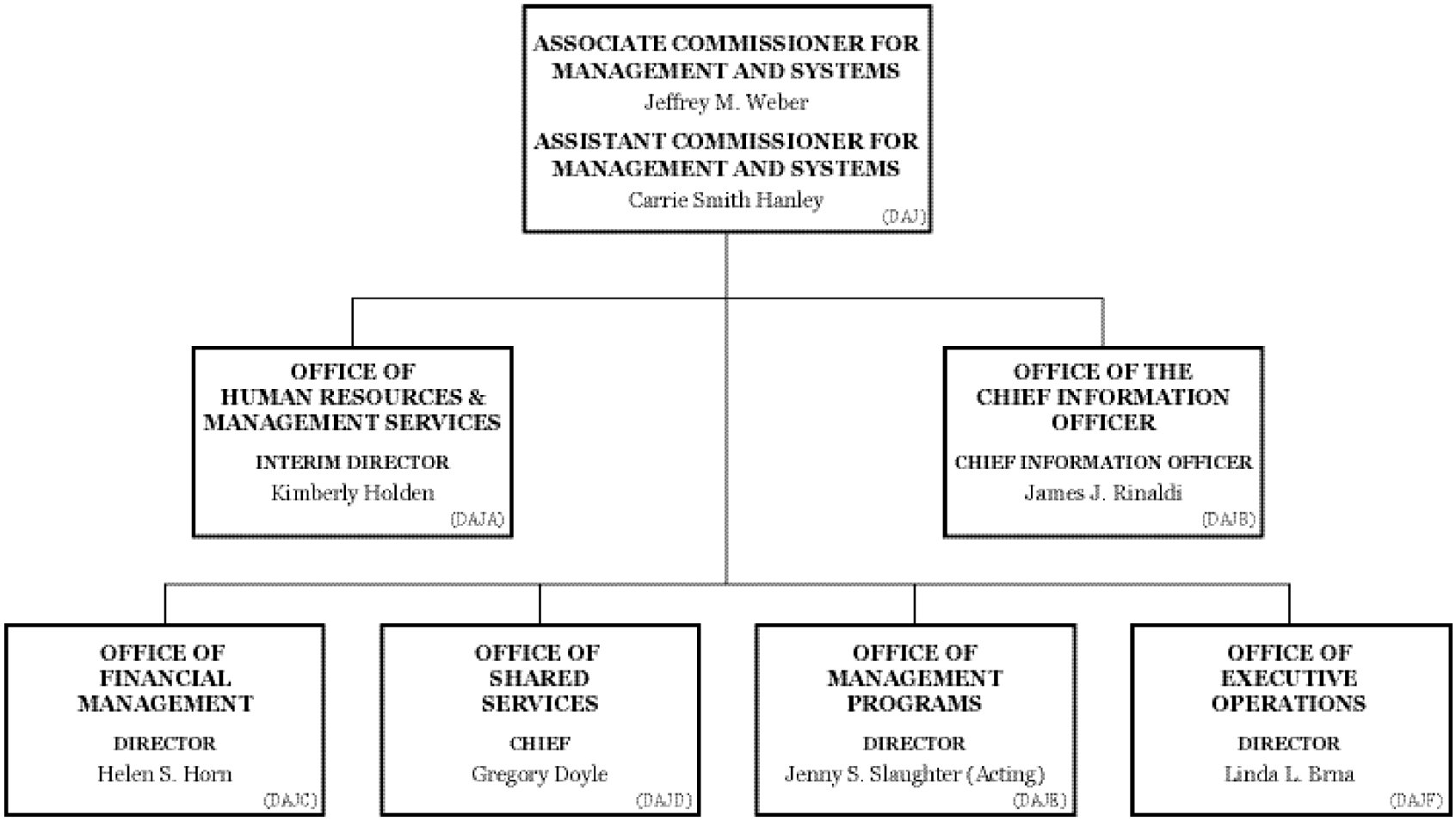
Additional information about OMS programs is available on FDA's Intranet at http://intranet.fda.gov/oms and on the Internet (at www.fda.gov) for information on PDUFA, Dockets Management, and the Yellow Book.

Also, please see the OMS One Book Service Directory at:
http://intranet.fda.gov/oms/omsonebook/oms_onebook.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES

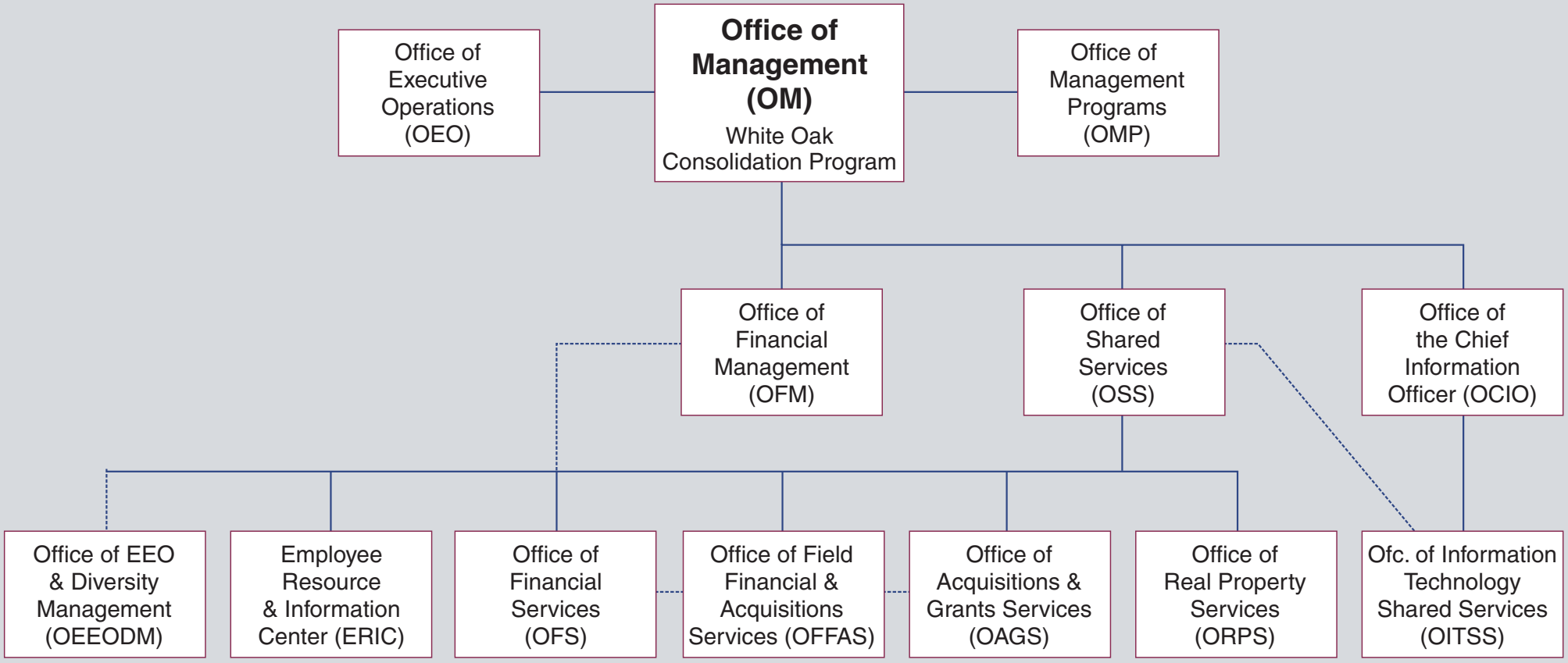
FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER
OFFICE OF MANAGEMENT AND SYSTEMS



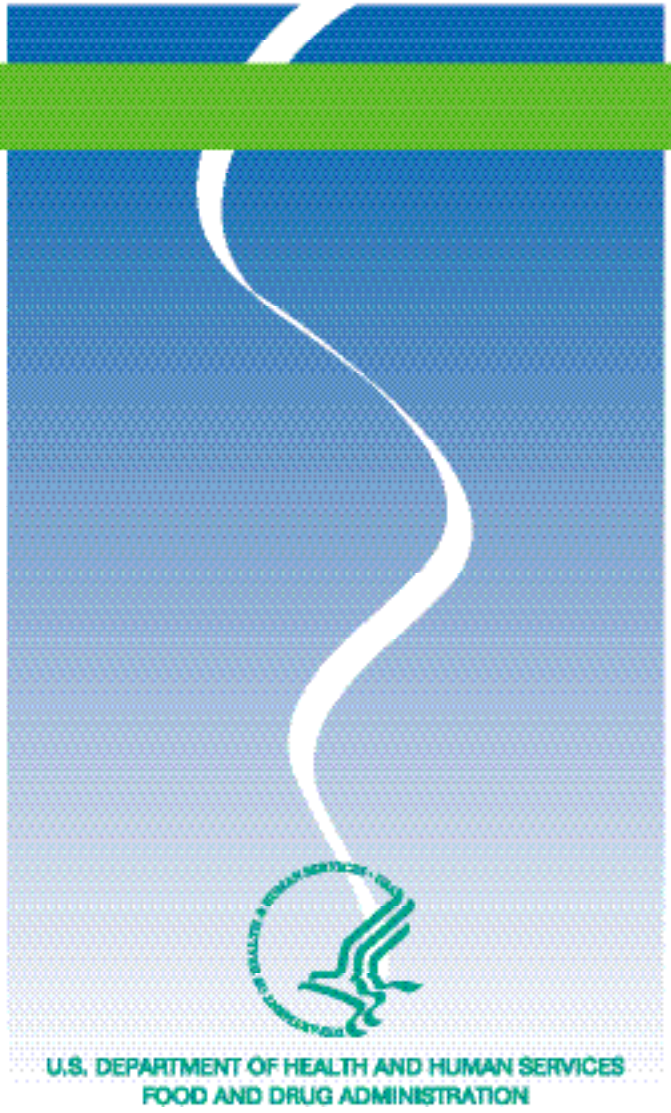
OMS Organization, FY 2003

The Office of Management



December 31, 2003

Office of Management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FOOD AND DRUG ADMINISTRATION