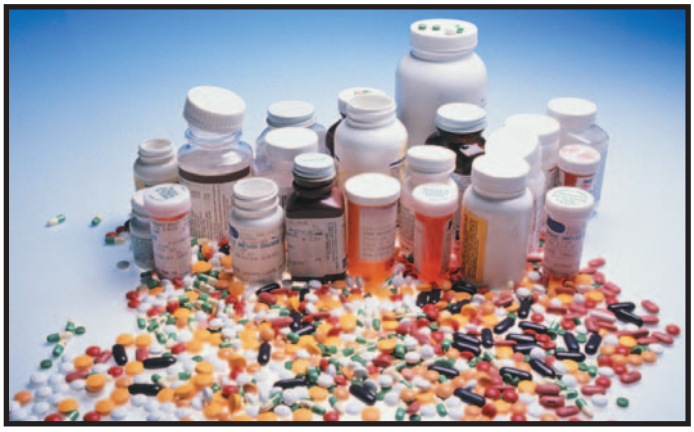
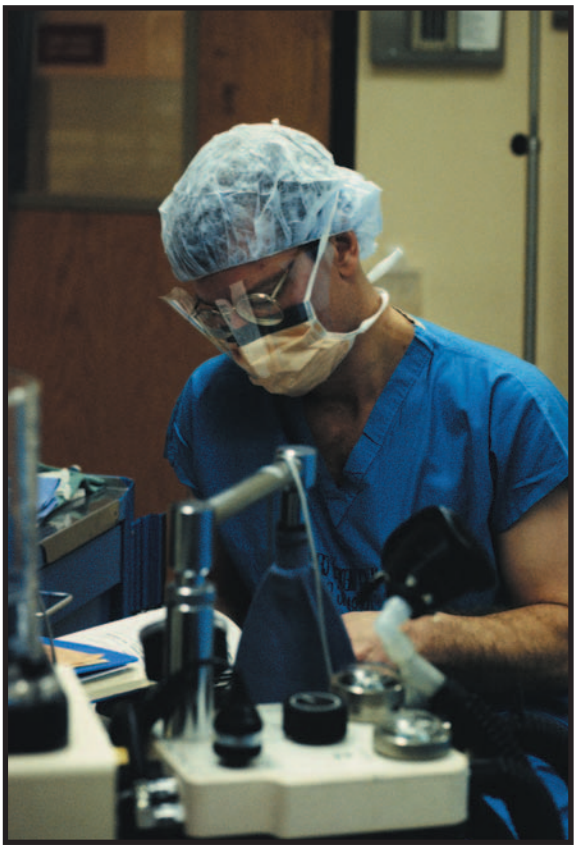
FDA's Annual Financial Report

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

FISCAL YEAR 2003





U.S. Department of Health and Human Services

Food and Drug Administration
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November 7, 2003

Commissioner's Message

I present to you the Food and Drug Administration's (FDA) Annual Financial Report for fiscal year (FY) 2003. I am pleased to report that FDA has earned its sixth consecutive "clean" opinion on its audited financial statements. By comparing the fiscal information from these statements with the summary performance information reported under the Government Performance and Results Act, FDA is able to demonstrate how this investment yields valuable results.

FDA has made significant progress during FY 2003 in implementing the President's Management Agenda (PMA) and the Department of Health and Human Services' secretarial goal for administrative consolidation. The PMA lays out a framework for an effective Federal government, through five Executive Branch-wide initiatives addressing human capital, financial management, electronic government, competitive sourcing, and budget and performance integration. Early in the year, FDA initiated a strategic planning process to guide the Agency to meet its public health challenges and other responsibilities. The fruit of that effort was the release of the Agency's Strategic Action Plan in August, which has as one of its goals the improvement of FDA's infrastructure through strengthening its workforce, management systems, stakeholder communications, information technology, and physical headquarters consolidation.

During FY 2003, we developed the plans for consolidating FDA's administrative services delivery by implementing a new shared services organization whose concept is used extensively in the private sector. Nearly all of FDA's organizations will be restructured to improve organizational responsiveness and meet the human capital goal. Improving FDA's financial management systems is an ongoing project and FDA is participating in the design of the Department's new financial management system as well as creating financial applications for its user fee programs. As part of an electronic government project, FDA helped to launch a new electronic portal for one-stop viewing of Federal regulations. FDA is a leader in competitive sourcing, having completed six studies. These competitions, all of which were won as most efficient organizations by Federal employees who administered the functions, will save the Agency approximately $3.27 million annually. The results of these efforts will be to redirect these reform savings to mission-critical areas and areas of national priority including food security, counterterrorism – medical countermeasures, bovine spongiform encephalopathy prevention, antimicrobial resistance, and patient safety.

The Reports Consolidation Act of 2000 requires that I, as the Agency Head, give an assertion on the information in this report. So, as Agency Head, I assert that the financial information in this report is complete and reliable, based on data in FDA's financial information systems, and is reported in conformance with Generally Accepted Accounting Principles. Further, it has been deemed to "fairly represent" the financial condition and results of operation of the Agency by the Department's Office of Inspector General. For program performance information, the FY 2003 Performance Reports of the Department of Health and Human Services (DHHS) components will include descriptions of the means DHHS programs use to verify and validate performance data and related data issues, including the completeness and reliability of the data. Where required, the programs have included discussions of actions planned and completed to improve the completeness and reliability of data.

I welcome your interest in FDA and its programs. In these challenging and uncertain times, taxpayers can be assured that FDA stands ready to protect the health and well being of all Americans.

Mark B. McClellan, M.D., Ph.D.

November 7, 2003

Chief Financial Officer's Message

I am pleased to present you with the Food and Drug Administration's Annual Financial Report for Fiscal Year (FY) 2003. The goal of this report is to update you on our stewardship of resources and how we are achieving the Agency's mission.

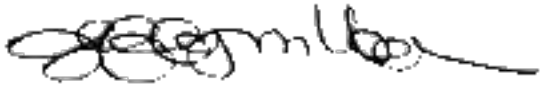
This is the sixth consecutive year FDA has received an unqualified opinion on our financial statements. It is also the sixth consecutive year that our auditors did not identify and report material weaknesses in FDA's internal controls. The FY 2003 financial statements have been prepared in accordance with all new accounting standards that were required in FY 2003 by the Office of Management and Budget and the Federal Accounting Standards Advisory Board. We will continue to work diligently to implement all new accounting standards in a timely manner.

FDA's balance sheet shows an increase in the net position due to receiving additional funding related to counterterrorism activities and other initiatives such as generic drug review and patient safety. FDA's FY 2003 budgetary authority was $1.40 billion, excluding $340 million from user fees and reimbursable collections. The amount of user fees increased due to the reauthorization of the Prescription Drug User Fee Act in 2002 and the establishment of a new user fee for the review of medical devices. FDA's total program level was $1.91 billion that included offsetting collections, carry-over balances from earlier years and adjustments. Of this amount, $1.82 billion was obligated during FY 2003. FDA's net costs have also reflected these increases as shown on the Consolidated Statements of Net Cost. The largest percentage increase was in the Foods' Program which received substantial funding in food security counterterrorism activities.

FDA has made significant progress in implementing the President's Management Agenda and the Department of Health and Human Services' secretarial goal for administrative consolidation. FDA is implementing a new shared services organization that will deliver economical administrative services to FDA's centers and offices nationwide. This venture will prepare FDA's national headquarters as it begins its permanent relocation to its new modern campus located at the Federal Research Center at White Oak, Maryland. This process will be transitioned over several years. Implementation of the President's Management Agenda is also preparing FDA to integrate its budget and planning processes to create a performance based budget that will align performance and cost information necessary to support resource allocation decisions.

Working in partnership with FDA's program managers, my staff and I support the Commissioner's priorities by providing oversight and cost effective, strategic management of the Agency's limited resources. As the Chief Financial Officer, I remain fully committed to the stewardship responsibilities needed to continue to maintain the highest level of accountability for the management of the Agency's financial resources.

We appreciate your interest in this report and hope that you find it useful and informative. If you wish to discuss this report, please contact Peter Kelchner, Chief, CFO Liaison Branch, Division of Accounting, at PKelchne@oc.fda.gov or 301-827-4792.



Preface

The Food and Drug Administration (FDA) is pleased to present its fiscal year 2003 financial report. The report's management discussion and analysis (MD&A) has been streamlined and realigned to meet the accelerated financial reporting requirements and to anticipate changes envisioned by the Office of Management and Budget for Executive Branch's financial reports. This realignment focuses on Agency level performance and accomplishments.

Section I – "Management Discussion and Analysis" (MD&A) is designed to provide a high level overview of the Agency's mission and how it accomplishes that mission. The MD&A is organized into four chapters containing the following:

- Agency Overview Chapter – Provides mission, strategic goals, and organizational structure. Discusses assurance statements, reliability of performance data, accounting presentation requirements, and challenges and future trends affecting FDA's financial condition.

- Program Management Chapter – Discusses FDA's strategic goals, select performance goals, and performance results.

- Operational Effectiveness Chapter – Highlights FDA's progress implementing the President's Management Agenda.

- Fiscal Responsibility Chapter – Reports on the results of the financial statement audit and analyses FDA's financial condition as displayed in the consolidated principal financial statements.

Section II – "Consolidated Principal Financial Statements" provides the principal financial statements and explanatory notes.

Section III – "Required Supplementary Information" contains unaudited financial statements that provide a level of detail regarding the status of budgetary resources, net costs by program and by type, deferred maintenance, and intragovernmental transactions in three categories (assets, liabilities, and revenues and expenses).

Section IV – "Required Supplementary Stewardship Information" reports on research and development expenses covered under stewardship reporting.

Section V – "Reports on the Audit of FDA's FY 2003 Financial Statements" contains the Office of Inspector General's Transmittal Letter; three auditors' reports on consolidated financial statements, internal controls over financial reporting, and compliance with laws and regulations; and the FDA response to the auditors' report.

Appendices – Defines a list of FDA acronyms used in the report.

Report Availability and Contact Information:

The FDA Annual Financial Report for FY 2003 is available on the Office of Financial Management Web Page at: www.fda.gov/oc/oms/ofm/accounting/ofmaccounting.htm. For questions regarding the Annual Financial Report, please contact:

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Section I -- Management Discussion and Analysis

Agency Overview

As part of the Department of Health and Human Services, FDA has broad responsibilities for promoting and protecting the health of consumers in the United States. Decisions made by FDA affect every consumer every day. To illustrate:

- Last year consumers spent almost $1.5 trillion - more than 20 percent of which was on products that FDA regulates;

- Public and private entities invest an estimated $50 billion annually in biomedical research and technology, and FDA judges the safety and often the efficacy of this expanding scientific revolution;

- FDA has over 10,000 personnel, and is responsible for monitoring over 100,000 U.S. and foreign firms that manufacture or process FDA regulated products; and,

- FDA monitors the safety of over 8 million import shipments that enter this country each year.

Mission

The FDA is responsible for protecting our Nation's public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Strategic Goals

To successfully accomplish its mission, FDA leadership identified five strategic goals (described in more detail in the Program Management chapter) that will focus Agency resources in a range of activities from broad to narrow pursuits.

The broadest goal is efficient risk management that covers FDA's product life cycle approach from research and development through production, distribution and use. The other goals are focused on counterterrorism, consumer information, and adverse events and medical errors. The remaining goal focuses on the Agency's infrastructure and various management improvements. These strategic goals fit into the larger strategic framework envisioned by DHHS' eight strategic goals. FDA's mission pertains to four

of the DHHS strategic goals.[1] A summary[2] of DHHS and FDA strategic goals and their desired outcomes are listed in Table 1.

Table 1 – DHHS and FDA Strategic Goals and Outcomes

DHHS STRATEGIC GOALS[3]	FDA STRATEGIC GOALS	DESIRED OUTCOMES
Reduce the Major Threats to the Health and Well-Being of Americans	Protecting America from Terrorism	Risks to U.S. citizens posed by potential or real terrorist attacks are lowered.
Enhance the capacity and productivity of the Nation's Health Science Research Enterprise	Efficient Risk Management	Because of the Agency's timely science-based decisions, millions of Americans can get the medicines and medical devices they need and be assured of safe and effective products.
Improve the Quality of Health Care Services	Improving Patient and Consumer Safety	Significant reduction in the annual 100,000 deaths, injuries, and illnesses is achieved because a safety net has been established which monitors medical products at all stages in the life cycle – from production through consumption.
	Improving Healthcare through Better Information	
Achieve Excellence in Management Practices	Smarter Regulation through a Stronger Workforce	State-of-the-art scientists and health professionals make critical risk management decisions.
		Streamlined Agency and cost-effective performance optimally organized to support mission-critical activities.
		Citizen-centered agency accountable for results.

FDA's strategic goals, which shape the annual performance goals, are grouped in seven major programs in the FY 2003 Final Revised FDA Performance Plan.[4] These programs are: Agency-wide; Foods; Human Drugs; Biologics; Animal Drugs and Feeds; Medical Devices and Radiological Health; and National Center for Toxicological Research.[5] With the exception of the Agency-wide program, the other programs also serve as the budget line items in FDA's budget.

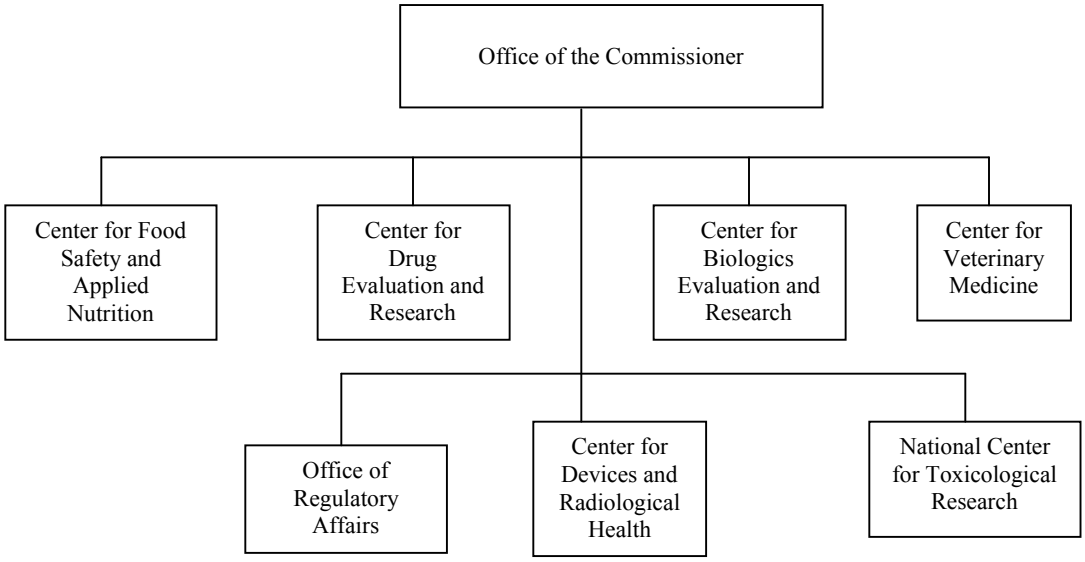
[1] Refer to the FY 2003 DHHS Performance and Accountability Report, December 2003, for examples of FDA performance goals achieving the intent of the DHHS Strategic Goals.
[2] Please note that the DHHS and FDA plans are continually being updated and the titles of the goals may have changed to reflect the latest policy decision. For the FY 2003 Annual Financial Report, the FDA goals are taken from the Congressional Justification, Performance Plan, dated January 2003.
[3] Source: DHHS Strategic Plan for Fiscal Years 2003 through 2008 (Draft), July 29, 2002.
[4] Source: The FY 2003 Revised Final Performance Plan is available on FDA's web-site at: http://www.fda.gov/ope/fy04plan/2004pp-mainpage.html. FDA's Performance Report for FY 2003 will be available on FDA's web site by the spring of 2004.
[5] For the annual financial report, the select performance goals supporting the five strategic goals are found in the Program Management chapter.

Organizational Structure

FDA is organized into eight major components consisting of the Office of the Commissioner and its components, the Office of Regulatory Affairs (ORA) and its Field organizations, and six Centers as displayed in Figure 1 below:

- Center for Food Safety and Applied Nutrition (CFSAN);
- Center for Drug Evaluation and Research (CDER);
- Center for Biologics Evaluation and Research (CBER);
- Center for Veterinary Medicine (CVM);
- Center for Devices and Radiological Health (CDRH); and,
- National Center for Toxicological Research (NCTR).

Figure 1



The Office of the Commissioner

This component consists of nine subordinate offices that provide legal guidance, develop budgets, plans and policies, direct public, congressional, and consumer affairs programs, promote the Agency's international operations, and deliver administrative services.

The Office of Management and Systems was reorganized to improve its customer service by combining like functions, and be better positioned for migration to the Office of Shared Services in Fiscal Year 2004. The reorganization includes:

- The Office of Facilities, Acquisitions, and Central Services was abolished and realigned into two components - the Office of Real Property Services and the Office of Acquisitions and Grants Services;

- Within the Office of Human Resources and Management Services, the Division of Management Programs was elevated to an Office status to group non-human resources functions into one office. Three divisions and one staff were realigned to create the new office – supporting FDA's Freedom of Information activities, paperwork reduction and records management, administrative dockets, management programs, ethics and standards of conduct activities;

- All of the Agency's financial systems are now centrally managed under the Deputy Chief Financial Officer and Director, Office of Financial Management; and,

- The Office of Shared Services [6] was created to manage those administrative functions that will be operating under a "shared services" arrangement, providing services to FDA components on fee-based service agreement.

The Centers

Five of the six centers are product centers that perform premarket review, conduct postmarket assurance activity, take enforcement actions, and provide scientific and administrative support. The sixth center, NCTR, performs regulatory research for the product centers. Except for NCTR, which is headquartered in Jefferson, Arkansas, the Office of the Commissioner, the Centers, and ORA are headquartered in the Washington, D.C. metropolitan area. The Centers administer the six program areas listed above. Five of the six programs receive substantial "front line" support from ORA's field organization.

The Office of Regulatory Affairs

This component is composed of a headquarters unit and a nationwide field force. The ORA, (the Field), has 4,004[7] full-time equivalents.

The Field supports Agency premarket activities by conducting preapproval inspections and laboratory method validations when requested by program managers responsible for premarket application decisions. Inspections, either of foreign or domestic establishments, include bioresearch monitoring inspections of clinical research, and inspections of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in the application. Laboratory method validations are also conducted to confirm that the methods described in the premarket application work as indicated.

Field investigators and laboratory analysts also conduct domestic and foreign inspections for postmarket compliance purposes. Postmarket foreign inspections in the human drug, biologic, animal drug and feeds, and medical device and radiological health programs are

[6] The Office of Shared Services will be operational on October 1, 2003. More explanation is provided in the Program Management chapter.
[7] This number was reported on a budgetary report to the Department on October 22, 2003.

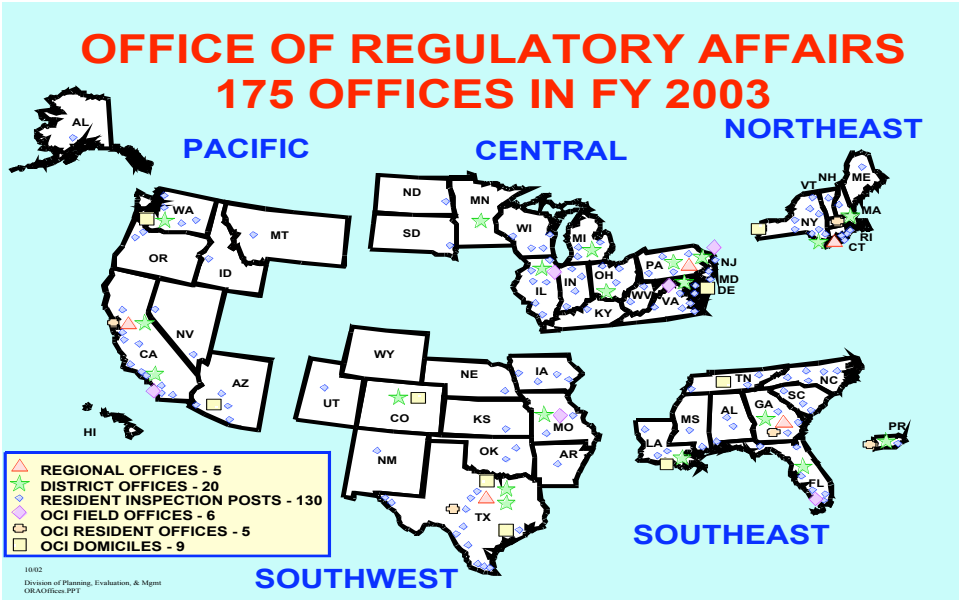
conducted to assess Good Manufacturing Practices. This is consistent with the biennial inspection requirement that Congress requires of domestic manufacturers in these programs. The ORA also monitor and sample imports to ensure the safety of the food supply and medical products.

Besides conducting regular surveillance of regulated products, the Field workforce also responds to emergencies by immediately mobilizing to investigate reports of product problems including tampering incidents, food borne illnesses, natural disasters, and those which may be the result of terrorist activities.

To complement the regular field force, the Office of Criminal Investigations (OCI) investigates instances of criminal activity in the regulated industries. Agents are given intensive training at the Federal Law Enforcement Training Center in Glenco, Georgia and are assigned to offices throughout the country.

Field facilities include Regional Offices, District Offices, laboratories, OCI field offices, and resident posts. The five Regional Offices coordinate FDA activities with state authorities. The 20 District Offices provide services to investigators and compliance action staff, and are the main control points for day-to-day operations in their assigned areas. There are 130 resident inspection posts, which are smaller offices that serve as a base for investigators allowing FDA investigative staff to be widely dispersed to respond to emergencies whenever they occur, as quickly as possible to lower a potential harm. Thirteen FDA laboratories provide for basic field product testing capability. Six OCI offices, five resident offices, and nine domiciles are also located throughout the country. FDA maintains offices and staff in 49 of the States, and in the District of Columbia and Puerto Rico. See Figure 2 for a map of ORA's field locations.

Figure 2



Assurance, Reliability, and Requirements

Integrity Act Statements

The Federal Accounting Standards Advisory Board requires the Management Discussion and Analysis to address the systems, controls, and legal compliance[8] that support preparing financial statements and financial documentation. This is achieved through the annual reporting of Federal Managers' Financial Integrity Act (FMFIA) in Section II (management controls) and Section IV (financial management systems).

FDA has employed a "bottom-up" approach to allow management throughout FDA to become involved in the FMFIA review and reporting process. This approach uses management control information from a variety of sources to promote greater accountability and self-identification and resolution of organizational weaknesses. This has resulted in controls that benefit rather than encumber FDA management. The Agency is in a better position to identify and aggressively correct weaknesses, and implements proper safeguards to prevent waste, fraud, and mismanagement of resources.

The only material weakness disclosed under FMFIA that FDA continues to report is an item that has been reported each year since 1989. It relates to the low percentage of the rapidly rising number of imported food items that FDA inspects each year. FDA is not ready to declare this weakness resolved until the results are recognized by the recently hired staff, whose impact will not be achieved until they have been fully trained in food inspections.

Management Controls Statement

During FY 2003, FDA assessed its management controls using a variety of tools, and each major FDA component submitted an assurance statement signed by their component head. No new material weaknesses were identified.

Financial Systems Conformance Statement

FMFIA Section IV requires a "conformance statement" attesting that the Agency's financial management systems conform to Executive Branch requirements. In the FY 2003 Conformance statement, FDA determined that its financial management systems were in conformance with the Office of Management and Budget (OMB) Circular A-127. This determination was based on a review of previous audit findings, completed corrective actions, and the design and implementation of the new financial management system developed to bring all of the Agency's financial systems into

[8] These responsibilities are defined in numerous laws and administrative requirements, including the Federal Financial Management Improvement Act, FMFIA, OMB Circulars A-123 and A-127, and OMB Bulletin 01-02.

substantial compliance to Section 803(a) of the Federal Financial Management Improvement Act.

Performance Data Reliability

The OMB requested that Federal agencies explain the procedures management has designed and followed to provide reasonable assurance that reported performance information is relevant and reliable. The Agency's explanation of its performance data verification and reliability methods are found in the FDA FY 2003 Final Revised Performance Plan (See footnote #3).

Accounting Presentation Requirements

In the Fiscal Responsibility chapter, a discussion of FDA's financial condition is presented. One of the key accounting requirements revolves around the term, "net program costs," which are defined as the expenses for a program, including allocating indirect expenses (such as, administrative, field operations, rent, and other overhead), less exchange revenue. Under the Government Management Reform Act of 1994, Executive Branch agencies are required to determine the full cost of their operations. The Statement of Net Cost has been prepared in conformance with accounting principles generally accepted in the U.S. (GAAP), and the form and content for entity financial statements as specified by the OMB. The GAAP for Federal entities are the standards prescribed by the Federal Accounting Standards Advisory Board, which is the official accounting standards setting body for the Federal government. The financial statements are different from the financial reports prepared pursuant to OMB directives used to monitor and control the use of budgetary resources.

In addition, FDA records transactions on an accrual accounting and budgetary bases. Under the accrual method, revenues are recognized when earned and expenses are recognized when a liability is incurred, without regard to receipt or payment of cash. Budgetary accounting principles are designed to recognize the obligation of funds according to legal requirements, which, in many cases, is before the occurrence of an accrual-based transaction.

Challenges and Future Trends

The FDA faces many key challenges. The following are viewed as being among the most significant issues to FDA's mission or to the Nation's well-being, complexity, cost, or urgency of need for management improvement.

Counterterrorism - Food Safety

The FDA is responsible for the safety and security of eighty percent of the nation's food supply. The possibility of food products used as a vehicle for a terrorist attack could potentially affect millions of Americans. FDA must have the capability to be vigilant in

assessing, and then quickly and effectively reducing risks associated with unexpected and potentially widespread health and safety threats to the U.S. public. The unpredictability and wide variety of ways that potential acts of terrorism can be launched complicate preparedness and the ability to quickly and effectively respond to just such an attack.

Counterterrorism – Medical Countermeasures

Another challenge for FDA is being prepared to meet the threat of terrorist attack with a biological, chemical, radiological, or nuclear agent. FDA's role is to facilitate the development of appropriate medical products (human and animal drugs, vaccines and other biological products, blood and blood products, medical devices) available to prevent, diagnose, and treat illnesses resulting from a terrorist attack. This work requires substantial scientific resources and close working relations with product applicants because they have little financial incentives for developing new treatments, or the basic research supporting product applications for treating radiation, chemical, or pathogens is out-dated.

Foreign Imports of FDA-Regulated Products

The growth of international trade has lead to a tripling of imports over the past ten years, with products entering the U.S. through one of approximately 300 U.S. Customs ports found in the country. Inspections and import surveillance are the primary means of assuring the safety of marketed products. Consumers rely on the FDA to prevent dangerous and unreliable products from entering U.S. commerce. Public safety and confidence could be jeopardized by a failure to increase surveillance activities. Although the FDA continues to undertake activities to improve the safety of imported products, there is often no substitute for physically looking at these products. FDA is monitoring regulated products in an environment that has become significantly more complex over the past several years.

Medical Product Safety

FDA has assumed a significant watchdog role for postmarket surveillance. When FDA approves drugs and other medical products, such as devices and vaccines, it takes precautions to make sure these products are safe when they are marketed. That is not the end of the story. Product safety develops over the many years that make up a product's lifetime in the marketplace. It is important for FDA to continually monitor approved products on the market and track trends associated with them, to ensure a quick response to get the products off the market.

Office of Inspector General's Top Management Challenges

The Office of Inspector General (OIG) identified eight management challenges affecting the management and performance of the DHHS. The Reports Consolidation Act of 2000 requires the Inspector General to report in the annual Performance and Accountability

Report the department's top management challenges. The law also requires the OIG to assess the Department's progress in addressing the challenges.

Three of the FY 2003 DHHS management challenges were the same findings as in the FY 2002 review. These challenges are bioterrorism preparedness, protection of critical infrastructure, and grants management. While the OIG did not address specific findings to FDA, the Agency has striven in the past year to strengthen its emergency preparedness capacity and physical security of its laboratories and offices. The Agency is improving its security of its critical infrastructure by streamlining and reorganizing its chief information office, and enhancing its information systems internal controls and continuity business planning efforts. The Agency is also participating in the E-Grants project which will provide greater electronic delivery of grants information and management capabilities to Federal agencies, its grantees, and prospective grantees.

Program Management Chapter

This chapter provides an overview of FDA's strategic goals, select performance goals, and their results.

Introduction

Eleven performance goals were chosen to provide a representative example of the five strategic goals.[9] Table 2 shows these goals and the corresponding strategic goal.

The first strategic goal focuses on FDA's infrastructure—providing the scientific and administrative support to FDA programs. The other four strategic goals focus mission-critical activities—ranging in scope from broad to narrow. The broadest goal is Efficient Risk Management covering the gamut of FDA's regulatory activities from product review, postmarket surveillance, inspection, and enforcement. The remaining goals are narrower in scope—directed at providing consumers with health information; reducing medical errors and adverse events, or protecting the public and foods supply from terrorist attack.

Table 2 - Strategic Goals and Select Performance Goals

Strategic Goal	Select Performance Goals
Efficient Risk Management	Review and act on 90 percent of priority original NDA submissions within six months.
	Complete review and action on 90 percent of Premarket Approval Application (PMA) of an estimated 80 PMA first actions within 180 days.
	Meet the biennial inspection statutory requirement by inspecting 50 percent of registered blood banks, source plasma operations, and biologics manufacturing establishments.
Improving Healthcare through Better Information	Enhance the transparency of the NARMS program to stakeholders, the public, and other interested parties by increased reporting and communicating of NARMS results and program information.
Improving Patient and Consumer Safety	Streamline adverse drug event reporting system.
	Expand implementation of the MeDSuN system to a network of 240 facilities.
Protecting America from Terrorism	Inspect ninety percent of high risk domestic food establishment once every year.
	Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment.
Smarter Regulation through a Stronger Workforce	Implement shared services concept and consolidate functions in the agency.
	Maintain an unqualified audit opinion with no material weaknesses.
	Increase the percentage of commercial FTE that will be reviewed for outsourcing.

[9] For a complete review of the FY 2003 performance goals, please see the Congressional Justification, Performance Plan, January 2003 on FDA's web-site at: http://www.fda.gov/ope/fy04plan/2004pp-mainpage.html. FDA's Performance Report for FY 2003 will be available on FDA's web site by spring of 2004.

Efficient Risk Management – Overview

FDA oversees the public health standards of a range of industries that produces almost $1.5 trillion worth of regulated products. Traditionally, FDA has viewed this regulation in two parts: premarket and postmarket.

Premarket -- FDA must assure the safety and effectiveness of drugs, biologics, food additives, medicated animal feeds, and medical devices before they are allowed on the market. This challenge means keeping pace with the increasing scientific complexity of products that emerge from a $50 billion a year research and development effort that is funded with both private and public resources. FDA scientists must accurately judge the readiness of these products to be marketed, and help these innovative products reach the market as quickly as possible.

There must also be a sufficient number of reviewers to handle the product review workload to provide timely feedback to application sponsors to identify and address deficiencies. Any delays might:

- Postpone critically needed disease prevention and treatment, especially for a growing population of elderly and immune-compromised patients;
- Increase the cost of bringing a new product to market by lengthening the time a product is in development; and,
- Result in fewer low-cost alternatives for patients (including children and the elderly).

Postmarket -- FDA must also monitor the safety of products once they are on the market. U.S. consumers spend an estimated $326 billion annually on medical products that are produced world-wide, and make their way to the market through a wide variety of distribution channels. To ensure that these products are safe, the Agency must oversee their entire life cycle - from production through distribution, and use or consumption. The desired outcome is to contribute to improving the health status of U.S. citizens by minimizing the risks associated with use of medical products and the consumption of food in the U.S.

Select Performance Goals and Results

FDA Strategic Goal	Select Performance Goal
Efficient Risk Management	Review and act on 90 percent of priority original NDA submissions within six months.
	Complete review and action on 90 percent of Premarket Approval Application of an estimated 80 PMA first actions within 180 days.
	Meet the biennial inspection statutory requirement by inspecting 50 percent of registered blood banks, source plasma operations, and biologics manufacturing establishments.

Three performance goals[10] were chosen for the Human Drugs, Medical Devices and Radiological Health, and Biologics Programs. The first two represent premarket activities, while the remaining goal concerns postmarket activities.

Explanation of Performance Goal

Review and act on 90 percent of priority original NDA submissions within six months.

Context - A major objective of the Human Drugs Program is to reduce the time for FDA's drug review process. Priority new drug applications (NDA) are those medications that intended to treat serious or life-threatening diseases as AIDS, AIDS-related diseases, cancer, and heart disease; or those products that demonstrate the potential to address unmet medical needs.

Results

CDER exceeded its FY 2002 performance target. CDER reviewed and acted on 11 Priority NDAs; however, final data will be available by the end of FY 2003. (See Table 3 below).

Table 3
Fiscal Year 2002 Cohort (as of 04/30/03)

Submission Type	Number of Submissions Filed	Goal (months)	Number of Reviews "On Time"	Percent of Reviews "On Time"
NDAs - Priority	12	90% in 6 mo.	11	92%

Explanation of Performance Goal

Complete review and action on 90 percent of Premarket Approval Application of an estimated 80 (PMA) first actions within 180 days.

Context - Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. A first action constitutes a comprehensive review of the application package initially reviewed by the FDA and the FDA's response back to the product sponsor.

[10] The performance targets for the three performance goals are not in FY 2003. The earliest available data for the three goals is FY 2002.

Results

FDA reported that it achieved a 97 percent completion of review and action for 33 PMAs first actions within 180 days.

Explanation of Performance Goal

Meet the biennial inspection statutory requirement by inspecting 50 percent of registered blood banks, source plasma operations, and biologics manufacturing establishments.

Context - FDA is required by law to conduct biennial inspections of all licensed establishments to determine compliance with Current Good Manufacturing Practice regulations and to ensure compliance with applicable product and establishment standards and license commitments. FDA also conducts biomedical research inspections to review pivotal clinical trial data and inspections of new tissue-cellular based products.

Results

CBER reported that it had exceeded its performance measure. Fifty-two percent of its inventory (blood banks, source plasma operations, and biologics manufacturing establishments) was inspected.

This goal includes inspections done by FDA directly or through state contracts or partnership agreements. The law requires FDA to conduct inspections of manufacturing facilities covered under the statute once every two years. There are 2,693 establishments in the Biologics Program inventory.

Improving Healthcare through Better Information - Overview

Clear and effective communication between FDA and its constituents is vital to FDA's mission as a public health agency. Consumers and health professionals need timely information in order to make informed decisions regarding diet, nutrition, and safe and effective health care. The desired outcome is to ensure that consumers, health professionals, and other FDA stakeholders have accurate and timely information about potential benefits and health consequences associated with the products regulated by FDA. FDA's communication approach must consistently factor in the technical complexity, uncertainty of information, urgency of decisions, different levels of scientific understanding and perceptions of risk.

Select Performance Goals and Results

FDA Strategic Goal	Select Performance Goal
Improving Healthcare through Better Information	Enhance the transparency of the NARMS program to stakeholders, the public, and other interested parties by increased reporting and communicating of NARMS results and program information.

This performance goal is from the Animal Drugs and Feeds Program.

Explanation of Performance Goal [11]

Enhance the transparency of the National Antimicrobial Resistance Monitoring System (NARMS) program to stakeholders, the public, and other interested parties by increased reporting and communicating of NARMS results and program information.

Context - The NARMS is a major national surveillance effort in cooperation with FDA, CDC, and USDA to detect emerging antibiotic resistance among foodborne pathogens and the possible associated health hazards through systematic collection, analysis and interpretation of antimicrobial susceptibility surveillance data. NARMS is adding to our knowledge of drug susceptibility and is helping ensure the continued effectiveness of human and veterinary drugs. The performance goal and target were revised in FY 2003 to reflect the use of NARMS data to communicate with the public on antibiotic resistance.

Results

CVM accomplished this goal through various activities including poster sessions and presentations of NARMS information at scientific forums (sponsored by the American Society of Microbiology, the American Veterinary Medical Association, the United States Department of Agriculture and the Centers for Disease Control and Prevention). Other means of communication included: a NARMS article in the FDA Veterinarian as well as an article on the Mexico project in Antimicrobial Agents and Chemotherapy; updated NARMS information on FDA's website (refer to http://www.fda.gov/cvm/index/narms/narms_pg.html); and, a Spanish translation of the NARMS program brochure. In addition, there is the publication of the Annual Report of NARMS animal, human and retail meat data.

Improving Patient and Consumer Safety – Overview

The prevalence of avoidable health complications, which involve the use of FDA-regulated products, presents a challenge for the Agency. A 1999 Institute of Medicine report estimated that as many as 100,000 Americans die each year as a result of medical errors, which are projected to rank as the eighth leading cause of death in the U.S. Misuse of pharmaceuticals is associated with about 3 million hospital admissions annually, with drug-related adverse events in the ambulatory population costing Americans approximately $75 billion annually.

FDA's central public health role is to ensure that medical products (drugs, biologics, and devices) are proven safe and efficacious prior to marketing, and that these products continue to be safely used once approved and marketed. FDA must monitor over 40,000 manufacturing establishments and almost 10,000 mammography facilities. In addition,

[11] The performance target for FY 2003 meets the intent of the strategic goal – communicating results to various stakeholders.

FDA examines drugs, biologics, animal drugs and feeds, and medical devices that cross our borders annually.

Even with a thorough premarket review process, the risks associated with medical products are never fully revealed during the premarket review process, as new safety findings may emerge after approval, when a wider patient population uses products under a broader range of clinical circumstances. In some of these cases, preventable complications and adverse events may occur that were not observed before product approval. Thus, FDA must assure a postmarket system operate effectively to protect the American public.

There is a significant need for more data from health care providers who prescribe or use medical products. FDA must identify alternative methods to obtain safety data to reduce the public's risk of unsafe products, or in many cases, receiving the wrong dose or product. Automatic data collection on medication errors and adverse events will enable the Agency to limit adverse health outcomes associated with FDA regulated products. To address this opportunity, FDA will continue to partner with provider networks and organizations and continue to work with other government agencies to obtain a more consistent stream of safety data.

Virtually all medical therapies have side effects. It is important for these side effects to be well understood so that we can be sure a product's benefits outweigh its risks. But, preventable adverse events are a different health hazard: they are avoidable medical complications that need not and should not occur. FDA continues to help health professionals avoid medical errors that lead to adverse events. The desired outcome is to reduce adverse events related to FDA-regulated products by improving postmarket surveillance and helping to prevent adverse outcomes related to medical errors.

Select Performance Goals and Results

FDA Strategic Goal	Select Performance Goals [12]
Improving Patient and Consumer Safety	Streamline adverse drug event reporting system.
	Expand implementation of the MeDSuN system to a network of 240 facilities.

Two performance goals were chosen from the Human Drugs, and Medical Devices and Radiological Health Programs.

Explanation of Performance Goal

Enhance postmarketing drug safety (formerly Streamline Adverse Drug Event Reporting System [AERS]). The FY 2002 performance target was used -- Expedite processing and evaluation of adverse drug events through implementation of AERS which allows for electronic periodic data entry and acquisition of fully coded information from drug companies.

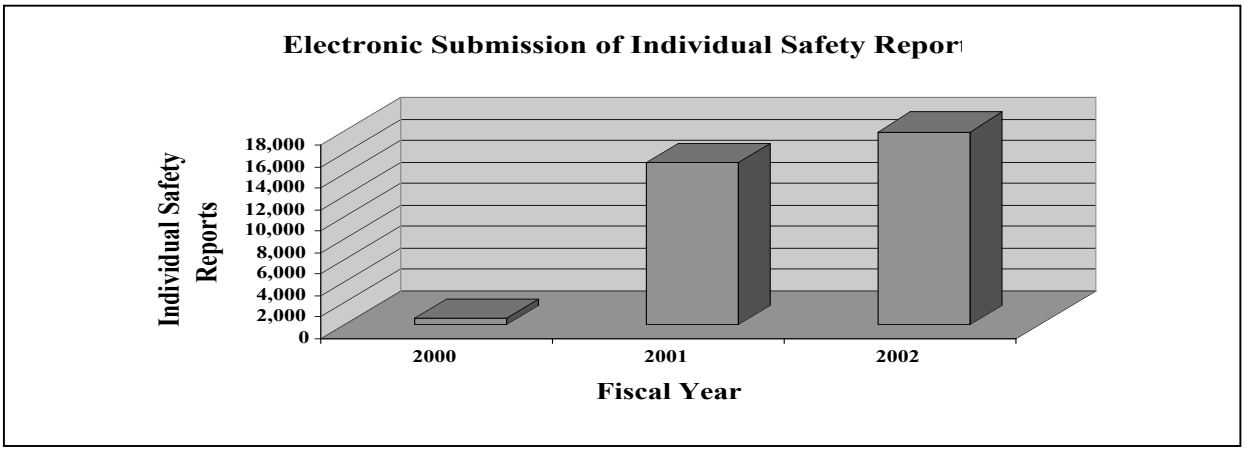
[12] The performance goals in this section are from FY 2002.

Context - The Adverse Event Reporting System (AERS) is a computerized information database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. AERS system combines the voluntary adverse drug reaction reports from health care professionals, consumers, and manufacturers. When a signal of potential adverse reaction is detected, safety evaluators consult with product reviewers, medical officers, and epidemiologists to review available data and consider further options. As FDA discovers new information about a drug's safety profile, the Agency may decide to disseminate risk information, such as "*Dear Health Care Practitioner*" letters, and may initiate regulatory action.

Results

AERS version 4.0, the Windows/Oracle upgrade, was implemented in FY 2002. Approximately 20 percent of expedited individual safety reports were submitted electronically in FY 2002. CDER implemented an Electronic Submission Product Test Pilot for AERS in October 2000. This pilot provided a mechanism for companies to test and send electronic submissions of expedited reports via physical media or gateway directly into AERS. The pilot moved to a production phase in FY 2002 where over 17,000 individual case safety reports were submitted electronically (see Figure 3 below).

Figure 3



Explanation of Performance Goal

Expand implementation of the MeDSuN system to a network of 240 facilities – the FY 2002 performance target is to recruit a total of 80 facilities for the network.

Context - The FDA Modernization Act gives FDA the option to replace universal user facility reporting with the Medical Product Surveillance Network (MeDSuN) system composed of a network of user facilities that constitute a representative profile of user reports. FDA estimates that there may be as many as 300,000 injuries and deaths annually associated with device use and mis-use. MeDSuN will give FDA the health information it needs to identify and address some of those problems.

MeDSuN is based on the premise that a select group of highly trained reporting facilities can provide high quality, informative reports that can be representative of user facility device problems in general.

Results

In FY 2002, FDA recruited, trained and had functioning 80 facilities for the network.

When fully implemented, MeDSuN will reduce device-related medical errors, serve as an advanced warning system; and create a two way communication channel between FDA and the user-facility community.

Protecting America from Terrorism – Overview

A combination of public health and law enforcement responsibilities defines FDA Counterterrorism activities. Regardless of the circumstances, FDA must uphold its responsibility for ensuring the safety of approximately 80 percent of the Nation's food supply, as well as ensuring the availability of safe and effective drugs, vaccines, blood products, medical devices, and animal drugs and feed. The scope of the Agency's Counterterrorism activities includes both the civilian and military sectors of the population.

Select Performance Goals and Results

FDA Strategic Goal	Select Performance Goals
Protecting America from Terrorism	Inspect ninety percent of high risk domestic food establishment once every year.
	Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment.

The two performance goals represent the Foods and National Center for Toxicological Research Programs' contribution to FDA's counterterrorism strategic goal. The first goal reflects a postmarket activity while the second goal is a research activity.

Explanation of Performance Goal

Inspect ninety-five percent of high risk domestic food establishment once every year.

Context: The Agency has defined high-risk establishments as those producing foods with the greatest risk for microbial contamination and those foods requiring specific components for a safe and nutritious product. High-risk domestic food establishments include those involved in the manufacture of low acid canned food products, infant formula products, heat and serve products, ready to eat products, and other products that do not require heating to a temperature sufficient to kill bacteria prior to consumption.

Results

In FY 2002, FDA conducted 6,784 domestic inspections of firms that produce "high risk" foods which exceeded the goal of inspecting 95 percent (of 6,650) of the high risk domestic food establishments.

Explanation of Performance Goal

Catalogue biomarkers and develop standards to establish risk in a bioterrorism environment. The performance target for FY 2002 was to continue the development of solid-phase colorimetric bacterial detection system.

Context - FDA's National Center for Toxicological Research (NCTR) is responsible for conducting this goal. NCTR scientists had developed this methodology to rapidly identify biomarkers of toxicity associated with FDA-regulated products. With the increased potential of a bioterrorist attack, this research has switched to biological warfare agents. NCTR is conducting this research in collaboration with other components of FDA, DHHS, and the Department of Defense.

The identification of biomarkers is important because it will allow rapid identification of and response to potential contamination. These proteins identify specific genes that are potential targets for introduction of foodborne pathogenicity. The methodology as well as the biomarkers will be useful for rapid identification of hazards.

Results

Chemical sensor technology for the assessment of food quality was further developed and the concept evolved into both a commercial version and a consumer version. The research extended to detect other endpoints that are measures of product quality and freshness. As an extension of this work, an interagency agreement was established with the Federal Aviation Administration to detect explosives in airline cargo. Studies are being conducted to compare and contrast several new mass spectrometry techniques to more rapidly evaluate microbial risk.

Smarter Regulation through a Stronger Workforce – Overview

With the new demands imposed by the terrorist threat and continual explosion of new health care products, FDA must seek to achieve excellence in management practices. By embracing the President's Management Agenda[13] and the Secretary's One-HHS initiative, FDA is continuing to transform itself into an organization that is more streamlined, cost-effective, oriented toward strategic alliances, Internet-based and citizen-centered. The desired outcomes for the Strong FDA goal are to:

[13] The President's Management Agenda will be discussed in more detail in the Operational Efficiency chapter.

- Ensure that state-of-the-art scientists and health professionals are recruited and retained so that the people in the U.S. can benefit from scientifically sound risk management decisions;
- Operate a streamlined Agency that is optimally organized to support mission-critical activities;
- Maximize cost-effective performance of functions by achieving a rational balance of in-house and outsourced activities;
- Enhance capacity to produce program performance data and management control systems that allow the Agency to maximize performance relative to targeted public health outcomes; and,
- Continue to improve FDA's management and core operations, making it as responsive to the Nation's needs as possible.

Select Performance Goals and Results

FDA Strategic Goal	Select Performance Goals
Smarter Regulation through a Stronger Workforce	Implement shared services concept and consolidate selected functions in the Agency.
	Increase the percentage of Commercial FTE that will be reviewed for outsourcing.

As shown in the table above, two performance goals[14] were chosen to highlight the strategic goal of a Strong FDA. These goals focus on administrative consolidation and competitive sourcing.

Explanation of Performance Goal

Implement a shared services concept and consolidate selected functions in the Agency – FY 2003 Target - Begin implementation of shared services concept.

Context - This goal supports the Agency's efforts to implement the strategic human capital initiative of the President's Management Agenda and Secretarial initiatives. As a multi-year performance goal, during FY 2001, FDA met its performance target of consolidating various staffs in the Office of the Commissioner. In FY 2002, a contract was awarded to study the best method for delivering administrative services in FDA. A recommendation was made and later accepted by FDA to develop a shared services model for delivering administrative services.

[14] The performance goals are the FY 2003 targets. The clean audit opinion target will be not determined until late October 2003.

Results

FDA completed the design and stand-up phases to launch the new Office of Shared Services[15] in FY 2003. The Office of Shared Services (OSS) was designed to be a customer-focused organization that realigns agency resources while providing high quality administrative services from a single organization. This organization will enable FDA to achieve both efficiency and effectiveness and allows FDA Centers to establish service priorities and services will be tailored to meet their individual needs. Service level agreements will be drawn between administrative service providers and customers (FDA Centers).

Explanation of Performance Goal

Increase the percentage of commercial FTE that will be reviewed for competitive sourcing – FY 2003 Performance Target is 10 percent of commercial activities.

Context - This goal responds to the competitive sourcing initiative of the President's Management Agenda. Under the Federal Activities Inventory Reform Act (FAIR), agencies are to identify those activities considered to be commercial in nature and subject to sourcing competitions. This initiative requires agencies to identify a percentage of commercial activities for competition studies. By focusing on desired results and outcomes, the objective becomes identifying the most efficient means to accomplish the task.

Results

In FY 2003, FDA studied the following activities, representing an additional 10 percent of the agency's commercial FTEs (general accounting in the Office of Regulatory Affairs field components, biological technician and physical science technician services, and facilities and real property management services).

[15] More descriptive information on the Shared Services Organization is found in the Operational Efficiencies chapter in the presentation addressing FDA's implementation of the President's Management Agenda.

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Operational Effectiveness

This chapter highlights FDA's implementation of the President's Management Agenda.

President's Management Agenda

The goal of the President's Management Agenda (PMA) is to improve the management and performance of the Executive Branch. The reform is far-reaching – transforming the Federal Government into a citizen-centered, results-oriented, and market-based organization that provides high quality service to its citizens. Five government-wide goals are identified focusing on changes to the government's infrastructure and management operations. These goals are presented in Table 4. Each Executive Branch department is responsible for implementing the Agenda. As part of the DHHS, FDA is implementing the President's Management Agenda as well as the Secretary's management improvement goals.[16]

Table 4 – President's Management Agenda Goals and Objectives

Goal	Objectives
Strategic Management of Human Capital	Treat human capital as a resource that should be planned and managed
	Reduce layers in government
	Identify core competencies to do mission work
	Consolidate administrative functions
	Use flexible tools to recruit, retrain, and reward employees
Competitive Sourcing	Compete the performance of tasks identified as commercial-in-nature
	Compare government performance with private sector performance
	Select best value to the government
Improved Financial Performance	Maintain a clean (or unqualified) audit opinion with no material weakness
	Create financial information systems that produce accurate and timely information to support operating, budget, and policy decisions
	Measure the real cost and performance of programs using the budget process
Expanded Electronic Government	Create easy-to-find single points of access to government services for citizens
	Automate internal processes to reduce costs internally in the Federal government
	Reduce the reporting burden on businesses
	Share information more quickly between Federal, State, local, and tribal governments
Budget and Performance Integration	Integrate performance review with budget decisions
	Improve program performance by developing outcome measures, monitoring performance and linking associated cost
	Use full cost of resources
	Align budget accounts with outputs

[16] One of the Secretary's management goals is to centralize policy and support functions – known as the "One-DHHS" policy. Under this policy, a centralized financial management system and consolidated human resources management office are being created.

A performance summary of the five government-wide goals follows:

Strategic Management of Human Capital

This PMA goal calls for two major activities: de-layering of the Federal bureaucracy and workforce planning. These initiatives are intended to improve quality service to the American public by reducing management layers between the public and the Agency decision-makers and by identifying the critical skills needed to support the Agency's mission. Under this goal, the DHHS and FDA are performing various consolidation initiatives.

De-Layering Project

Organizational de-layering addresses the Agenda's requirement to ensure that no more than four organizational levels exist between the citizen and the Agency decision-maker. Seven organizational reviews were completed within the Centers and OC, with the Office of Regulatory Affairs remaining to be reviewed.

Strategic Workforce Planning

FDA has been engaged in strategic workforce planning. The investments of the previous years enabled FDA to expeditiously recruit and staff more than 800 employees hired from the FY 2002 Counter-Terrorism funding. FDA used an enhanced recruitment strategy to achieve such remarkable results without an increase in HR staff. These results include:

- Implemented an automated application system "Quick Hire;"
- Instituted a Recruitment Referral Program;
- Placed a listing of FDA vacancies on FDA's Internet site;
- Partnered with colleges and universities with suitable degree programs; and
- Increased the use of special hiring authorities for student interns.

Improving the retention of employees was another effort. The quality of work life program and other HR flexibilities helped to attract prospective employees and to retain employees whom are already onboard. FDA established an Elder Care Program and a Student Loan Repayment Program as other incentives to retain staff.

Departmental Consolidation of Human Resources

DHHS decided to consolidate its human resources (HR) at the department level as part of the "One-HHS" vision. FDA had decentralized its HR in recent years and delegated it to its center components. In FY 2002, FDA consolidated its seven separate HR components into one unit. During FY 2003, the Department implemented plans for consolidating all HR components under the HHS.

FDA Administrative Consolidation

In conjunction with consolidating its various headquarters components at the White Oak Campus, the Agency has decided to redesign its method of delivering administrative services. Headquarters components are spread over 40 different buildings in the metropolitan Washington, D.C. area. Each component has created a support unit to manage administrative services. To plan for an orderly transition, FDA contracted with a management consultant to study the organizational structure for providing administrative services and to recommend the most efficient realignment of Agency resources that would provide high quality administrative services from a centralized source without jeopardizing the primary Agency's mission. The management consultant recommended that the shared services concept would be the best approach given the geographic dispersion of FDA. This concept is based in part on the premise that these services could be provided on a fee-reimbursable basis to the FDA Centers.

The concept of the shared services organization includes a governance mechanism, the linkages between the providers and customers and the performance measures, management focusing on identification of performance measure areas by functions, and Service Level Agreement candidates. Agreement was reached on which functions would be in the new Shared Services Organization (SSO), and what functions would remain in the FDA Centers. A final report was provided on September 16, 2002, recommending a shared services organization by which administrative services should be provided and a proposed a general organizational structure to facilitate the management of service delivery.

After FDA accepted the report, detailed design work on each of the major functional components of the SSO model began. Functional teams consisting of FDA subject matter experts in facilities, information technology (IT), procurement, equal employment opportunity (EEO), and financial services were established in early October 2002. A shared services steering committee was established to provide oversight to the functional teams and ensure that the outcome of the combined efforts of FDA and the management consultant provide an appropriate organization model and optimal service delivery.

The SSO has created a portfolio of services that are aligned with FDA's Centers' needs. The portfolio will contain a set of offerings including transactional services, products and information, including specialized services to fit specific customer segments. The organization ensures a high level of customer satisfaction with multiple mechanisms to ensure employees are well served, can provide feedback, and have ease of access.

Efforts on cross-functional activities such as information technology, workload and FTE requirements, and customer relationship management also began. Activities supporting the design and development of the SSO included:

- Conducted focus groups to create and deliver targeted information on shared services and other change initiatives;

- Completed recommendations by subject matter experts for the organization structure for the SSO;

- Presented blueprint for shared services, including the organization structure recommendations on proposed staffing levels, to FDA senior management;

- Completed site visits by senior managers and the management consultant to FDA regional offices to learn how administrative services are delivered to the field;

- Staffed functional and strategic implementation teams and began work on preparing for migration to the FDA shared services model;

- Developed field (NCTR and ORA) blueprint for shared services and completed it in August 2003; and,

- Identified those administrative employees who will be transferred to the SSO.

The SSO will provide program support services in the following functions:

- Facilities – facilities resources, real estate management, and design and construction;

- IT – on-site desktop management services, help desk services, remote access and application and database development services, etc. Alone, the field represents more than 200 office locations, serviced from 26 IT sites, and providing 21 current IT services;

- EEO and Diversity Management – direct interaction with EEO professionals, and greater standardization, efficiency and oversight; and,

- Finance and Procurement – financial and procurement transactional operations.

These functions will be combined into six new offices: the Employee Resource and Information Center, Office of Real Property Services, Office of Information Technology Shared Services, Office of Equal Employment Opportunity and Diversity Management, Office of Financial Services, and the Office of Acquisitions and Grants Services. An interim Chief of Shared Services was selected to facilitate the stand up of the Office of Shared Services in the fall of 2003.

The SSO will be governed by a council to include representatives of both providers and customers which will create a partnership between both providers and customers. Service level agreements formalize performance expectations such as costs and establish how business units support the process. The shared services model is designed to help FDA to focus on its core business; create satisfied customers and employees; leverage technology and information; and more effectively manage costs.

The shared services initiative is considered as a complementary strategy to administrative consolidation and the President's Management Agenda. Together, the two strategies should lead to a more effective organization which is guided by unified policies, implements cost-effective processes and provides customer-responsive services. To do this FDA is moving toward competency-based business processes that depend on the correct mix of skills and abilities, and is providing training to reinforce the skills needed by employees.

FDA Strategic Action Plan

Complementing the workforce restructuring plan is the Strong FDA strategic goal of the Agency's Strategic Action Plan that issued in August 2003. Strategic management of human capital is an objective of the Strong FDA goal. To achieve this objective, FDA will be working on three initiatives intended to build and maintain a strong science base; recruit, train, and retain a highly skilled workforce; and enhance workforce diversity.

Competitive Sourcing

The PMA challenges the Executive Branch to open up its tasks, such as data collection, administrative support, and payroll services, determined to be commercial in nature, to competition so that both Federal and private sector service providers may compete to perform these functions. The competition results in cost savings to the taxpayers while maintaining high quality service to the government.

The President's goal is for Federal agencies to study 50 percent of their commercial workforce by fiscal year 2006. The OMB established goals for Federal agencies to study 5 percent of their commercial workforce in FY 2002 and 10 percent in FY 2003. The FDA's goals are derived from the number of commercial positions on FDA's 2001 Federal Activities Inventory Reform Act report. In 2001, FDA reported 1,454 commercial full-time-equivalent positions.

In April 2002, FDA began A-76 studies on the following commercial activities to meet OMB's goals for FY 2002:

- Graphic arts/visual information services;
- Television studio services at the Center for Devices and Radiological Health;
- Library services; and,
- Web publishing services.

In August 2002, FDA began A-76 studies on the following commercial activities to meet OMB's goals for FY 2003:

- Facilities and real property management services;
- General accounting services for the Office of Regulatory Affairs; and,
- Biological technician and physical science technician services.

Both the FY 2002 and FY 2003 studies were completed in September 2003. The Government won competition for these activities and is transitioning into the Most Efficient Organization (MEO) status, and will begin standing these organizations up in December 2003 and in April 2004, respectively.

In summary, FDA completed all scheduled standard cost comparisons in an average of 12 months or less, and met the both the old and new revised competitive sourcing standards for success. FDA's experience with the competitive sourcing initiative has replicated the research finding that A-76 competitive sourcing studies typically result in a reduction of about 20 percent in costs even if the Federal organization retains the function in-house. The total expected savings over a five-year performance period is $13,600,000 with no involuntary separations. All studies resulted in the function being retained in-house. The MEOs are presently in the process of being implemented.

Improved Financial Performance

This PMA goal is directed to ensure that Federal agencies produce accurate and timely financial information to support operating, budget, and policy decisions. This is accomplished through a variety of activities to improve timeliness, enhance usefulness, and ensure reliability. The Table 5 illustrates some of the methods to achieve these outcomes.

Table 5 – Financial Performance Outcomes and Methods

Outcome	Methods
Improve Timeliness	Re-engineer reporting processes and expand use of web-based technologies
	Institute quarterly financial statements
	Accelerate end-of-year reporting
	Measure systems' compliance with agencies ability to meet OMB and Treasury requirements accurately and timely
Enhance Usefulness	Require comparative financial reporting
	Report specific financial performance measurements
	Integrate financial and performance information
Ensure Reliability	Obtain and sustain clean audit opinions for components of agencies, agencies, and the government as a whole

Modernize Financial Systems

In June 2001, the Secretary chose to implement two centralized financial management systems – one serving the Centers for Medicare and Medicaid and its contractors, and the other one serving the rest of the Department. Since that time, FDA has been participating in the DHHS effort of designing the Unified Financial Management System (UFMS). For a more complete description of the UFMS, view the web page at: http://www.hhs.gov/ufms/.

As a strategic partner in the success of UFMS, FDA's Office of Financial Management (OFM) works with organizations across the Agency to implement the new financial

system as well as to modernize or reengineer existing applications (e.g., converting them to web-based version). FDA's planning efforts began in FY 2001 with Travel Manager, Automated Accounts Payable System and the Agency Location Code Unification projects. FDA also identified and dedicated resources to DHHS to support its Global Design efforts.

In FY 2002, FDA launched its own initiative called Financial Enterprise Solutions (FES) to integrate financial and business systems to improve operating efficiency of FDA programs. FDA is standardizing its systems throughout the Agency. Its Headquarters' Accounts Payable system was implemented in July 2002 throughout FDA's field accounting points. The Travel Manager, an off-the-shelf system, which will reimburse FDA staff for their work related travel, was implemented in FDA during FY 2003. In recognition of their successful collaboration on improving travel management, FDA and the National Institutes of Health received a travel management award from the Government Executive Magazine in June 2003. Other financial applications being modernized include the Purchase Request Information System (PRISM), user fee billing and collection systems, and a new accounting system.

FES also involves preparing FDA for its new financial environment by developing financial reports and a data warehouse, cleaning data in existing systems, and managing changes. Preparation activities have continued in FY 2003 with data clean-up and developing requirements for a reporting architecture.

Financial Reporting and Accountability

FDA is preparing for the accelerated financial reporting requirements in FY 2003 and FY 2004 by upgrading the methods used to create and review financial statements, performing quarterly reconciliations on property and other accounts, and training staff on these procedures.

FDA is enhancing its program accountability through the use of performance contracts that tie an individual senior executive performance to the achievement of specific performance plan objectives. This enhancement is contributing to creating a culture of accountability starting from the FDA Commissioner to the lowest program official.

Accountability is also advanced by following through on commitments made in audit reports' corrective action plans. OFM reported that an outstanding audit finding was resolved when the electronic interface between the Agency's general ledger accounting system and the Property Management Information System was completed. This improvement will permit the timely reconciling of property and financial information, and will contribute to the Agency's meeting its accelerated financial reporting requirements. OFM and the Office of Information Resources Management continued to make corrective actions on the FDA's information systems controls governing the FDA IT network and various financial management systems' applications.

Expanded Electronic Government

The PMA challenge for this goal is to secure greater services at lower cost through electronic government, or E-government to meet the high public demand for this important service. The goal is to champion citizen-centered electronic government that will result in a major improvement in the Federal government's value to the citizen. Federal agencies accomplish this directive by improving their information technology management and simplifying their business processes. In addition, by unifying their information flows across lines of business, agencies can reduce their operating costs, provide citizens with reader access to government services, and make government more transparent and accountable.

FDA continued its progress towards the consolidation of its IT infrastructure by collaborating with DHHS towards achieving its "One HHS" goals and objectives; initiating efforts to accomplish the IT consolidation goals mandated by the reauthorization of the Prescription Drug User Fees Act (PDUFA); and, establishing an IT Shared Services organization to manage the FDA's consolidated IT infrastructure.

Collaboration at DHHS and with Others

FDA has made significant contributions to this effort by providing key IT and financial technical personnel to actively participate each of the Department project teams. This collaborative effort also extends to the UFMS, the Enterprise Human Resource Planning project and HHS Corporate University. Agency IT staff have also made contributions as part of the development of the HHS 5-Year IT Strategic Plan. The FDA has begun the development of an Enterprise Architecture (EA), having completed an "As Is" baseline. The EA efforts continue to be closely aligned with the DHHS EA Program.

Federal Health Architecture (FHA) -- FDA is participating with the Department, who is a managing partner, in this initiative. The FHA is a set of guiding technology and management principles that will impact the health industry by enabling innovation in care, reduced cost, and improved access and enhanced public health threat preparedness. FDA is participating in the interagency work group, which will create and develop an FHA business case; develop a pilot "Single Line of Business" architecture as a proof of concept; and promote the adoption of FHA principles across the public and private health sectors.

E-Rulemaking -- FDA has assumed a leadership role in the Department for the On-line Rulemaking Initiative – the formal launch of Phase I of www.regulations.gov <http://www.regulations.gov> was successfully held on January 23, 2003. The team is now involved in the Phase II requirements process. The team has a representative on the technical and the legal workgroups. The legal workgroup is currently identifying the legal issues that will have to be resolved before moving to a central system. The technical workgroup is currently working to define the technical blueprint/road map for the construction of the eRulemaking system.

The Online Rulemaking initiative is one of the initiatives designed to improve both business and citizen access to the Federal rulemaking process. To date, there have been almost 2,000,000 hits on the website. This represents an average of about 60,000 to 75,000 hits per day with a total of 12 to 20 electronic comments being submitted per day; no comments have come in through the website for HHS OPDIVs. Comments made to the Helpdesk about the site have been very positive. Work has begun on structuring Module 2, and a team has been set up to provide continuing maintenance and web site change control. Cooperation among the partner agencies remains very encouraging.

Budget and Performance Integration

This PMA initiative is the keystone for the success of the other initiatives because improvements in the management of human capital, competitive sourcing, improved financial performance, and expanding electronic government will matter little if they are not linked to better results. The goal of this initiative is provide a greater focus on performance and incorporate a performance review with budget decisions.

Program Assessment Rating Tool (PART) Evaluation

In FY 2002, OMB developed a performance evaluation methodology entitled, program assessment rating tool or PART, to provide a rationale review of Federal programs based on four areas: purpose, planning, management, and results & accountability.

In June 2002, five FDA programs were chosen for the OMB FY 2004 PART evaluation. OMB gave the five programs (Foods, Human Drugs, Biologics, Devices, and Animal Drugs) a rating of "results not demonstrated" with a composite score of 59.

As a result of the FY 2004 PART evaluation, FDA agreed to develop specific corrective action plans for these five programs. The development of the outcome goals began during the fall of 2002, as one of the promised corrective actions, but was not completed in time to be included in the Congressional Justification's FY 2004 Performance Plan. Since that time, continuing through the strategic planning process up to the preparations for the OMB FY 2005 PART review, several proposals for long term outcome goals were developed and presented in May 2003 during the FY 2005 OMB PART Review.

In the FY 2005 review, OMB decided to review FDA as a single entity and not five programs. At the PART review, FDA presented a set of long-term outcome goals[17] and answer questions that were raised during the FY 2004 PART review. OMB indicated that FDA had improved its score.[18]

[17] These outcome goals will be contained in the Congressional Justification – Performance Plan available in March 2004.

[18] Further elaboration and the results of these scores will be contained in the President's FY 2005 Budget document that should be available in March 2004.

Agency Strategic Plan

The Agency conducted an extensive planning process by which it created a strategic plan with strategic goals, objectives, and action plan. Strategic planning workgroups, composed of representatives from the Centers, Office of Regulatory Affairs, and the Office of the Commissioner, 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 intent of the action plan was to develop the capacity and processes necessary for the Agency to meet its agreed-upon performance commitments and outcome goals that are formulated in the Annual Performance Plans. The Strategic Action Plan[19] was issued in August 2003 and can be reviewed at www.fda.gov/oc/mcclellan/strategic.html.

Results and Accountability

To create organizational culture that focuses on outcomes and results, performance contracts requiring senior program managers to commit to a level of performance as it is articulated in a specific performance goal have been instituted. This engagement by the program managers will provide a greater incentive for the organization to achieve results. During FY 2003, FDA incorporated the Department's 10 Program Goals and Management Objectives in developing the 2003 Performance Contracts for the Commissioner, all SES's and all GS-15's. FDA has now cascaded the plans to all employees nationwide.

[19] The Strategic Action Plan incorporates the latest strategic thinking that has evolved since the Congressional Justification – Performance Plan which is the source document for performance information in the FY 2003 Annual Financial Report.

FISCAL RESPONSIBILITY CHAPTER

This chapter addresses the results of the financial statement audit and discusses FDA's financial condition as displayed in the consolidated principal financial statements.

Financial Statements Audit

FDA's Office of Financial Management (OFM) prepared annual financial statements as set forth by the requirements of OMB Bulletin 01-09, "Form and Content of Agency Financial Statements," and Federal Accounting Standards Advisory Board standards. The independent accounting firm of Ernst and Young issued the audit opinion and three reports of findings and recommendations addressing consolidated financial statements, internal controls over financial reporting, and compliance with laws and regulations. Several performance measures address the results of the financial statements audit. These are summarized in Table 6 for the past five years.

Table 6 – Five Year Trend of Financial Statement Audit Results

Measures	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
Timely audit opinion	Yes	Yes	Yes	Yes	Yes
Clean (or unqualified) audit opinion	Yes	Yes	Yes	Yes	Yes
No. of material weaknesses [20]	0	0	0	0	0
No. of reportable conditions [21]	3	1	1	1	2
No. of instances of non-compliance with Federal Financial Management Improvement Act (FFMIA)	1	1	1	1	1

For the five reporting periods (FY 1999 through 2003), FDA earned five unqualified[22] or "clean" opinions from the independent audit firm that has audited its financial statements.

[20] As defined in OMB Bulletin 01-02, "Audit Requirements for Federal Financial Statements," material weaknesses in internal control are reportable conditions in which the design or operation of the internal control does not reduce to a relatively low level the risk that errors, fraud or noncompliance in amounts that would be significant or "material" in relation to the Principal Statements being audited, or "material" to a performance measure or aggregation of related performance measures, may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

[21] American Institute of Certified Public Accountants standards define reportable conditions as significant deficiencies in the design or operation of internal control that could adversely affect the entity's ability to record, process, summarize, and report financial data consistent with the assertions of management in the financial statements.

[22] An unqualified opinion is a statement by the auditor that an entity's financial statements present fairly, in all material respects, the financial position, results of operation, and other financial aspects of an organization in conformity with accounting principles generally accepted in the U.S. (GAAP) applicable to the entity.

The independent auditors also reported on FDA's internal controls and compliance with laws and regulations that impact on the reliability of the financial statements. In the last five periods, FDA received no material weaknesses. The auditors disclosed a new reportable condition addressing financial systems and analyses regarding systems integration, processes and analyses, and the timeliness of reconciliations. FDA expects to resolve the new condition in FY 2004. As reported last year, information systems controls remain a reportable condition. FDA is working on taking corrective actions, and its final resolution is estimated to take several more years.

The finding of non-compliance with the Federal Financial Management Improvement Act remains. This finding focused on deficiencies in three areas: cost management, accounts receivables, and property management. The corrective actions taken in the property management have been completed. The deficiency in accounts receivable should be resolved in FY 2004, while cost management will be resolved when FDA's financial system is fully implemented in FY 2007.

Financial Analysis

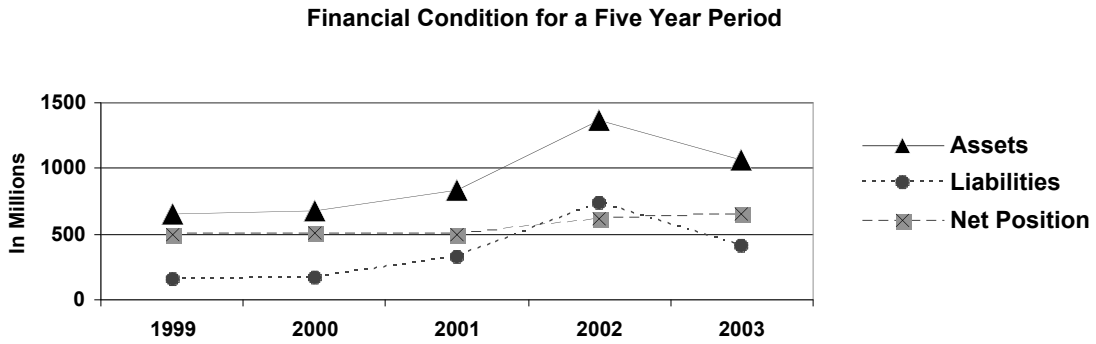
Financial statement reporting is required to be displayed in several formats as specified by the Federal Accounting Standards Advisory Board and OMB Bulletin 01-09, "Form and Content of Agency Financial Statements." We are showing a five year trend with commentary highlighting the changes from the previous year (FY 2002).

Balance Sheet

Balance Sheet	Reports the operating assets, liabilities, and net position. Presents a "snap-shot" of FDA's financial condition as of the fiscal year-end.

The Consolidated Balance Sheets continues to show an increase in the net position (assets less liabilities). Figure 4 shows a five year trend of assets, liabilities, and net position. For FY 2003, the assets primarily decreased because of the large civil monetary penalties' accounts receivable collections in FY 2003 that were assessed in FY 2002.

Figure 4



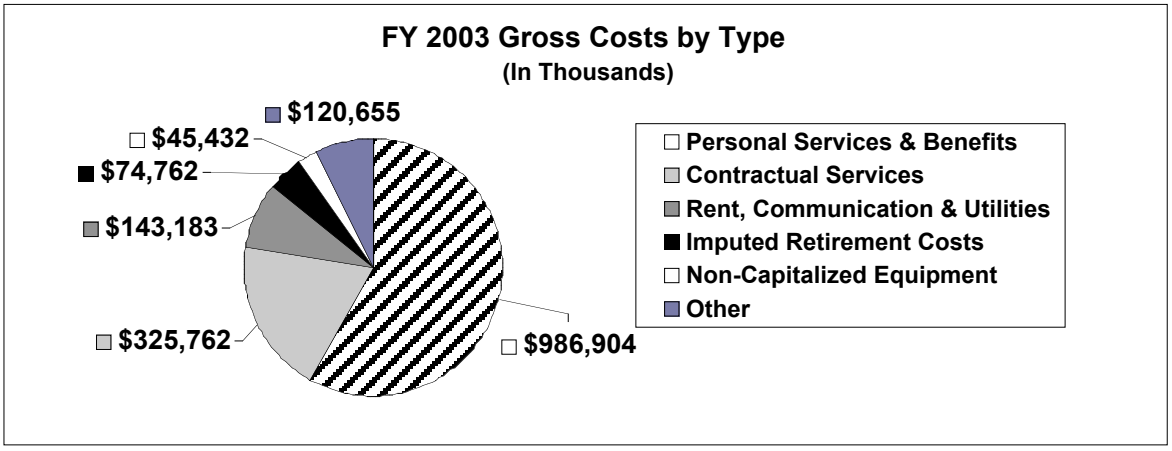
Net Costs

Net Cost	Breaks down total expenses by the six major programs of FDA's budget, net of exchange revenues and after allocation of indirect expenses such as administrative, field operations, rent, and other overhead.

Gross FY 2003 expenses were $1.70 billion, which includes projects funded by user fees. Deducting $288 million in earned revenues (e.g., user fees), FY 2003 net costs were $1.41 billion. This compares with gross expenses of $1.49 billion and net costs of $1.30 billion for FY 2002. Amounts reported on the Consolidated Statements of Net Cost include allocation of expenses incurred by FDA's Office of Commissioner and Office of Regulatory Affairs, both of which provide crosscutting services to the responsibility segments.

Figure 5[23] illustrate FDA's costs by expense type.

Figure 5



- Personal Services & Benefits rose by 13.7 percent from $867 million in FY 2002 to $986 in FY 2003, because of budgetary increases in funding to support food security, imports and inspectional activities, new drug approvals, adverse reporting systems, and counterterrorism activities.

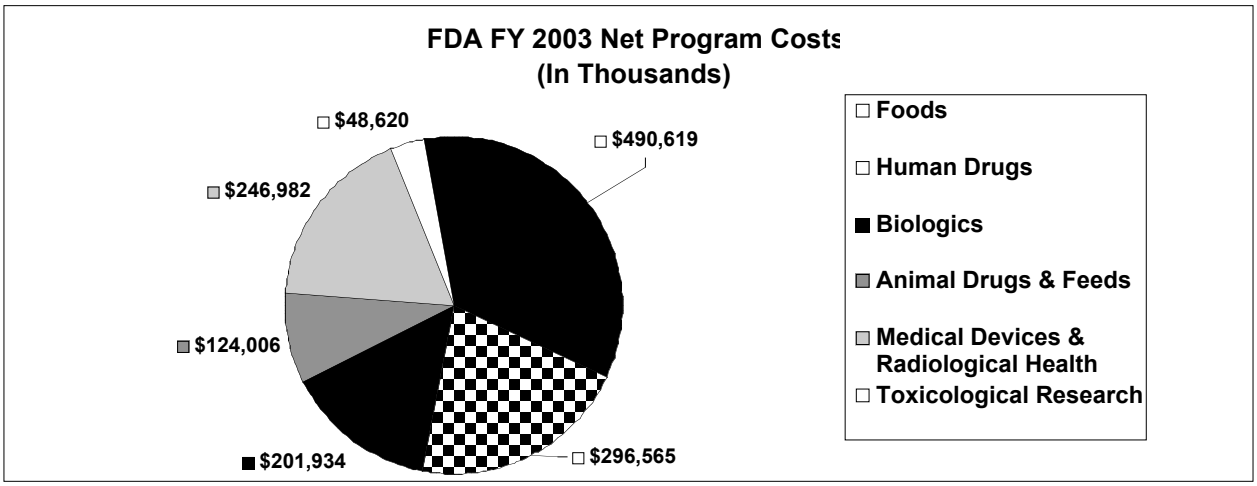
- Contractual Services increased by 18.6 percent from $274 million in FY 2002 to $325 million in FY 2003, because of budgetary increases in funding to support orphan product grants and food safety.

[23] Source: Supplemental Statement of Net Cost by Expense Type and Program, FY 2003. Please note that some rounding differences may show a different total than the supplemental statement.

- Rent, Communications, and Utilities increased by 10 percent from $130 million in FY 2002 to $143 million in FY 2003, because of budgetary increases in funding to hire 832 FTEs, improve the security of the Agency's facilities, and develop a state-of-the-art crisis management center.

Figure 6[24] illustrate FDA's expenses by program. These are the budget programs reported under GPRA, which represent FDA's major responsibility segments.

Figure 6



The differences in the net program costs from FY 2002 to FY 2003 are shown below:

- The Foods Program's FY 2003 net costs increased by 13.8 percent due to budgetary increases to support counterterrorism activities related to food security; and imports and inspectional activities.

- The Human Drugs Program's FY 2003 net costs grew by 5.8 percent due to increases in user fees authorized by PDUFA III, and budgetary increases directed at counterterrorism activities related to medical countermeasures, generic drugs, and patient safety and adverse events system.

- The Biologics program's FY 2003 net costs increased by 7.7 percent due to funding increases for counterterrorism and patient safety.

- The Animal Drugs and Feeds Program's FY 2003 net costs increased by 10 percent from FY 2003 because of funding increases for the food safety related activities including Bovine Spongiform Encephalopathy (BSE) and antimicrobial resistance.

[24] Source: Supplemental Statement of Net Cost by Program Costs by Appropriation, FY 2003.

- The Devices and Radiological Health Program's net costs increased by 2.5 percent from FY 2003 due to a funding increase for counterterrorism and patient safety including funding for the MedSun adverse event reporting system.

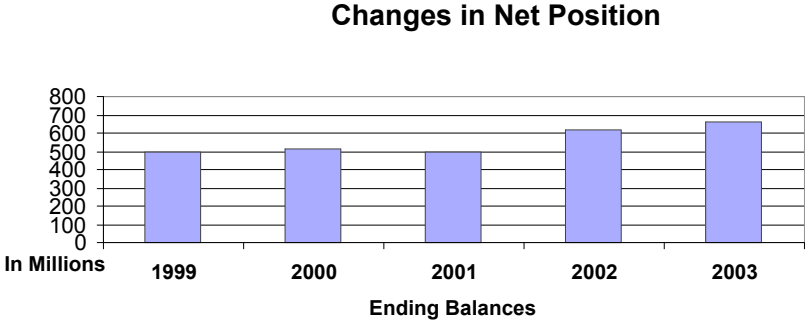
- The National Center for Toxicological Research Program's net costs increased by 6.4 percent in FY 2003 due to a funding increase for counterterrorism research.

Changes in Net Position

Changes in Net Position[25]	Provides information on the changes in financial position from year to year and the causes of the changes.

The Consolidated Statements of Changes in Net Position show an increase in FY 2003 due in part to appropriations increases covering improvements to the generic drug review, counterterrorism activities, patient safety and reducing medical errors. Figure 7 shows the five year trend of ending balances.

Figure 7



[25] The Consolidated Statements of Changes in Net Position reports the change in net position during the reporting period. Net position is affected by changes to its two components: Cumulative Results of Operations and Unexpended Appropriations. The statement format is designed to display both components of net position separately to enable the user to better understand the nature of changes to net position as a whole. Both components of net position are also reflected as line items on the Balance Sheet. Budgetary appropriations received in this statement tie directly to the Combined Statements of Budgetary Resources. The Other Financing Sources section of this statement will tie directly to the Consolidated Statements of Financing. The Net Cost of Operations line ties directly to the Consolidated Statements of Net Cost.

Financing

Financing	Discloses the resources used to finance operations and relationship of total resources to the net cost of operations. This statement is designed to explain the relationship of budgetary obligations to costs recorded in the financial statements.

The Consolidated Statements of Financing is designed to report the difference in accrual based measures used in the Consolidated Statements of Net Cost and obligation-based measures used in the Combined Statements of Budgetary Resources. To understand these differences, information is needed to reconcile financial (proprietary) net cost of operations with obligations of budgetary authority.

Some obligations or non-budgetary resources do not result in expenses on the Consolidated Statements of Net Cost for the period in which the obligation was made or the non-budgetary resource recognized. FDA's obligations that do not result in expenses consist of three items:

- Change in budgetary resources obligated but goods or services not yet provided;
- Resources that finance the acquisition of assets and liquidation of liabilities; and,
- Resources that fund expenses recognized in earlier periods.

FDA's change in budgetary resources obligated but not yet provided was $62.1 million in FY 2003. This amount represents obligations recorded during FY 2003 for which expenses will not be incurred until a subsequent period. The acquisition of assets and liquidation of liabilities totals $55.1 million. These items are subtracted in the reconciliation because they are included in obligations, as adjusted and non-budgetary financing sources, but not in the net cost of operations. Resources that fund expenses recognized in earlier periods, totaling $4.8 million, represent unfunded expenses recognized in prior periods but paid with FY 2003 obligations.

Costs that do not require current year resources are costs that do not require financing by either budgetary or non-budgetary resources. FDA's primary cost in this category is depreciation and amortization totaling $19.4 million. Depreciation and amortization should be added in the reconciliation because it is part of the net cost of operations but not included in current year obligations, as adjusted and non-budgetary resources.

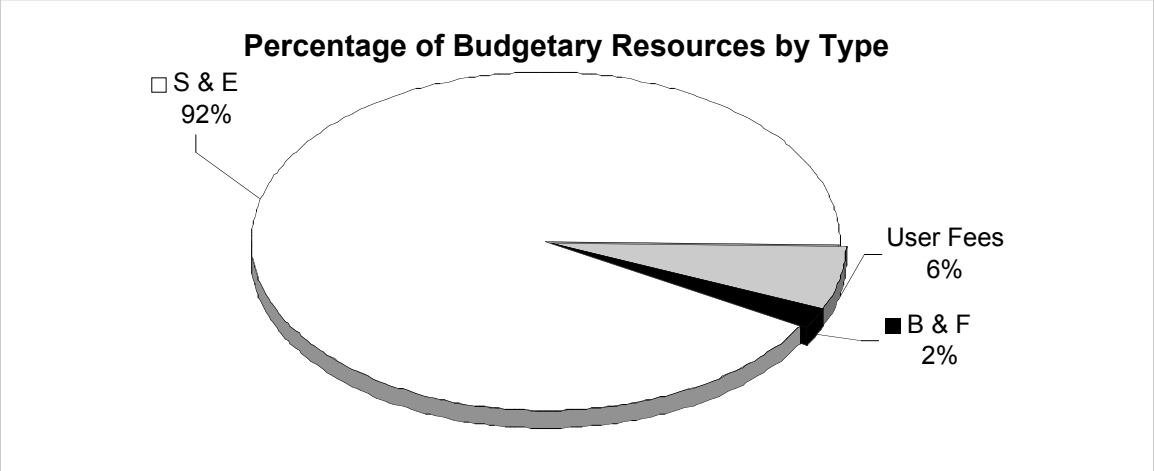
The costs of the Federal government are not always funded in the period the costs are incurred. Costs of this nature are incurred in the current reporting period, but are normally funded through appropriations in subsequent years. Costs which are funded in future periods total $5.9 million, as of September 30, 2003, and represent an increase in financing sources yet to be provided. The primary items in this category are unfunded annual leave expense and exchange revenue receivable from the public. The unfunded annual leave expense experienced an increase of $10.3 million, and the exchange revenue receivable from the public experienced an increase of $5.6 million. The increase in costs funded in future periods is in the reconciliation because it is part of the net cost of operations but not in obligations as adjusted and non-budgetary resources.

Budgetary Resources and Outlays

Budgetary [26] Resources	Provides information on total budgetary resources available, the status of those resources, and outlays. Helps to assess budget execution and whether budgetary accounting rules are being followed.

As presented in the Combined Statements of Budgetary Resources, FDA's budget authority for FY 2003 was $1.40 billion, not including spending authority of $340 million from user fee and reimbursable collections. Total budget authority, as of September 30, 2003, including offsetting collections, carry-over balances from earlier years and adjustments, was $1.91 billion. Of this amount, $1.82 billion was obligated during FY 2003. Figure 8 shows the percentage of budgetary resources[27] by major type -- salaries and expenses; user fees; and buildings and facilities.

Figure 8



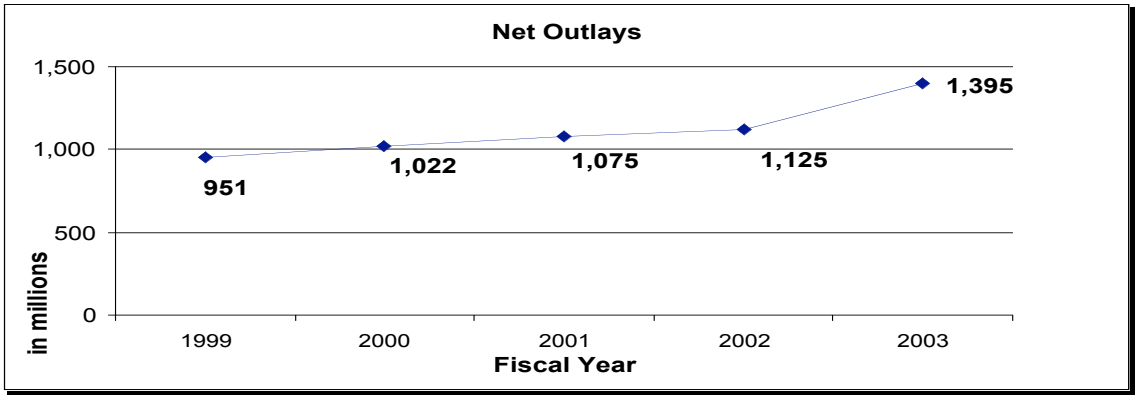
Total outlays were about $1.40 billion during FY 2003, which represents a 24 percent increase over FY 2002 total outlays of $1.13 billion.

[26] One must be careful to recognize the differences between expenses recorded on an accrual basis of accounting as compared to obligations reported on the Combined Statements of Budgetary Resources.

[27] Source: Combining Statement of Budgetary Resources for the Year Ended September 30, 2003.

Figure 9 [28] shows FDA's outlay trend over the past five fiscal years.

Figure 9



For FY 2003, FDA received budgetary increases to cover the counterterrorism activities, improving the generic drug review, and improvements to FDA's post-approval surveillance to ensure patient safety and identify adverse events associated with products on the market.

[28] Source: Combined Statement of Budgetary Resources, FY 2003

Limitations to the Financial Statements

For the preparation of the FDA's annual financial report, the OMB has asked that the following statements be included to remind readers of the basis for financial statements prepared for Federal Government activities.

The statements should not be interpreted as limitations in the usefulness of financial statements in evaluating Federal operations, but only as a reminder that they cover the activities of a component of a sovereign entity and may differ from results reported in budgetary documents or in style from annual reports prepared by private sector entities.

- The financial statements have been prepared to report the financial position and results of operations of FDA, pursuant to the requirements of 31 U.S.C. 3515(b).

- While the statements have been prepared from the books and records of FDA in accordance with GAAP and the formats prescribed by OMB, the statements are in addition to the financial reports used to monitor and control budgetary resources, which are prepared from the same books and records.

- The statements should be read with the realization that they are for a component of the U. S. Government, a sovereign entity. One implication of this is that liabilities cannot be liquidated without legislation that provides the resources to do so.

- The Required Supplementary Information and Required Supplementary Stewardship Information sections are unique to Federal financial reporting. These sections are required under OMB Bulletin 01-09 and are unaudited.

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Section II -- Consolidated Principal Financial Statements

U.S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED BALANCE SHEETS

As of September 30, 2003 and 2002

(In Thousands)

	2003	2002
ASSETS		
Intragovernmental:		
Fund Balances with Treasury (Note 2)	$688,111	$710,703
Accounts Receivable (Note 3)	18,914	11,330
Other Assets (Note 6)	8,581	13
Total Intragovernmental Assets	**715,606**	**722,046**
With the Public:		
Accounts Receivable, Net (Note 3)	57,587	379,134
Cash (Note 4)	155	155
General Property, Plant & Equipment, Net (Note 5)	292,240	260,982
Other Assets (Note 6)	254	292
Total Assets With the Public	**350,236**	**640,563**
TOTAL ASSETS	**$1,065,842**	**$1,362,609**
LIABILITIES		
Intragovernmental:		
Accounts Payable	$10,844	$13,249
Accrued Payroll and Benefits (Note 9)	7,682	11,819
Resources Payable to Treasury (Note 3)	49,219	373,027
Other Liabilities (Notes 11 & 13)	924	1,229
Total Intragovernmental Liabilities	**68,669**	**399,324**
With the Public:		
Accounts Payable	67,106	80,208
Accrued Payroll and Benefits (Note 9)	93,958	109,658
Federal Employee and Veterans' Benefits (Note 8)	22,397	21,100
Environmental and Disposal Costs (Note 7)	5,484	4,218
Accrued Grant Liability, Net (Note 10)	1,197	97
Other Liabilities (Notes 11 & 13)	148,952	128,488
Total Liabilities With the Public	**339,094**	**343,769**
TOTAL LIABILITIES	**407,763**	**743,093**
Commitments and Contingencies (Note 12)		
NET POSITION		
Unexpended Appropriations	407,134	414,490
Cumulative Results of Operations	250,945	205,026
TOTAL NET POSITION	**658,079**	**619,516**
TOTAL LIABILITIES AND NET POSITION	**$1,065,842**	**$1,362,609**

The accompanying notes are an integral part of these statements.

U. S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED STATEMENTS OF NET COST

For the Years Ended September 30, 2003 and 2002

(In Thousands)

	2003			
	Intragovernmental		With the Public	
Program /Activity	Gross Costs	Less: Exchange Revenue	Gross Costs	Less: Exchange Revenue
Foods	$ 145,060	$ 5,362	$ 354,470	$ 3,549
Human Drugs	134,384	4,384	355,707	189,142
Biologics	60,242	5,801	169,507	22,014
Animal Drugs and Feeds	44,298	1,418	81,126	-
Devices and Radiological Health	76,487	5,412	207,186	31,279
National Center for Toxicological Research	10,448	19,611	57,783	-
Total	**$ 470,919**	**$ 41,988**	**$ 1,225,779**	**$ 245,984**

	2002			
Foods	$ 121,589	$ 1,733	$ 319,274	$ 8,077
Human Drugs	89,745	827	327,787	136,303
Biologics	47,490	6,170	158,030	11,934
Animal Drugs and Feeds	35,073	308	78,500	529
Devices and Radiological Health	63,587	2,149	188,649	9,202
National Center for Toxicological Research	8,134	12,072	49,619	-
Total	**$ 365,618**	**$ 23,259**	**$ 1,121,859**	**$ 166,045**

The accompanying notes are an integral part of these statements.

U.S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED STATEMENTS OF CHANGES IN NET POSITION

For the Years Ended September 30, 2003 and 2002

(In Thousands)

	2003		2002	
	Cumulative Results of Operations	Unexpended Appropriations	Cumulative Results of Operations	Unexpended Appropriations
Beginning Balances	$205,026	$414,490	$170,986	$329,498
Budgetary Financing Sources:				
Appropriations received	-	1,390,702	-	1,386,051
Appropriations transferred-in-out	-	4,417	-	-
Other Adjustments (rescissions, etc)	-	(22,540)	-	(32,096)
Appropriations used	1,379,935	(1,379,935)	1,268,963	(1,268,963)
Other Financing Sources:				
Transfers-in/out without reimbursement	(52)	-	226	-
Imputed financing from costs absorbed by others	74,762	-	63,024	-
Total Financing Sources	1,454,645	(7,356)	1,332,213	84,992
Net Cost of Operations	(1,408,726)		(1,298,173)	
Ending Balances	**$250,945**	**$407,134**	**$205,026**	**$414,490**

The accompanying notes are an integral part of these statements.

U.S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED STATEMENTS OF FINANCING

For the Years Ended September 30, 2003 and 2002

(In Thousands)

	2003	2002
RESOURCES USED TO FINANCE ACTIVITIES:		
Budgetary Resources Obligated:		
Obligations incurred	$1,823,455	$1,657,502
Less: Spending authority from offsetting collections and recoveries	(453,450)	(436,041)
Obligations net of offsetting collections and recoveries	1,370,005	1,221,461
Less: Offsetting receipts	(1,878)	(1,794)
Net obligations	1,368,127	1,219,667
Non-budgetary Resources:		
Transfers in/out without reimbursement	(52)	226
Imputed financing from costs absorbed by others	74,762	63,024
Net non-budgetary resources used to finance activities	74,710	63,250
Total resources used to finance activities	**1,442,837**	**1,282,917**
RESOURCES USED TO FINANCE ITEMS NOT PART OF THE NET COST OF OPERATIONS:		
Change in budgetary resources obligated for goods, services, and benefits ordered but not yet provided	(62,145)	(115,544)
Adjustments other than collections made to compute net budgetary resources that do not affect cost of operations:		
Recoveries of prior-year authority	50,223	39,679
Increase in unfilled customer orders	7,905	139,092
Resources that fund expenses recognized in prior periods	(4,806)	(4,646)
Resources that finance the acquisition of assets or liquidation of liabilities	(55,053)	(70,415)
Total resources used to fund items not part of the net cost of operations	**(63,876)**	**(11,834)**
Total resources used to finance the net cost of operations	**1,378,961**	**1,271,083**
COMPONENTS OF THE NET COST OF OPERATIONS THAT DO NOT REQUIRE OR GENERATE RESOURCES DURING THE REPORTING PERIOD:		
Components not requiring or generating resources:		
Depreciation and amortization	19,365	17,317
Losses on disposition of assets	4,449	28
Other	39	(2,166)
Total components not requiring or generating resources	23,853	15,179
Components requiring or generating resources in future periods:		
Change in exchange revenue receivable from public	(5,637)	3,984
Annual leave expense from increase in annual leave liability	10,252	8,102
Other	1,297	(175)
Subtotal	5,912	11,911
Total components of net cost of operations that do not require or generate resources during the reporting period	**29,765**	**27,090**
Net cost of operations	**$1,408,726**	**$1,298,173**

The accompanying notes are an integral part of these statements.

U.S. Department of Health and Human Services

Food and Drug Administration

COMBINED STATEMENTS OF BUDGETARY RESOURCES

For the Years Ended September 30, 2003 and 2002

(In Thousands)

	2003	2002
BUDGETARY RESOURCES:		
Budget authority :		
Appropriations received	$1,392,580	$1,387,845
Net transfers	4,417	-
Unobligated balance:		
Beginning of period	222,169	85,716
Spending authority from offsetting collections:		
Earned		
Collected	328,318	200,281
Receivable from federal sources	4,243	3,110
Change in unfilled customer orders		
Advance received	11,714	127,291
Without advance from federal sources	(3,809)	11,800
Subtotal	340,466	342,482
Recoveries of prior year obligations	112,984	93,559
Temporarily not available pursuant to public law	(138,869)	(127,224)
Permanently not available	(22,540)	(29,930)
Total Budgetary Resources	**$1,911,207**	**$1,752,448**
STATUS OF BUDGETARY RESOURCES:		
Obligations incurred :		
Direct	$1,798,325	$1,635,738
Reimbursable	25,130	21,764
Subtotal	1,823,455	1,657,502
Unobligated balance:		
Apportioned	66,083	75,180
Unobligated balance not available	21,669	19,766
Total Status of Budgetary Resources	**$1,911,207**	**$1,752,448**
RELATIONSHIP OF OBLIGATIONS TO OUTLAYS:		
Obligated balance, net, beginning of period	$488,687	$394,029
Obligated balance, net, end of period:		
Accounts receivable	(13,672)	(9,430)
Unfilled customer orders from federal sources	(17,910)	(21,719)
Undelivered orders	382,403	369,330
Accounts payable	110,822	150,506
Outlays:		
Disbursements	1,737,081	1,454,375
Collections	(340,032)	(327,572)
Subtotal	1,397,049	1,126,803
Less: Offsetting receipts	(1,878)	(1,794)
Net Outlays	**$1,395,171**	**$1,125,009**

The accompanying notes are an integral part of these statements.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NOTES TO FISCAL YEAR 2003
CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

(In Thousands)

Note 1 – Summary of Significant Accounting Policies

A. Reporting Entity

The Food and Drug Administration (FDA) is a separate operating division (OPDIV) and reporting entity of the Department of Health and Human Services (DHHS), and is a scientific regulatory agency. FDA's primary objective is to protect and promote the health and well-being of consumers in the United States. FDA's resources are organized into six "programs" as follows: Foods, Human Drugs, Medical Devices & Radiological Health, Biologics, Animal Drugs & Feeds, and Toxicological Research. In addition to its programs, FDA has separate budgets for buildings and facilities (construction and repair), GSA rental payments, other activities (policy and administrative), and special purpose (contingency and cooperative research and development agreements).

The agency currently maintains two general funds, a deposit fund, revolving fund, trust fund, and several special purpose funds. All appropriations have been consolidated for the purposes of displaying the accompanying principal financial statements. Supplementary information schedules following these notes present budgetary resources and costs by appropriation. Appropriations reported as part of FDA's financial statements are as follows:

Treasury Fund Symbol	Appropriation Description
75_0600	Salaries and Expenses
75X0600	User Fees Account/Contingency Fund
75X0601	Building Delegation
75X0603	Buildings and Facilities
75X4309	Revolving Fund for Certification and Other Services
75X5148	Cooperative Research and Development Agreements
75_/_0600	Patents and Royalties/White Oak Moving Costs
75X8147	Gift Fund
75F3875.6 and 75F3885.6	Budget Clearing
753099, 752499, 752449, 751099, 751499	Miscellaneous Receipts

B. Basis of Presentation

The financial statements have been prepared from the accounting records of FDA in conformity with accounting principles generally accepted in the United States of America

(GAAP) and the form and content for entity financial statements specified by the Office of Management and Budget (OMB) in OMB Bulletin 01-09, *Form and Content of Agency Financial Statements*. GAAP for Federal entities are the standards prescribed by the Federal Accounting Standards Advisory Board (FASAB), which is the official accounting standards setting body for the Federal Government. The consolidated statements are different from the financial reports, also prepared by FDA, pursuant to OMB directives, used to monitor and control the use of budgetary resources. FDA has no material intra-entity transactions that need to be eliminated from the financial statements.

C. Basis of Accounting

FDA records transactions on the accrual accounting basis and budgetary basis. Under the accrual method, revenues are recognized when earned and expenses are recognized when a liability is incurred, without regard to receipt or payment of cash. Budgetary accounting principles, on the other hand, are designed to recognize the obligation of funds according to legal requirements, which, in many cases, is prior to the occurrence of an accrual-based transaction. Budgetary accounting provides a means to track the status of budgetary authority to help avoid over expending or over obligation of appropriations. Budget authority is the authority to acquire goods and services and to make payments in accordance with applicable laws and regulations. The recognition of budgetary accounting transactions is essential for compliance with legal constraints and controls over the use of Federal funds.

D. Budgets and Budgetary Accounting

Each of FDA's funds and appropriations is financed by a combination of sources. These sources include direct appropriations from Congress, Congressional authorization to obligate collections, funding received from other Federal agencies, and receipts received through reimbursable agreements. Recognition and measurement of budgetary resources, for purposes of preparing the Combined Statements of Budgetary Resources, is based on budgetary concepts and definitions provided by OMB Circular A-11, *Preparation, Submission and Execution of the Budget.*

FDA has Cooperative Research and Development Agreements (CRADA), where it has cooperative agreements with academia and private sector companies. The purpose of CRADA is to strengthen research efforts and enhance the necessary resources required to achieve scientific objectives while simultaneously transferring new technology to the private sector for development and eventual use by the public. The CRADA appropriation is a no-year type account, and funding is submitted to FDA by the partner for services, facilities, equipment, or other resources to support the research or development efforts outlined in the CRADA. In FY 2003, FDA received approximately $1,900 ($1,800 for FY 2002) related to these agreements.

E. Assets

Entity assets are those assets which the reporting entity holds and has the authority to use in its operations. Non-entity assets are assets the entity holds, but does not have authority to use. FDA has one non-entity asset for accounts receivable related to civil monetary penalties (CMPs) to report. Therefore, assets reported on the financial statements are entity assets that FDA is able to use in its operations, except for accounts receivable related to CMPs as further described in Note 3 and 15.

Intragovernmental assets are those that arise from transactions with other Federal entities. Assets With the Public are those that arise from transactions with state or local government agencies, or the general public.

F. Fund Balances with Treasury

Fund balances with Treasury are the aggregate amount of funds available to incur expenditures and pay liabilities. FDA does not maintain cash in commercial bank accounts. Although cash receipts are deposited with commercial banks which have been designated by the Secretary of the Department of the Treasury (Treasury) as official depositories to hold U.S. Government funds, the funds are electronically transferred to Treasury at the end of each business day. Treasury processes receipts and disbursements, either directly or through the DHHS Payment Management System (PMS).

Fund balances with Treasury cash balances are reconciled monthly with balances reported by Treasury and adjusted at year-end to the reconciled Treasury balances. Any discrepancies that may occur are primarily due to timing differences on transactions involving the DHHS PMS and DHHS Central Payroll systems.

G. Accounts Receivable, Net

Accounts receivable consist of amounts owed to FDA by other Federal entities and the public. Intragovernmental accounts receivable are primarily related to amounts due from the Department of Justice (DOJ) for payments to DOJ by organizations for civil monetary penalties and amounts billed under interagency agreements. Receivables arising from CMPs are recorded when the penalties are assessed by DOJ and FDA.

Public accounts receivable primarily represent amounts due from organizations for CMPs not yet remitted to DOJ, all user fees billed in accordance with the Prescription Drug User Fee Act, Medical Device User Fee Modernization Act, Mammography Quality Standards Act, and user fees related to FDA's issuance of export certificates. Amounts due for public

receivables are stated net of an allowance for uncollectible accounts. The allowance is based on past collection experience and an analysis of outstanding balances. No allowance is established for intragovernmental receivables, as they are considered fully collectible.

H. Advances

It is FDA's policy to advance funds to grant recipients so that recipients may incur expenses related to the approved grant. Advances are only made within the amount of the recorded grant obligation and are intended to cover immediate cash needs. Advances are reported net of accrued grantee expenditures, and an "Accrued Grant Liability, Net" is reported when accrued expenditures exceed advances as of September 30. Other advances with the public are related to travel and emergency salary payments made to FDA employees and are reported in Note 6, "Other Assets." All advances are considered current assets.

I. General Property, Plant and Equipment, Net (PP&E)

PP&E is capitalized at cost if the initial acquisition cost is $25 or more and if the asset has an estimated useful life of two years or more. In accordance with Statement of Federal Financial Accounting Standards No. 10, Accounting for Internal Use Software, FDA implemented the DHHS-wide policy which requires internal use software be capitalized using a threshold of $1,000, and an estimated useful life of not less than two and no more than five years. Capitalized costs include all direct and indirect costs. Enhancements to existing internal use software are capitalized when the life cycle costs of the development stage are $1,000 or more, and they result in significant additional capabilities.

PP&E with an acquisition cost of less than the capitalization threshold is expensed when purchased. The cost of PP&E acquired under a capital lease is the amount recognized as a liability for the capital lease at its inception. PP&E acquired through donation is recorded at its estimated fair value. The cost of PP&E transferred from other Federal entities is the net book value from the transferring entity.

PP&E is depreciated on a straight-line basis over the estimated useful life of the asset. Land and land rights, including permanent improvements, are not depreciated. Normal maintenance and repair costs are expensed as incurred.

Amounts disbursed for major construction and software projects that are ongoing at year-end are classified as construction and software in-progress. Such expenditures are subsequently reclassified as depreciable PP&E upon project completion and acceptance.

During FY 2003, FDA incurred a loss of $3,802 on the disposition of the CDER Corporate Database Redesign project. The project was in the developmental phase, and costs were

accumulated as required by SFFAS #10. However, the funding had been exhausted, and management determined that the project would not be completed. Therefore, the accumulated book value for the software was reduced to zero, and the loss recognized in FY 2003.

The General Services Administration (GSA), which charges rent based on commercial rental rates for similar properties, provides the majority of space and property that FDA occupies. Therefore, the cost of GSA owned properties is not recorded in FDA's financial statements.

J. Liabilities

A liability for Federal accounting purposes is a probable and measurable future outflow or other sacrifice of resources as a result of past transactions or events. Since FDA is a component of the U.S. Government, a sovereign entity, its liabilities cannot be liquidated without legislation that provides resources to do so. Payments of all liabilities other than contracts can be abrogated by the sovereign entity. Intragovernmental liabilities arise from transactions with other Federal entities.

Liabilities Covered by Budgetary Resources are those liabilities funded by available budgetary resources, including: (1) new budget authority, (2) spending authority from offsetting collections, (3) recoveries of unexpired budget authority, (4) unobligated balances of budgetary resources at the beginning of the fiscal year, and (5) permanent, indefinite appropriation or borrowing authority. The majority of liabilities covered by budgetary resources include amounts payable to vendors who have provided goods or services to FDA or for accrued payroll.

Liabilities Not Covered by Budgetary Resources are incurred when funding has not yet been made available through Congressional budget authority. FDA recognizes such liabilities for employees' annual leave earned but not taken, amounts billed to FDA by the Department of Labor for Federal Employee's Compensation Act payments, capital leases, contingent legal liabilities, and environmental cleanup activities scheduled to begin beyond the current fiscal year being reported.

K. Accounts Payable

Accounts payable consists of amounts owed for goods and services received, progress in contract performance by others, and other miscellaneous payables.

L. Resources Payable to Treasury

FDA records amounts equal to the asset accounts receivable for civil monetary penalties as non-entity liabilities payable to the Department of Treasury's miscellaneous receipt account.

M. Accrued Grant Liability, Net

DHHS Program Support Center (PSC) performs the daily grant accounting functions for FDA and reports the necessary information on a monthly basis to FDA for grant advances and expenditures. Separate algorithms are used by DHHS to calculate accruals for "block" and "non-block" grant programs and related contracts. The algorithms, which have been approved by OMB and the General Accounting Office, compute average daily spending rates for each grant in order to estimate the portion of the unspent grant amount to be accrued at year-end. Only non-block grants apply to FDA.

For non-block grants, grantees draw funds commensurate with their immediate cash needs which are recorded as advances. Grantees submit quarterly reports summarizing expenditures paid. The process adopted by DHHS to estimate a year-end grant accrual relies on historical spending patterns to predict unreported grantee expenditures. The method separates the accrual into two components. The first component represents the amount of expenditures expected to be reported by grantees for the fourth quarter ending September 30 excluding the expenses incurred but not reported (IBNR) which is discussed below. It is calculated with a data regression model that uses historical grantee advance and expenditure data.

To estimate the second component, IBNR expenses, DHHS gathered information on spending patterns of grantees to identify unreported expenses at fiscal year-end and determined that grantees typically had year-end IBNR expenses equal to approximately two weeks of annual expenditures. Together, the estimated amount of expenditures expected to be reported by grantees for the fourth quarter ending September 30 and the estimated IBNR expenses represent the total amount reported as the accrued grant liability.

N. Deferred Revenue

The passage of PDUFA III allowed FDA to accelerate the FY 2003 and FY 2004 billing and collection of advanced fees from the drug industry during FY 2002 and FY 2003. The PDUFA fees collected in advance of FY 2003 and FY 2004 cannot be used until the new fiscal year, and therefore are considered unavailable until such time.

Statutory provisions require that services provided by FDA's Color Additive Certification Program be performed only upon advance payment of fees by those requesting certification services. Related deposits on-hand are reported on the Balance Sheet as "other liabilities" and are recognized as revenue upon completion of testing of a manufacturer's sample.

O. Accrued Payroll, Unfunded Leave, and Accrued Benefits

These liabilities represent salaries, wages, leave, and benefits earned by employees, but not disbursed as of September 30. Annual leave is accrued as earned and reduced as used. The balances of accrued annual and credit leave are analyzed and adjusted quarterly to reflect current pay rates. Sick leave and other types of nonvested leave are expensed as taken but not accrued when earned.

P. Federal Employee and Veterans' Benefits

The liability for Federal Employee and Veterans' Benefits consists of the actuarial portions of future benefits earned by Federal employees and Veterans, but not yet due and payable. These costs include pensions, other retirement benefits, and other post-employment benefits. These benefit programs are administered by the Office of Personnel Management (OPM) and not by FDA, except as discussed below. Therefore, FDA does not recognize the liability for pensions, other retirement benefits, and other post-employment benefits. FDA does, however, recognize the imputed cost and imputed financing related to these benefits in the Consolidated Statement of Net Cost and the Consolidated Statement of Changes in Net Position, respectively.

FDA employs members of the Commissioned Corps, who have their own retirement plan. Congress annually funds this plan with amounts as may be required through the enactment of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts.

Although FDA contributes toward the provision of pension benefits for eligible employees and makes the necessary payroll withholding, it does not account for the assets of the retirement plans. FDA also does not have actuarial data with respect to accumulated plan benefits or the unfunded liability relative to its eligible employees. These amounts are reported by the respective plan administrators and are not allocated to the individual employers. OPM also accounts for all health and life insurance programs for retired eligible employees.

Pensions: Pensions provide benefits upon retirement and may also provide benefits for death, disability, or other termination of employment before retirement. Pension plans may also include benefits to survivors and dependents, and they may contain early retirement or other special features. Most FDA employees participate in the Civil Service Retirement System (CSRS) or the Federal Employee Retirement System (FERS). Under CSRS, FDA makes matching contributions equal to 7.0 percent of basic pay. For FERS employees, FDA contributes the employer's matching share for Social Security and contributes an amount equal

to one percent of employee pay to a savings plan and matches up to an additional four percent of pay. Most employees hired after December 31, 1983, are covered by FERS. OPM reports on CSRS and FERS assets, accumulated plan benefits, and unfunded liabilities, if any, applicable to Federal employees.

Other Retirement Benefits (ORB): Retirement benefits other than pensions are all forms of benefits to retirees or their beneficiaries provided outside the pension plan. Examples include health and life insurance. Retirement health care benefits are the primary ORB expense.

Other Post-employment Benefits (OPEB): Post-employment benefits other than pensions include all types of benefits provided to former or inactive, but not retired, employees, their beneficiaries, and covered dependents. Inactive employees are those who are not currently rendering services to their employers and who have not been terminated, but who are not eligible for an immediate annuity, including those temporarily laid off or disabled. OPEB includes salary continuation, severance benefits, counseling and training, continuation of health care or other benefits, and unemployment and workers' compensation benefits paid by the employer entity.

Q. Obligations Related to Canceled Appropriations

Payments may be required of up to one percent of current year appropriations for valid obligations incurred against prior year appropriations that have been canceled. The total potential payments related to canceled appropriations is estimated to be approximately $58 and $275 as of September 30, 2003 and 2002, respectively.

R. Revenues and Other Financing Sources

Funding for FDA is classified as revenue or other financing sources. Revenue is an inflow of resources that the Government demands, earns, or receives by donation. Revenue comes from two sources: exchange transactions and nonexchange transactions. Other financing sources include appropriations used, imputed financing sources, and transfers of assets between FDA and other Federal entities.

Exchange and Non-Exchange Revenue: Exchange revenues are those that derive from transactions in which both FDA and another party receive value, including revenue from (1) firms submitting applications to FDA for review of new human drugs, biologics, and medical devices, (2) owners or lessees of facilities which conduct breast cancer screening or diagnosis through mammography activities, (3) firms requesting certification that drugs or medical devices which they are exporting meet certain requirements, and (4) manufacturers of color additives. These revenues are presented in FDA's Consolidated Statements of Net Cost and serve to reduce the reported cost of operations borne by the taxpayer. Non-exchange

revenue derives from the Government's sovereign right to demand payment. Non-exchange revenue is recognized when a reporting entity establishes a specifically identifiable, legally enforceable claim to cash or other asset such as interest receivable on delinquent debts. It is recognized to the extent that the collection is probable and the amount is reasonably estimable.

Appropriations Used: Congressional appropriations are the primary funding source for FDA's programs. For financial statement purposes, appropriations used are recognized as a financing source as expenses are incurred. Under accrual accounting, operating expenses are recognized in the current period while expenditures for capital assets are not recognized as expenses until they are consumed. Financing sources for these expenditures, which are derived from both current and prior year appropriations and operations, are recognized on this same basis.

Imputed Financing Sources: These sources are an "other financing source" that reflect costs incurred by one Federal entity and paid by another Federal entity. These are also known as inter-entity costs. OMB is limiting the inter-entity costs to be recognized by Federal agencies to the following: (1) employee's pension benefits, (2) the health, life insurance, and other benefits for retired employees, (3) other post-employment benefits for retired, terminated, and inactive employees, which include severance payments, training, counseling, continued health care, and unemployment and worker's compensation under the Federal Employees' Compensation Act, and (4) losses in litigation proceedings to account for Treasury Judgment Fund transactions. FDA includes applicable imputed costs in the Consolidated Statements of Net Cost, and an imputed financing source is recognized in the Consolidated Statements of Changes in Net Position.

Transfers-In/Out: Intragovernmental transfers of budget authority (i.e. appropriated funds) or of assets without reimbursement are recorded at the book value of the transferring entity.

S. Contingencies

A contingency is an existing condition, situation, or set of circumstances involving uncertainty as to possible gain or loss to FDA. The uncertainty will ultimately be resolved when one or more future events occur or fail to occur. A contingent liability is recognized when a past transaction or event has occurred, a future outflow or other sacrifice of resources is more likely than not, and the related future outflow or sacrifice of resources is measurable.

T. Use of Estimates in Preparing Financial Statements

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

(In Thousands)

U. Reclassifications

Certain FY 2002 balances reported previously have been reclassified to conform to FY 2003 financial statement presentation.

Note 2 - Fund Balances with Treasury

FDA's undisbursed account balances are listed below by fund type:

	2003	2002
Appropriated General Funds	$ 473,438	$ 460,793
Other Funds	210,866	244,851
Revolving Funds	3,807	5,059
Total Fund Balances with Treasury	**$ 688,111**	**$ 710,703**

Status of Fund Balances with Treasury

	2003	2002
(1) Unobligated Balance		
(a) Available	$ 66,083	$ 75,180
(b) Unavailable	160,538	146,836
(2) Obligated Balanced not yet Disbursed	461,490	488,687
Total	**$ 688,111**	**$ 710,703**

No restrictions on Fund Balances with Treasury exist at September 30, 2003 and 2002.

(In Thousands)

Note 3 - Accounts Receivable, Net

Accounts Receivable, Net consist of the following:

	2003		
	Gross Receivable	Allowance	Net Receivable
Intragovernmental			
Civil Monetary Penalties	$ 20	$ -	$ 20
Interagency Agreements	18,894	-	18,894
Total Intragovernmental	**18,914**	**-**	**18,914**
With the Public			
Civil Monetary Penalties	49,199	-	49,199
Prescription Drug User Fee Act	6,629	670	5,959
Medical Device User Fee and Modernization Act	780	-	780
Mammography Quality Standards Act	1,031	88	943
Travel Refunds & Miscellaneous	173	52	121
Export Reform & Enhancement Act	556	19	537
Other	48	-	48
Total With the Public	**58,416**	**829**	**57,587**
Total	**$ 77,330**	**$ 829**	**$ 76,501**

(In Thousands)

	2002		
	Gross Receivable	Allowance	Net Receivable
Intragovernmental			
Civil Monetary Penalties	$ 20	$ -	$ 20
Interagency Agreements	11,310	-	11,310
Total Intragovernmental	**11,330**	**-**	**11,330**
With the Public			
Civil Monetary Penalties	373,007	-	373,007
Prescription Drug User Fee Act	2,863	557	2,306
Mammography Quality Standards Act	1,151	145	1,006
Travel Refunds & Miscellaneous	2,295	63	2,232
Export Reform & Enhancement Act	605	35	570
Other	13	-	13
Total With the Public	**379,934**	**800**	**379,134**
Total	**$391,264**	**$ 800**	**$ 390,464**

Civil Monetary Penalties

The FDA is authorized by the Food, Drug, and Cosmetic Act to assess and collect civil monetary penalties for violations in areas such as illegally manufactured, marketed, and distributed animal feeds and drug products. CMP cases initiated by FDA General Counsel are submitted to the Department of Justice (DOJ) for final adjudication. CMPs assessed by DOJ are collected and subsequently forwarded to FDA, net of a 3% fee.

CMP collections are considered FDA's only non-entity asset because they are immediately forwarded to the Department of Treasury and cannot be used for FDA operations. FDA penalties collected in FY 2003 total $398,481 ($373,746 for FY 2002) net of DOJ fees of approximately $11,954 ($11,212 for FY 2002). Receivables arising from CMPs are recorded when the penalties are assessed by FDA/DOJ. FDA has recorded intragovernmental accounts receivable totaling $20 ($20 for FY 2002) based on settlement agreements or court decisions against private entities who submitted payment to DOJ however FDA has not yet received the payment from DOJ as of September 30. A corresponding non-entity custodial liability, Resources Payable to the Department of Treasury, of $49,219 ($373,027 for FY 2002) is recorded on the balance sheet.

(In Thousands)

Note 4 - Cash

All cash on hand consists of petty cash funds and is considered an entity asset. The petty cash funds are used for miscellaneous reimbursements for local travel, undercover criminal investigations, and other miscellaneous expenses. The total balance of petty cash funds as of September 30, 2003 and 2002, is $155.

Note 5 - General Property, Plant, and Equipment, Net

Balances for the major categories of FDA Property, Plant, and Equipment, Net are listed below:

	2003			
Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulated Depreciation	Net Book Value
Personal Property:				
Laboratory and Office Equipment	10	$ 101,502	$ 49,906	$ 51,596
ADP and Telecom Equipment	8	34,873	15,741	19,132
Internal Use Software	4	1,457	1,092	365
Capital Lease - Security System	20	1,380	272	1,108
Total Personal Property		139,212	67,011	72,201
Real Property:				
Buildings, Facilities, & Structures	5 - 50	281,077	102,041	179,036
Capital Lease - Structure	30	806	134	672
Land	N/A	8,957	-	8,957
Total Real Property		290,840	102,175	188,665
In Progress:				
Construction	N/A	13,460	-	13,460
Software	N/A	17,914	-	17,914
Total In Progress		31,374	-	31,374
Total		**$ 461,426**	**$ 169,186**	**$ 292,240**

(In Thousands)

2002				
Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulated Depreciation	Net Book Value
Personal Property:				
Laboratory and Office Equipment	10	$ 87,291	$ 46,608	$ 40,683
ADP and Telecom Equipment	8	28,420	14,250	14,170
Internal Use Software	4	1,457	729	728
Capital Lease - Security System	20	1,380	201	1,179
Total Personal Property		118,548	61,788	56,760
Real Property:				
Buildings, Facilities, & Structures	5 - 50	227,282	94,363	132,919
Capital Lease - Structure	30	806	107	699
Land	N/A	8,957	-	8,957
Total Real Property		237,045	94,470	142,575
In Progress:				
Construction	N/A	49,083	-	49,083
Software	N/A	12,564	-	12,564
Total In Progress		61,647	-	61,647
Total		**$ 417,240**	**$ 156,258**	**$ 260,982**

Note 6 - Other Assets

Other Assets is comprised of the following:

	2003		2002	
	Intra-governmental	With the Public	Intra-governmental	With the Public
Travel and Employee Advances	$ -	$ 254	$ -	$ 292
Prepaid Subscriptions	-	-	13	-
NCTR Energy Conservation Project	8,581	-		-
Total Other Assets	**$ 8,581**	**$ 254**	**$ 13**	**$ 292**

(In Thousands)

The FDA, National Center for Toxicological Research (NCTR) and the Department of Energy, Bonneville Power Administration (BPA) entered into an interagency agreement in August 2003 that states that BPA will provide financing for the Energy Conservation Project (ECP). The purpose of the interagency agreement is to finance energy conservation improvements at the Jefferson Laboratories in Jefferson, Arkansas to comply with Executive Order 13123. Executive Order 13123 mandates that energy consumption be reduced 30% by the year 2005, and 35% by the year 2010. BPA will fund into an escrow account $8,620 to be used for construction period costs including accrued interest at 5.88%. In addition, NCTR will earn interest income at the rate of 0.75% on the balance in the escrow account during the construction period. Beginning on January 1, 2005, NCTR will repay the loan in ten annual payments of $1,112 at the 5.88% interest rate.

Note 7 - Environmental and Disposal Costs

Environmental and Disposal Costs are the costs of removing, containing, or disposing of material or property that consists of hazardous waste at (1) permanent or temporary sites selected for closure or shutdown, (2) active sites undergoing renovations, and (3) active sites not scheduled for closure or renovation. FDA's cleanup costs are primarily related to the closure and subsequent decommissioning of laboratory facilities related to its field and headquarters consolidation efforts. In many instances, FDA has performed laboratory operations using various chemical, biological, and/or radiological materials in these facilities for over 30 years. As a result of such use, the decommissioning of each building or facility is planned so the Federal government will take all actions required of it under the terms of the related lease and by all applicable federal, state, and local environmental laws.

FDA's estimated liability for government-related future cleanup of hazardous waste does not consider the effect of future new technology, laws, or regulations. The method of assigning cost is based on estimated costs of similar remediation projects. The following table presents FDA's estimated cleanup cost liability as of September 30, 2003 and 2002:

	2003	2002
Liabilities Covered By Budgetary Resources	$ 2,473	$ 1,262
Liabilities Not Covered By Budgetary Resources	3,011	2,956
Total Environmental and Disposal Costs	**$ 5,484**	**$ 4,218**

Note 8 - Federal Employee and Veterans' Benefits

The Federal Employees Compensation Act (FECA) provides income and medical cost protection to covered Federal civilian employees injured on the job; employees who have incurred a work-related occupational disease; and beneficiaries of employees whose death is

(In Thousands)

attributable to a job-related injury or occupational disease. The FECA program is administered by the U.S. Department of Labor, which initially pays valid claims and unpaid billings and is subsequently reimbursed from the Federal agencies employing the claimants. The actuarial liability for future workers' compensation benefits is determined using a method that utilizes historical benefit payment patterns related to a specific incurred period to predict the ultimate payment related to that period. Consistent with the past practice, these projected
annual benefit payments have been discounted to present value using OMB's economic assumptions for 10-year Treasury notes and bonds. The present value of these estimates was calculated using a discount rate of 3.84 percent in the first year and thereafter for FY 2003 (4.85 percent in the first year and thereafter for FY 2002).

To provide more specifically for the effects of inflation on the liability for future workers' compensation benefits, wage inflation factors (cost of living adjustments or COLAs) and medical inflation factors (consumer price index medical) are applied to the calculation of projected future benefits. These factors are also used to adjust the methodology's historical payments to current year dollars. The methodology also includes a discounting formula to recognize the timing of compensation payments per year instead of one lump sum per year.

This liability at September 30, 2003 and 2002, amounted to $22,397 and $21,100, respectively, and is considered a liability not covered by budgetary resources.

Note 9 - Accrued Payroll and Benefits

Accrued Payroll and Benefits consist of the following:

	2003					
	Intragovernmental			With the Public		
	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total
Accrued Payroll	$ -	$ -	$ -	$ 26,248	$ -	$ 26,248
Accrued Leave	-	-	-	147	67,563	67,710
Payroll Withholding	4,004	-	4,004	-	-	-
Accrued Workers' Compensation	-	3,678	3,678	-	-	-
Total	**$ 4,004**	**$ 3,678**	**$ 7,682**	**$ 26,395**	**$ 67,563**	**$ 93,958**

(In Thousands)

2002

	Intragovernmental			With the Public		
	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total
Accrued Payroll	$ -	$ -	$ -	$ 47,202	$ -	$ 47,202
Accrued Leave	-	-	-	137	62,319	62,456
Payroll Withholding	8,449	-	8,449	-	-	-
Accrued Workers' Compensation	-	3,370	3,370	-	-	-
Total	**$ 8,449**	**$ 3,370**	**$ 11,819**	**$ 47,339**	**$ 62,319**	**$109,658**

Note 10 – Accrued Grant Liability, Net

	2003	2002
Grant Advances Outstanding (before year-end grant accrual)	$10,321	$ 8,548
Less: Estimated Accrual for Amounts Due to Grantees	11,518	8,645
Accrued Grant Liability, Net	**$ 1,197**	**$ 97**

Note 11 - Other Liabilities

Other Liabilities consist of the following:

2003

	Intragovernmental			With the Public		
	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total
Capital Lease	$ -	$ 924	$ 924	$ -	$ 541	$ 541
Deferred Revenue		-	-	139,498	-	139,498
Other	-	-	-	293	8,620	8,913
Total	**$ -**	**$ 924**	**$ 924**	**$ 139,791**	**$ 9,161**	**$148,952**

(In Thousands)

	2002					
	Intragovernmental			With the Public		
	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total	Liabilities Covered by Budgetary Resources	Liabilities Not Covered by Budgetary Resources	Total
Capital Lease	$ -	$ 947	$ 947	$ -	$ 599	$ 599
Contingent Liability	-	-	-	-	160	160
Deferred Revenue	282	-	282	127,709	-	127,709
Other	-	-	-	20	-	20
Total	**$ 282**	**$ 947**	**$ 1,229**	**$ 127,729**	**$ 759**	**$ 128,488**

All other liabilities are considered current except for the capital lease liability. The portion of the total capital lease liability of $1,465 ($1,546 for FY 2002) considered current is $98 ($86 for FY 2002), and the remaining balance, $1,367 ($1,460 for FY 2002), is considered non-current. See Note 13 for more information on capital leases.

Note 12 - Commitments and Contingencies

Commitments

FDA is committed for goods and services that have been ordered, but have not yet been delivered. As of September 30, 2003 and 2002, FDA's undelivered orders were $364,418 and $350,397, respectively. The entire balance has been funded with budgetary resources received in FY 2003 and prior years.

A summary of long-term commitments for construction and software development projects over $5,000 per project is as follows:

Fiscal Year	Amount
2004	$ 26,715
2005	28,814
2006	10,680
2007	8,939
2006	5,842
Total	**$ 80,990**

(In Thousands)

Contingencies

FDA is party in various administrative proceedings, legal actions, and claims brought against it. In the opinion of FDA management, legal counsel, and DHHS legal counsel, the ultimate resolution of these proceedings, actions, and claims will not materially affect the financial position or net costs of FDA. These cases are administered and resolved by the U.S. Department of Justice and any amounts necessary for resolution are obtained from a special Judgment Fund maintained by the U.S. Department of the Treasury under title 31 United States Code, section 1304. Unfavorable judgments do not result in claims against FDA directly. Losses paid by the Judgment Fund on behalf of FDA do not require reimbursement. As of September 30, 2003, FDA was not required to accrue any legal contingent liability ($160 for FY 2002).

Note 13. Leases

Future lease payments are as follows:

Fiscal Year	Capital Leases	Operating Leases	
2004	$ 232	$ 133,115	
2005	222	136,667	
2006	222	139,959	
2007	222	144,091	
2008	222	148,338	
2009 and Thereafter	1,425	665	**
Total Future Lease Payments	2,545	$ 702,835	
Less: Imputed Interest	(1,080)		
Total Capital Lease Liability (Note 11)	**$ 1,465**		

** Future Lease payments are expected; however, dollar figures for GSA cannot be reasonably estimated.

As of September 30, 2003 and 2002, FDA had one personal property capital lease for a security system used at its Jamaica, NY field office. The lease has 16 years remaining of its 20-year life. Real property capital leases consist of two leases for a cooling tower at FDA's Arkansas Regional Laboratory. Both leases have a life of 10 years. The total capital lease liability is considered unfunded as of September 30, 2003 and 2002.

Operating leases for real property cover GSA and non-GSA leased assets. Operating leases comprise the majority of FDA's fiscal year 2003 and 2002 real property rental expense and have terms of more than two years. GSA charges FDA rates that approximate commercial rates for comparable space. FDA may elect to terminate these leases with 120 days notice to GSA at any time. FDA has the authority to lease its own space for laboratories, testing materials, etc. because, in many cases, GSA does not own property that will satisfy the needs of FDA's scientific and research activities. For FY 2003, FDA had five (five for FY 2002) non-GSA operating leases consisting mostly of laboratories and office space.

Operating leases for personal property are for the rental of GSA vehicles at FDA's headquarters and at its field offices. As of September 30, 2003, FDA maintained approximately 1,005 (975 for FY 2002) vehicles leased from GSA. GSA charges FDA rates that are less than commercial rates for comparable vehicles. FDA may elect to terminate these leases within 120 days notice to GSA, at any time.

Note 14 - Combined Statements of Budgetary Resources

The Statement of Budgetary Resources (SBR) was prepared on a "combined" basis and does not contain intra-FDA eliminations, which may result in a distortion of reported total budgetary resources compared to actual budgetary resources received by FDA as a whole.

Salaries and Expenses (S&E), FDA's largest appropriation, is a one year appropriation. FDA has a number of "no-year" or "permanent indefinite" funds. These funds are the Revolving Fund for Certification, Building and Facilities; and Cooperative Research and Development Agreements. Permanent indefinite funds are available until they are no longer deemed necessary in supporting the agency's mission. FDA also has a multi-year appropriation to record collections and disbursements for patents and royalties.

FDA received 72.9% or $1,392,580 (79.2%, or $1,387,845 for FY 2002), of its total FY 2003 budgetary resources of $1,911,207 ($1,752,448 for FY 2002) through appropriations. FDA's S&E account was appropriated $1,382,702 ($1,179,670 for FY 2002), which accounts for 99.3% (85% for FY 2002) of the total appropriations received. Permanent indefinite appropriations are available for FDA to accomplish its mission until expended or Congress enacts legislation to rescind or cancel remaining budget authority.

Other sources of funding included reimbursable programs and unobligated carryovers from prior years. Reimbursable programs, which provide funds from other Federal or private entities in exchange for goods or services, account for about 17.8% of total FY 2003 (19.5% for FY 2002) budgetary resources. Unobligated carryovers represent amounts of spending authority that have not been committed or earmarked for expenditure. Carryovers represent about 11.6% of FY 2003 (4.9% for FY 2002) budgetary resources.

FDA has both Category A (apportioned over a time period) and Category B (apportioned by activity/project) obligations. Category A obligations totaled $1,776,791 ($1,496,157 for FY 2002). Category B obligations totaled $46,664 ($161,345 for FY 2002).

FDA has a Contingency Fund that was established in FY 1983 whereby funds are to be used for unusual direct costs of product emergencies (i.e., Tylenol incident, Breast Implant Hotline, etc.). The fund was justified for costs of overtime, travel, and the cost of buying samples and other supplies for national public health emergencies and for contracts with the states as needed. Two rules were set for the use of this fund: (1) only for emergency costs exceeding $100 over the normal budget and (2) any use has to be specifically apportioned and approved by OMB. During FY 2003, FDA requested and was approved by OMB to utilize the balance of this account ($1,160) in support of food safety and security activities, including testing methodologies, reagents and chemical supplies. FDA is not requesting additional resources for this account.

FDA received $168,100 in funding in FY 2002 ($17,000 of which was rescinded), to remain available until expended, to support Counter Terrorism projects that recognize the important role FDA plays in protecting the public health. The attacks of September 11, 2001 and subsequent national events resulted in an accelerated and intensified need for attention to activities related to counter terrorism. FDA's focus is in three key areas: food safety, safe and effective medical products, and physical security. The amount obligated for counter terrorism projects through FY 2003 was approximately $150,000.

FDA received $5,000 in funding in FY 2003, to remain available until expended, to support research related to food safety and security. The Executive Office of the President transferred this amount and the Congress was notified as required by the Emergency Response Fund (PL 107-38). Approximately $967 was obligated in FY 2003.

The Prescription Drug User Fee Act of 1992 (PDUFA) was re-authorized by the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, PL 107-188). This change allowed FDA to accelerate the FY 2004 billing and collection of advanced fees from the drug industry during FY 2003. The PDUFA fees collected in advance of FY 2004 cannot be used until the new fiscal year (October 1, 2003) and passage of an FDA appropriation, and therefore, are considered unavailable until FY 2004. In FY 2003 FDA obligated $200,155.

The Federal Food, Drug and Cosmetic Act was amended to include the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) by PL 107-250. This act allows the FDA to collect fees for the review of most medical device applications. Billing and collections to this account began with the enactment of the FY 2003 Appropriations. In FY 2003 FDA obligated $14,838.

(In Thousands)

FDA has the authority to collect fees for the Mammography Quality Standards Act of 1992 and for the Export Reform and Enhancement Act of 1996. These sources of funding are included as well as the unobligated carryovers from prior years.

Statement of Federal Financial Accounting Standard (SFFAS) No. 7, "Accounting for Revenue and Other Financing Sources" calls for explanations of any material differences between the information required by paragraph 77 of SFFAS 7 and the amounts described as "actual" in the "*Budget of the United States Government"* (also called the "President's Budget"). Paragraph 77 of SFFAS 7 calls for presentation of total budgetary resources available to a reporting entity, the status of those resources, and outlays of the reporting entity.

Chapter 11, Title 31, U.S. Code requires: "On or after the first Monday in January but not later than the first Monday in February of each year, the President shall submit a budget of the United States Government for the following fiscal year." The FY 2005 President's Budget, with actual numbers for FY 2003, has not yet been published, and therefore no comparisons can be made between FY 2003 amounts presented in the SBR with amounts reported in the "actual" column of the President's Budget. The FY 2005 President's Budget is expected to be released on February 3, 2004, and may be obtained from the Office of Management and Budget or the U.S. Government Printing Office at that time.

The material differences between the balances reported in the "actual" column in the President's Budget and the SBR for FY 2002 are as follows:

	Budgetary Resources	Net Outlays
Statement of Budgetary Resources	$ 1,752,448	$ 1,126,803
Adjustment For Expired Accounts	(98,931)	-
Other Adjustments	127,223	-
President's Budget (actual)	**$1,780,740**	**$1,126,803**

The President's Budget does not include the expired year activity and includes only the current year budgetary transactions. Therefore, these amounts are subtracted from the SBR amounts. The DHHS budget office requested FDA to include the PDUFA FY 2003 collections received in FY 2002 as budgetary resources for the President's Budget. Pursuant to Public Law, these collections were not considered budgetary resources on the SBR because they were not available for use until October 1, 2002.

Note 15 – Custodial Activity

Custodial activity primarily involves collections for civil monetary penalties assessed by the Department of Justice on behalf of FDA. Penalties are assessed for violations in areas such as illegally manufactured, marketed, and distributed animal feeds and drug products. Total CMP collections in FY 2003 were $398,481 ($373,746 for FY 2002). CMP collections are immediately forwarded to the Department of Treasury when collected and cannot be used for FDA operations. Also see Note 3.

Section III - Required Supplementary Information (Unaudited)

U.S. Department of Health and Human Services

Food and Drug Administration

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2003

(In Thousands)

(Unaudited)

	User Fees Account 75X0600	CRADAs 75X5148	Building & Facilities 75X0603	Certification Fund 75X4309	GSA Building Delegation 75X0601	Salaries & Expenses 75_0600	Gift Fund 75X8247	White Oak 752.30600	Royalties 75_/_0600	Total
Budgetary Resources:										
Budget authority :										
Appropriations Received	-	1,878	8,000	-	-	1,382,702	-	-	-	1,392,580
Net Transfers	(187,309)	-	-	-	1,209	190,517	-	-	-	4,417
Unobligated balance:										
Beginning of Period	172,727	2,066	23,360	3,903	-	16,327	-	3,138	648	222,169
Net Transfers, actual	(22,683)	-	-	-	-	22,683	-	-	-	-
Spending authority from offsetting collections:										
Earned										
Collected	253,467	25	720	5,141	-	68,577	-	-	388	328,318
Receivable from Federal sources	-	-	-	-	-	4,243	-	-	-	4,243
Change in unfilled customer orders										
Advance Received	11,645	-	-	69	-	-	-	-	-	11,714
Without advance from Federal sources	(1,480)	-	-	-	-	(2,329)	-	-	-	(3,809)
Subtotal	263,632	25	720	5,210	-	70,491	-	-	388	340,466
Recoveries of prior year obligations	4,411	133	1,977	440	-	106,023	-	-	-	112,984
Temporarily not available pursuant to Public Law	(138,869)	-	-	-	-	-	-	-	-	(138,869)
Permanently not available	-	-	(52)	-	-	(22,488)	-	-	-	(22,540)
Total Budgetary Resources	91,909	4,102	34,005	9,553	1,209	1,766,255	-	3,138	1,036	1,911,207
Status of Budgetary Resources:										
Obligations incurred :										
Direct	46,664	1,643	17,043	7,855	1,209	1,720,234	-	3,138	539	1,798,325
Reimbursable	-	-	-	-	-	25,130	-	-	-	25,130
Subtotal	46,664	1,643	17,043	7,855	1,209	1,745,364	-	3,138	539	1,823,455
Unobligated balance:										
Apportioned	45,245	2,459	16,962	816	-	104	-	-	497	66,083
Unobligated balance not available	-	-	-	882	-	20,787	-	-	-	21,669
Total Status of Budgetary Resources	91,909	4,102	34,005	9,553	1,209	1,766,255	-	3,138	1,036	1,911,207
Relationship of Obligations to Outlays:										
Obligated balance, net, beginning of period	68,828	582	23,026	1,155	-	394,482	-	614	-	488,687
Obligated balance, net, end of period:										
Accounts receivable	-	-	-	-	-	(13,672)	-	-	-	(13,672)
Unfilled customer orders from Federal sources	(13,121)	-	-	-	-	(4,789)	-	-	-	(17,910)
Undelivered Orders	29,194	991	9,731	1,695	-	338,530	-	2,262	-	382,403
Accounts payable	6,715	17	2,332	414	-	101,028	-	316	-	110,822
Outlays:										
Disbursements	89,775	1,083	26,028	6,461	1,209	1,610,813	-	1,173	539	1,737,081
Collections	(265,113)	(25)	(720)	(5,210)	-	(68,576)	-	-	(388)	(340,032)
Subtotal	(175,338)	1,058	25,308	1,251	1,209	1,542,237	-	1,173	151	1,397,049
Less: Offsetting receipts	-	(1,878)	-	-	-	-	-	-	-	(1,878)
Net Outlays	(175,338)	(820)	25,308	1,251	1,209	1,542,237	-	1,173	151	1,395,171

U.S. Department of Health and Human Services

Food and Drug Administration

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2002

(In Thousands)

(Unaudited)

	User Fees Account 75X0600	CRADAs 75X5148	Building & Facilities 75X0603	Certification Fund 75X4309	GSA Building Delegation 75X0601	Salaries & Expenses 75_0600	Gift Fund 75X8247	White Oak 752.30600	Royalties 75_/_0600	Total
Budgetary Resources:										
Budget authority :										
Appropriations Received	168,100	1,754	34,281	-	-	1,179,670	40	4,000	-	1,387,845
Net Transfers	(126,395)	-	-	-	1,184	125,211	-	-	-	-
Unobligated balance:										
Beginning of Period	39,379	1,345	27,865	3,852	-	12,965	-	-	310	85,716
Net Transfers, actual	(35,416)	-	-	-	-	35,416	-	-	-	-
Spending authority from offsetting collections:										
Earned										
Collected	163,581	1	44	4,988	-	31,160	-	-	507	200,281
Receivable from Federal sources	-	-	-	-	-	3,110	-	-	-	3,110
Change in unfilled customer orders										
Advance Received	127,223	-	-	68	-	-	-	-	-	127,291
Without advance from Federal sources	14,600	-	-	-	-	(2,800)	-	-	-	11,800
Subtotal	305,404	1	44	5,056	-	31,470	-	-	507	342,482
Recoveries of prior year obligations	-	37	5,037	233	-	88,252	-	-	-	93,559
Temporarily not available pursuant to Public Law	(127,224)	-	-	-	-	-	-	-	-	(127,224)
Permanently not available	(17,000)	-	-	-	-	(12,930)	-	-	-	(29,930)
Total Budgetary Resources	206,848	3,137	67,227	9,141	1,184	1,460,054	40	4,000	817	1,752,448
Status of Budgetary Resources:										
Obligations incurred :										
Direct	161,345	1,071	43,867	5,237	1,184	1,421,963	40	862	169	1,635,738
Reimbursable	-	-	-	-	-	21,764	-	-	-	21,764
Subtotal	161,345	1,071	43,867	5,237	1,184	1,443,727	40	862	169	1,657,502
Unobligated balance:										
Apportioned	44,343	2,066	23,360	1,537	-	88	-	3,138	648	75,180
Unobligated balance not available	1,160	-	-	2,367	-	16,239	-	-	-	19,766
Total Status of Budgetary Resources	206,848	3,137	67,227	9,141	1,184	1,460,054	40	4,000	817	1,752,448
Relationship of Obligations to Outlays:										
Obligated balance, net, beginning of period	794	840	26,255	841	-	365,299	-	-	-	394,029
Obligated balance, net, end of period:										
Accounts receivable	-	-	-	-	-	(9,430)	-	-	-	(9,430)
Unfilled customer orders from Federal sources	(14,601)	-	-	-	-	(7,118)	-	-	-	(21,719)
Undelivered Orders	61,991	561	17,964	747	-	287,685	-	382	-	369,330
Accounts payable	21,438	20	5,062	408	-	123,346	-	232	-	150,506
Outlays:										
Disbursements	78,710	1,292	42,061	4,690	1,184	1,325,981	40	248	169	1,454,375
Collections	(290,804)	(1)	(44)	(5,056)	-	(31,160)	-	-	(507)	(327,572)
Subtotal	(212,094)	1,291	42,017	(366)	1,184	1,294,821	40	248	(338)	1,126,803
Less: Offsetting receipts	-	(1,754)	-	-	-	-	(40)	-	-	(1,794)
Net Outlays	(212,094)	(463)	42,017	(366)	1,184	1,294,821	-	248	(338)	1,125,009

U. S. Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL STATEMENT OF NET COST BY EXPENSE TYPE AND PROGRAM

For the Fiscal Year Ended September 30, 2003
(In Thousands)
(Unaudited)

Expense Type	Foods	Human Drugs	Biologics	Animal Drugs and Feeds	Devices and Radiological Health	National Center for Toxicological Research	TOTALS
Personnel Services and Benefits	277,605	310,975	136,461	64,870	169,882	27,111	986,904
Travel & Transportation	14,062	9,738	3,713	2,570	5,479	1,054	36,616
Rent, Communication, and Utilities	53,559	34,888	12,750	16,406	23,446	2,134	143,183
Printing & Reproduction	919	441	233	115	267	52	2,027
Contractual Services	87,918	79,999	50,993	28,060	54,732	24,099	325,801
Supplies and Materials	8,499	6,068	6,561	2,118	2,766	4,052	30,064
Non-Capitalized Equipment	12,685	15,936	5,388	2,572	5,238	3,607	45,426
Grants, Subsidies, Contributions	13,926	6,110	2,336	2,477	3,530	724	29,103
Insurance Claims & Indemnities	179	219	307	81	226	(13)	999
Depreciation	6,859	3,153	1,783	950	3,169	3,451	19,365
Bad Debts and Write-offs	28	24	9	2	7	5	75
Interest Expense	77	42	15	11	20	86	251
Imputed Retirement Costs	23,088	22,108	9,312	5,046	13,350	1,858	74,762
Loss on Disposition of Property	1,243	1,103	48	229	1,765	61	4,449
Applied Overhead	(1,117)	(713)	(160)	(83)	(204)	(50)	(2,327)
Gross Costs	499,530	490,091	229,749	125,424	283,673	68,231	1,696,698
Less: Earned Revenues	(8,911)	(193,526)	(27,815)	(1,418)	(36,691)	(19,611)	(287,972)
Net Cost	490,619	296,565	201,934	124,006	246,982	48,620	1,408,726

U. S. Department of Health and Human Services

FOOD AND DRUG ADMINISTRATION

SUPPLEMENTAL STATEMENT OF NET COST BY EXPENSE TYPE AND PROGRAM

For the Fiscal Year Ended September 30, 2002
(In Thousands)
(Unaudited)

Expense Type	Foods	Human Drugs	Biologics	Animal Drugs and Feeds	Devices and Radiological Health	National Center for Toxicological Research	TOTALS
Personnel Services and Benefits	248,308	267,497	118,501	59,743	151,044	22,690	867,783
Travel & Transportation	12,721	7,741	3,214	2,496	4,573	778	31,523
Rent, Communication, and Utilities	49,174	29,385	12,487	14,690	22,391	2,217	130,344
Printing & Reproduction	842	511	294	145	346	39	2,177
Contractual Services	69,962	69,722	43,766	21,844	47,236	21,027	273,557
Supplies and Materials	6,680	4,844	7,885	2,201	2,695	3,093	27,398
Non-Capitalized Equipment	19,919	12,654	8,913	4,945	7,176	1,802	55,409
Grants, Subsidies, Contributions	11,231	5,552	1,707	2,596	2,283	498	23,867
Insurance Claims & Indemnities	(31)	(6)	146	22	71	(43)	159
Depreciation	5,586	2,635	1,362	780	2,925	4,029	17,317
Bad Debts and Write-offs	(137)	(134)	(61)	(27)	(40)	(21)	(420)
Interest Expense	81	43	19	13	22	53	231
Imputed Retirement Costs	19,143	18,232	7,845	4,216	11,993	1,595	63,024
Loss on Disposition of Property	22	(1)	4	2	(16)	17	28
Applied Overhead	(941)	(941)	(125)	(62)	(148)	(39)	(2,256)
Other	(1,697)	(202)	(437)	(31)	(315)	18	(2,664)
Gross Costs	440,863	417,532	205,520	113,573	252,236	57,753	1,487,477
Less: Earned Revenues	(9,810)	(137,130)	(18,104)	(837)	(11,351)	(12,072)	(189,304)
Net Cost	431,053	280,402	187,416	112,736	240,885	45,681	1,298,173

(In thousands) Unaudited

Deferred Maintenance

Deferred maintenance is maintenance that was not performed when it should have been, that was scheduled and not performed, or that was delayed for a future period. Maintenance is the act of keeping property, plant, and equipment in acceptable operating condition, including preventive maintenance, normal repairs, replacement of parts and structural components, and other activities needed to preserve the asset so that it continues to provide acceptable services and achieves its expected life. Maintenance excludes activities aimed at expanding the capacity of an asset or otherwise upgrading it to serve needs different from, or significantly greater than, those originally intended. Maintenance expense is recognized as incurred.

FDA used the Condition Assessment Survey method (CAS) to identity and quantify deferred maintenance for all classes of property. CAS requires a periodic inspection of real property to determine its current condition and to estimate the costs likely to be incurred by the correction of any deficiencies.

FDA operates laboratory facilities and buildings throughout the United States, in which the Agency performs various aspects of its regulatory mission. This includes scientific testing, sampling, methods development, and research in connection with the evaluation or investigation of regulated products. Management's definition of critical maintenance is life-safety and environmental health projects, energy conservation projects, and projects in laboratories that are considered in poor condition. The following tables present FDA's real property for which deferred maintenance exists as of September 30, 2003 and 2002:

FY 2003

Category	Asset Condition	Cost to Return to Acceptable Condition	Critical Amount	Non-Critical Amount
Buildings	**Fair to Poor**	**$29,026**	**$3,816**	**$25,210**
Laboratories	**Fair to Poor**	**$8,230**	**$3,206**	**$5,024**
Utility Systems	**Poor**	**$8,725**	**$1,957**	**$6,768**
Utility Systems	**Good**	**$597**	**-**	**$597**
Total		**$46,578**	**$8,979**	**$37,599**

FY 2002

Buildings	**Fair to Poor**	**$25,837**	**$3,322**	**$22,515**
Laboratories	**Fair to Poor**	**$6,130**	**$1,638**	**$4,492**
Utility Systems	**Poor**	**$5,296**	**-**	**$5,296**
Total		**$37,263**	**$4,960**	**$32,303**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION

INTRAGOVERNMENTAL TRANSACTIONS

As of September 30, 2003 and 2002

(In Thousands)

(Unaudited)

Intragovernmental Assets

Agency	TFM Dept. Code	Fund Balance w/Treasury	Accounts Receivable	Other	Total
		2003			
Department of Agriculture	12		$ 344		$ 344
Department of Commerce	13		249		249
Department of Defense	17,21,57,97		3,698		3,698
Department of Energy	89		15	8,581	8,596
Department of Health and Human Services	75		12,503		12,503
Department of Interior	14		27		27
Department of Justice	15		782		782
Department of State	19		58		58
Department of Transportation	69		154		154
Department of Treasury	20,99	$ 688,111			688,111
Department of Veterans Affairs	36		41		41
Environmental Protection Agency	68		387		387
Department of Homeland Security	70		24		24
General Services Administration	47		192		192
National Aeronautics & Space Admin	80		34		34
Nuclear Regulatory Commission	31		335		335
Social Security Admin	28		20		20
All other Ferderal agencies			51		51
Total		**$ 688,111**	**$ 18,914**	**$ 8,581**	**$ 715,606**
		2002			
Department of Agriculture	12		$ 696		$ 696
Department of Commerce	13		77	$ 13	90
Department of Interior	14		63		63
Department of Defense	17, 21, 57, 97		2,268		2,268
Department of Energy	89		129		129
Department of Health and Human Services	75		5,125		5,125
Department of Justice	15		2,109		2,109
Department of Transportation	69		300		300
Department of the Treasury	20	$ 710,703	49		710,752
Department of Veterans Affairs	36		76		76
General Services Administration	47		47		47
National Aeronautics & Space Administration	80		67		67
Social Security Administration	28		1		1
State Department	19		304		304
Environmental Protection Agency	68		14		14
All Other Federal Agencies			5		5
TOTAL		**$ 710,703**	**$ 11,330**	**$ 13**	**$ 722,046**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
As of September 30, 2003 and 2002
(In Thousands)
(Unaudited)

Intragovernmental Liabilities

Agency	TFM Dept. Code	Accounts Payable	Accrued Payroll & Benefits	Other	Total
		2003			
Department of Defense	17,21,57,97	$ 1,019			$ 1,019
Department of Energy	89	91			91
Department of Health and Human Services	75	3,604			3,604
Department of Labor	16		$ 3,678		3,678
Department of Transportation	69				-
Department of Treasury	20,99	75	1,020	$ 49,219	50,314
General Services Administration	47	5,190		924	6,114
Office of Personnel Mgmt	24	2	2,984		2,986
All other Ferderal agencies		863			863
Total		**$ 10,844**	**$ 7,682**	**$ 50,143**	**$ 68,669**
		2002			
Department of Agriculture	12	$ 34			$ 34
Department of Defense	17, 21, 57, 97	126			126
Department of Justice	15	49			49
Department of Energy	89	580			580
Department of Health and Human Services	75	7,316			7,316
Department of Interior	14	2			2
Department of Labor	16		$ 3,370		3,370
Department of the Treasury	20		2,143	$ 373,027	375,170
Federal Emergency Management Agency	58			47	47
General Services Administration	47	4,419		947	5,366
Nuclear Regulatory Commission	31			235	235
Office of Personnel Management	24	26	6,306		6,332
All Other Federal Agencies		697			697
TOTAL		**$ 13,249**	**$ 11,819**	**$ 374,256**	**$ 399,324**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION

INTRAGOVERNMENTAL TRANSACTIONS

For the Year Ended September 30, 2003

(In Thousands)

(Unaudited)

Intragovernmental Revenues and Expenses

Agency	TFM Dept. Code	Revenues	Imputed Financing	Net Transfers	Expenses
Department of Agriculture	12				$ 4,409
Department of Commerce	13				1
Department of Defense	17,21,57,97	$2,788			3,004
Department of Education	91				
Department of Energy	89	6			5,153
Department of Housing & Urban Development	86				
Department of Health and Human Services	75	34,907	$ 18,617	$ 52	83,058
Department of Interior	14	54			454
Department of Justice	15	1,579			
Department of Labor	16				1,855
Department of State	19	504			6
Department of Transportation	69	331			
Department of Treasury	20,99		31		41,783
Department of Veterans Affairs	36	75			849
Agency for International Development	72				
Environmental Protection Agency	68	930			
Department of Homeland Security	70	18			
General Services Administration	47				140,398
National Aeronautics & Space Admin	80	192			
National Science Foundation	49				1
Nuclear Regulatory Commission	31	559			
Office of Personnel Mgmt	24		56,113		185,450
Small Business Admin	73				
Social Security Admin	28	40			
RRB	60				
All other Ferderal agencies		5			4,498
Total		**$ 41,988**	**$ 74,761**	**$ 52**	**$ 470,919**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
For the Year Ended September 30, 2002
(In Thousands)
(Unaudited)

Intragovernmental Revenues and Expenses

Agency	TFM Dept. Code	Revenues	Imputed Financing	Net Transfers	Expenses
Department of Agriculture	12	$ 25			$ 1,691
Department of Commerce	13				73
Department of Defense	17, 21, 57, 97	1,088			3,378
Department of Energy	89	29			$ 5,152
Department of Health and Human Services	75	18,844	$ 15,952	$ 226	78,027
Department of the Interior	14	130			430
Department of Justice	15	697			62
Department of Labor	16				1,677
Department of State	19	679			
Department of Transportation	69	319			759
Department of the Treasury	20	375			195
Department of Veterans Affairs	36	137			926
Environmental Protection Agency	68	837			145
Federal Emergency Management Agency	58				47
General Services Administration	47	7			126,590
National Aeronautics & Space Administration	80	82			
Nuclear Regulatory Commission	31				166
Office of Personnel Management	24		47,072		145,205
Social Security Administration	28	7			
All Other Federal Agencies		3			1,095
TOTAL		**$ 23,259**	**$ 63,024**	**$ 226**	**$ 365,618**

Section IV - Required Supplementary Stewardship Information (Unaudited)

The stewardship objective of Federal financial reporting requires reporting on the Federal Government's accountability over certain resources entrusted to it and certain responsibilities assumed by it that cannot be measured in traditional financial reports. Stewardship investments are substantial investments made by the Federal Government for the benefit of the nation. When incurred, they are treated as expenses in determining the net cost of operations. However, these items merit special treatment so that readers of Federal financial reports know the extent of investments that are made for long-term benefit. Federally financed research and development is a stewardship investment that should be measured in terms of expenses.

Research and development includes those expenses for basic research, applied research, and development that are intended to increase or maintain the national economic productive capacity or yield other benefits. FDA has two programs that meet the requirements of research and development investments: Orphan Products Development (OPD) Program and FDA Research Grants Program. While FDA's center components conduct scientific studies, FDA does not consider this type of research as "research and development" because it is used to support FDA's regulatory policy and decision-making processes.

Orphan Products Development Program

The OPD Program was established by the Orphan Drug Act (PL 97-414, as amended) with the purpose of identifying orphan products and facilitating their development. An orphan product is a drug, biological product, medical device, or medical food that is intended to treat a rare disease or condition (i.e., one with a prevalence of fewer than 200,000 people in the United States).

The Office of Orphan Products Development (OOPD) operates the OPD Program by administering an orphan product designation process, providing research study design assistance to sponsors of orphan products, encouraging sponsors to conduct open protocols (allowing patients to be added to ongoing studies), and managing a clinical research grants program. The OPD Program has been very successful with more than 240 drugs and biological products for rare diseases have been brought to market since 1983.

The Orphan Drug Act provides for granting special status to a product/indication combination upon a request of a sponsor, and if the product/indication combination meets certain criteria. This status is referred to as orphan designation. Orphan designation qualifies the sponsor to receive certain benefits (i.e., tax credit and exclusive marketing rights) from the Government in exchange for developing the orphan product.

OOPD also administers a clinical research grants program whose goal is to provide clinical

development of products for use in rare diseases or conditions where no current therapy exists or where current therapy would be improved. OOPD provides grants to conduct clinical studies intended to provide data acceptable to FDA that will either result in or substantially contribute to the approval of these products under the Federal Food, Drug, and Cosmetics Act.

New and continuing OPD studies strive to provide information on human safety and effectiveness of products for diseases and conditions such as dystonia, sickle cell disease, acute leukemia, cystic fibrosis, adrenoleukodystrophy, and tyrosinemia. The majority of research expenses are for salaries, wages, and non-payroll patient care costs.

Research Grants Program

The FDA Research Grants Program is a grants program listed as No. 93-103 under the *Catalog of Federal Domestic Assistance*, whose purpose is assist public and non-public institutions and for-profit organizations to establish, expand, and improve research, demonstration, education, and information dissemination activities concerned with a wide variety of FDA areas.

Research areas include: acquired immunodeficiency syndrome, biologics, blood and blood products, therapeutics, vaccines, allergenic projects, drug hazards, human and veterinary drugs, clinical trials on drugs and devices for orphan products development, nutrition, sanitation, microbiological hazards, medical devices and diagnostic products, radiation emitting devices and material, food safety, and food additives. Participating with the research grants are colleges, universities, profit-making organizations, nonprofit institutions, hospitals, and State and Local governments.

Examples of funded projects include: Radiation Effects and Exposure Criteria; Analytical Methodology for Animal Drug Tissue in Milk; Post Marketing Surveillance of Adverse Drug Reactions; International Program on Chemical Safety; Tobramycin for Inhalation in Patients with Cystic Fibrosis; Interferon Gamma Treatment of Osteoporosis; and Small Business Innovation Research: Phase 1 - Detection of Campylobacteria in Foods, Phase II - Point of Care Lead Instrument and Sensor.

Expenses

The following table presents the total expenses incurred in the FY's 1999-2003 (including expenses related to the OPD Program's administration, Office of the Commissioner overhead, and grants awarded in previous fiscal years) for each of FDA's research and development activities:

U.S. Department of Health and Human Services

Food and Drug Administration

RESEARCH & DEVELOPMENT
REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATIOM
For the Years Ended September 30, 2003 and 2002
(Unaudited)

Research and Development Expenses
(In Thousands)

PROGRAM	TYPE	Fiscal Year				
		03	02	01	00	99
Orphan Product Development	Development	$6,278	$5,961	$2,770	$3,070	$2,097
Orphan Product Research Grants	Applied Research	--	--	2,273	17,794	9,605
Research Grants Program (excluding Orphan Product grants)	Applied Research	25,387	22,994	20,813	4,752	6,990
Total		**$31,665**	**$28,995**	**$25,856**	**$25,616**	**$18,692**

NOTE:

Orphan Product Research Grant expenses are combined with Orphan Product Development for FY 2002 because it has been determined that it does not meet the definition of research.

Section V - Reports on the Audit of FDA's FY 2003 Financial Statements

JAN - 2 2004

TO: See Distribution List

FROM: Dennis J. Duquette
Deputy Inspector General for Audit Services

SUBJECT: Report on the Financial Statement Audit of the Food and Drug Administration for Fiscal Year 2003 (A-17-03-00003)

The attached final report presents the results of the audit of Fiscal Year's (FY) 2003 financial statements of the Food and Drug Administration (FDA). We contracted with Ernst & Young, LLP (EY), an independent certified public accounting firm, to perform the FDA audit that supports the departmentwide audit by the Office of Inspector General in accordance with the Government Reform Act of 1994.

Management is responsible for (1) preparing the financial statements in conformity with accounting principles generally accepted in the United States, (2) establishing, maintaining, and assessing internal controls to provide reasonable assurance that the broad control objectives of 31 U.S.C. 3512 (Federal Managers' Financial Integrity Act) are met, and (3) complying with applicable laws and regulations, including ensuring that FDA's financial management systems substantially comply with Federal Financial Management Improvement Act of 1996 (FFMIA) requirements.

The audit objectives were to determine whether (1) the FDA consolidated balance sheet as of September 30, 2003, and the related consolidated statement of net cost, statements of changes in net position and financing, and the combined statement of budgetary resources for the year then ended were fairly presented in all material respects; (2) FDA internal controls provided reasonable assurance that transactions were properly recorded and accounted for to permit the preparation of reliable financial statements; and (3) FDA complied with laws and regulations that could have a direct and material effect on the financial statements.

In EY's opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the FDA as of September 30, 2003 and its net costs, changes in net position, budgetary resources, and reconciliation of net costs to budgetary obligations for the year then ended, in conformity with accounting principles generally accepted in the United States. The financial statements of FDA as of September 30, 2002 were audited by other auditors whose report dated December 9, 2002 expressed an unqualified opinion on those financial statements.

The FDA is commended for sustaining it unqualified opinion. Furthermore, the report on internal controls noted no weaknesses considered to be material under standards established by the American Institute of Certified Public Accountants. The report did

note, however, certain matters relating to the internal controls over financial systems and analysis and information systems, which were considered to be reportable conditions.

Exclusive of the FFMIA, there were no reportable noncompliances with laws and regulations tested. The FDA's financial management systems did not substantially comply with FFMIA Federal financial management systems requirements and weaknesses in the systems access and application controls are significant departures from requirements specified by OMB.

In connection with the contract, we reviewed EY's report and related documentation and inquired of its representatives. Our review, as differentiated from an audit in accordance with U.S. generally accepted government auditing standards, was not intended to enable us to express, and we do not express an opinion on FDA's financial statements or conclusions on internal controls and compliance with laws and regulations. Our work was performed in conjunction with our opinion on the consolidated HHS financial statements, and reports on internal controls and compliance with laws and regulations. EY is responsible for the attached auditor's report dated October 28, 2003, and the conclusions expressed in the report. However, our review disclosed no instances where EY did not comply, in all material respects, with U.S. generally accepted government auditing standards.

We would appreciate your views and information on the status of any action taken or contemplated on the recommendations within the next 60 days. Should you wish to discuss this report, please call me or have your staff contact Joseph E. Vengrin, Assistant Inspector General for Financial Audits, at (410) 786-7103 or through email at jvengrin@oig.hhs.gov. Please refer to report number A-17-03-00003 in all correspondence relating to this report.

Attachment

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Report of Independent Auditors

To the Inspector General of the
Department of Health and Human Services, and
the Commissioner of the Food and Drug Administration

We have audited the consolidated balance sheet of the Food and Drug Administration (FDA), an operating division of the Department of Health and Human Services as of September 30, 2003, and the related consolidated statement of net costs, statement of changes in net position and financing and combined statement of budgetary resources for the fiscal year then ended. These financial statements are the responsibility of the FDA's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of FDA as of September 30, 2002 were audited by other auditors whose report dated December 9, 2002 expressed an unqualified opinion on those financial statements.

We conducted our audit in accordance with auditing standards generally accepted in the United States; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin 01-02, *Audit Requirements for Federal Financial Statements*. These standards and requirements require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the FDA as of September 30, 2003, and its net costs, changes in net position, budgetary resources, and reconciliation of net costs to budgetary obligations for the year then ended, in conformity with accounting principles generally accepted in the United States.

Our audit was conducted for the purpose of expressing an opinion on the basic financial statements taken as a whole. The information presented in the Management's Discussion and Analysis (MD&A), required supplementary stewardship information, and required supplemental information is not a required part of the FDA's financial statements, but is considered supplementary information required by OMB Bulletin 01-09, *Form and Content of Agency Financial Statements*. Such information has not been subjected to the auditing procedures applied by us in the audit of the financial statements, and accordingly, we express no opinion on it.

In accordance with *Government Auditing Standards*, we have also issued our reports dated October 28, 2003, on our consideration of the FDA's internal control over financial reporting and on our tests of its compliance with certain provisions of laws and regulations. Those reports are an integral part of an audit performed in accordance with *Government Auditing Standards* and should be read in conjunction with this report in considering the results of our audit.

Ernst & Young LLP

October 28, 2003

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Report on Internal Control

To the Inspector General of the
Department of Health and Human Services, and
the Commissioner of the Food and Drug Administration

We have audited the financial statements of the Food and Drug Administration (FDA), an operating division of the Department of Health and Human Services (HHS) as of September 30, 2003, and have issued our report thereon dated October 28, 2003. We conducted our audit in accordance with auditing standards generally accepted in the United States; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 01-02, *Audit Requirements for Federal Financial Statements*.

In planning and performing our audit, we considered FDA's internal control over financial reporting by obtaining an understanding of the agency's internal control, determined whether internal control had been placed in operation, assessed control risk, and performed tests of controls in order to determine our auditing procedures for the purpose of expressing our opinion on the financial statements. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 01-02. We did not test all internal control relevant to operating objectives as broadly defined by the Federal Managers' Financial Integrity Act of 1982 (FMFIA), such as those controls relevant to ensuring efficient operations. The objective of our audit was not to provide assurance on internal control. Consequently, we do not provide an opinion on internal control.

Our consideration of the internal control over financial reporting would not necessarily disclose all matters in the internal control over financial reporting that might be reportable conditions. Under standards issued by the American Institute of Certified Public Accountants, reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of the internal control that, in our judgment, could adversely affect the FDA's ability to record, process, summarize, and report financial data consistent with the assertions by management in the financial statements. Material weaknesses are reportable conditions in which the design or operation of one or more of the specific internal control components does not reduce to a relatively low level the risk that misstatements in amounts that would be material in relation to the financial statements being audited may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions. Because of inherent limitations in internal control, misstatements, losses, or noncompliance may nevertheless occur and not be detected. We noted certain matters discussed in the following paragraphs involving the internal control and its operation that we consider to be reportable conditions. However, none of the reportable conditions is believed to be a material weakness.

REPORTABLE CONDITIONS

FINANCIAL SYSTEMS AND ANYALYSIS

Overview

OMB Circular A-127 requires that financial statements be the culmination of a systematic accounting process. The statements are to result from an accounting system that is an integral part of a total financial management system containing sufficient structure, effective internal control, and reliable data. Without a single integrated financial management system to ensure timely and accurate financial data, poor policy decisions may occur, due to inaccurate or untimely information.

Our review of the internal control disclosed certain weaknesses in FDA's ability to report accurate financial information. FDA's central accounting system lacks integration with certain subsidiary systems, does not facilitate the preparation of the financial statements, and contains insufficient internal control to detect incorrect entries in a timely fashion. Additionally, certain reconciliation processes were not always adequately performed to ensure differences between subsidiary systems and the general ledger were properly identified, researched and resolved in a timely manner and that account balances were complete and accurate. Integrated financial systems are needed to ensure periodic analyses and reconciliations are completed to detect and resolve errors and irregularities in a timely manner.

Lack of Integrated Financial Management System

FDA's financial management systems, including its general ledger, accounts receivable, accounts payable, and payroll related systems, are not fully compliant with the Federal Financial Management Improvement Act of 1996 (FFMIA). FFMIA requires agencies to implement and maintain financial management systems that comply with Federal financial management systems requirements as defined by the Joint Financial Management Improvement Program (JFMIP). More specifically, FFMIA requires Federal agencies to have an integrated financial management system that provides effective and efficient interrelationships between software, hardware, personnel, procedures, controls, and data contained within the systems. The lack of an integrated financial management system impairs FDA's abilities to adequately support its financial balances reported. For example:

- During our testing of Accounts Payable, we noted that, to calculate the year-end accounts payable accrual, FDA's Office of Financial Management (OFM) uses a combination of reports and calculations from the accounting system and the Accounts Payable Subsidiary Ledger – Automated Accounts Payable System (AAPS). AAPS is utilized by OFM for payment of vendor invoices, and posts vendor invoices and subsequent payments simultaneously to the accounts payable standard general ledger account on the same day as

the payment is recorded. Therefore, the accounts payable always has a $0 balance. The actual amount presented on the financial statement for accounts payable is based on journal vouchers that are supported by FDA system queries and research. Lack of integration between subsystem and general ledger creates a risk of an understatement of accounts payable on the financial statement.

- Cost Allocation—Consistent with prior years, the core financial system does not assign indirect costs to interim and final cost objects, or allow for multilevel assignments and reassignments of cost. OFM instead relies on a cumbersome, labor-intensive process involving multiple layers of spreadsheets and analyses. Consequently, this process is prone to errors and potential misallocation of costs. In addition, FDA does not align its Statement of Net Cost with the major goals and outputs described in the strategic and performance plans.

Financial Analyses and Reporting

During fiscal year 2003, we found that certain reconciliation processes were not adequately performed to ensure that differences were properly identified, researched and resolved in a timely manner and that account balances were complete and accurate. The following represents specific areas we noted that need enhanced periodic reconciliation and analysis procedures.

- Fund Balance with Treasury – Treasury regulations require that each federal entity ensure that it, on a monthly basis, reconciles its financial records with Treasury's records and that it promptly resolves differences. If this reconciliation is not adequately performed, loss, fraud, and irregularities may occur and not be promptly detected. OFM is not consistently researching the differences between the SF-224 and the general ledger accounts, and is not following-up in a timely manner to ensure corrections. During our internal control testing, we reviewed the reconciliation schedules between the SF-224 and the general ledger for November 2002 and March 2003 to ensure differences were being identified and resolved, and we noted that there were significant differences that were not being resolved on a timely basis. For example, the November reconciliation showed a total difference of $24.7 million with 61 differences of greater than $100,000, as well as many smaller differences. On the March reconciliation, we noted that the total difference did decrease; yet it was still $14.4 million dollars with 44 differences of $100,000 or more, as well as many smaller differences. In addition, ten of the 44 differences from the March reconciliation were noted on the November reconciliation. Further, we noted that differences were not tracked within the General Ledger. Instead of recording differences to a suspense account, OFM tracks these transactions outside the system even when OFM has made payment and is awaiting further documentation.

- Undelivered Orders and Accounts Payable – During interim testing, we reviewed 40 unliquidated obligations as of June 30, 2003, and August 31, 2003, to verify that the obligations were valid and that the appropriate adjustments processed. We noted that 26 of

the sample items did not constitute a valid unliquidated obligation as of June 30, 2003, and should have been deobligated or cancelled. Upon further investigation as of August 31, 2003, we noted that four of the 26 items had been deobligated. During our year-end follow-up work, we reviewed the "Open Documents" report and noted that, although all of the remaining 22 items had been deobligated, an additional item totaling $1.2 million was deemed to be an invalid obligation. FDA concurred that this was an invalid obligation and that it should be deobligated.

In addition, as part of accrued liabilities testing, we reviewed 32 open payable balances as of June 30, 2003. We noted that six of these items in the tested population were invalid and should have been deobligated.

FDA has policies and procedures in place that require that all FDA offices perform periodic reviews of the unliquidated obligations and deobligate old and invalid obligations. However, FDA and its field offices are not strictly adhering to its policies. As a result, the Undelivered Orders and Accounts Payable balances in FDA's financial statements may be overstated, and the budget and execution controls process cannot work as intended due to the invalid Undelivered Orders in the system.

- Accounts Receivable – During our testing of accounts receivable, we noted that OFM performs manually intensive monthly reconciliations between the general ledger and subsidiary ledger. However, OFM does not follow-up on identified differences on a timely basis. Part 2, Chapter 40 of the HHS Accounting Manual states that each system should provide for (1) regular and routine reconciliation of the detail records to the general ledger accounts, (2) thorough investigations of differences, and (3) determination and initiation of corrective action". If differences are not corrected on a timely basis, they may result in the misstatement of accounts receivable and accounts payable on the financial statements.

- Duplicate Payments – During our tests of controls over the FDA cash disbursement process, we noted that in one item out of 23 selected for testing, the claim was reimbursed twice on the same payment schedule. Upon further review of the payment schedule, we noted that the same condition applied to two more payments made. The payees subsequently reimbursed all three duplicate payments.

  The payments in question were made through the Travel Payment System (TPS), which links travel vouchers entered by desk technicians to the Open Document Summary to locate the appropriate open obligation. TPS will create a partial or final system entry based on the amount obligated and the amount available, and the system will automatically display the obligation and all disbursement data made against the obligation. The accountant will then determine if the payment is either partial or final, and will verify and enter the amount owed to the traveler. In the case of the questioned payments, they were assigned both partial and final systems entries. When the final entry was posted, the system automatically obligated more funds to cover the deficiency that resulted from the partial payment that was not

detected by the payment auditor. Duplicate payments lead to overstatement of expenses and respective obligations in the financial statements, as well as an increased risk of a misappropriation of government funds.

- Payroll – During our payroll testing, we noted several instances where documentation was either missing or identified differences between the time and attendance system (EASE) and the source records or the HHS central payroll system. For example, we noted the following during our testing:

    - There were two instances in which the Earnings and Leave statement does not reflect the time off incentive award balances as shown on the EASE Leave Balance screen.
    - There were three instances in which the Administrative Time and Leave record did not reflect the time in the EASE system.
    - There were seven instances in which the leave balance on the Earnings and Leave statement did not agree to the balance in EASE.
    - FDA could not locate the personnel folder for one of our sample items.

  Oversight by FDA personnel and a lack of effective communication between timekeepers and the Center and Program Offices could cause the leave balance to be incorrect or result in discrepancies between the systems going unresolved. Effective internal controls should be in place in order to ensure that time and attendance transactions are properly entered into the payroll systems on a timely basis. Inaccurate leave balances may result in improper payment of wages to employees, incorrect deduction withholdings, and inaccurate accrued annual leave liability recorded on the financial statements.

Recommendations

FDA should continue to improve its internal control by implementing changes for effectively detecting errors and irregularities in a timely manner. We recommend that FDA strengthen controls to improve the reliability and documentation of its financial information to include:

- Continue to enhance its financial systems to ensure compliance with the FFMIA.

- Perform or oversee periodic reconciliations for all major financial balances and develop supporting documentation that reflects management's understanding of the composition of the accounts.

- Enhance high level exception driven analysis techniques to obtain reports each month and, array the reported information in a method that facilitates comparisons month to month, year to year against actual and budgeted amounts, and against FDA management expectations to identify and follow-up on emerging trends and anomalies in reported balances.

- Reiterate established policies and procedures to direct FDA program offices to review subsidiary ledgers and the status of funds for the current and prior years with obligated or available funding for reasonableness, obtain query access to financial systems to identify and investigate unusual items, and communicate the status of funds to OFM in a timely manner.

- Provide additional training for financial personnel to ensure that they understand the importance of posting entries correctly, performing account analyses and reconciliations, maintaining supporting documentation, and updating their knowledge of financial reporting requirements.

- Develop a process to properly age obligations, accounts receivable, accounts payable balances, undelivered orders, and advances so that enhanced analysis can be performed.

- Enhance procedures in place related to the payment process to ensure that the funds scheduled for payment are properly reviewed to minimize the risk of duplicate payments.

- Periodically analyze time and attendance personnel files to ensure complete and accurate information is maintained in the time and attendance system, as well as ensure that sufficient supporting documentation is maintained in the file and is adequately safeguarded. Timekeepers should review the leave information maintained in the EASE system in order to ensure that leave being accrued is accurate and that errors and corrections are researched and corrected immediately. Further, the Center and Program Offices should ensure that all timekeepers periodically audit the leave balance in order to ensure agreement between the EASE and the central payroll system.

INFORMATION TECHNOLOGY ACCESS AND SECURITY CONTROLS

As identified in FY 2002, the FDA relies on extensive, interchanged electronic data processing (EDP) operations at both its offices to process and account for FDA financial activity. Adequate internal controls over these operations are essential to the integrity, confidentiality, and reliability of critical data while reducing the risk of errors, fraud, and other illegal acts. As was noted by prior auditors in fiscal year 2002, in the course of the FY 2003 EDP review procedures we continued to find EDP general control weaknesses. Though our review did not identify specific exploitation of the identified vulnerabilities, such weaknesses could result in (1) unauthorized access to and disclosure of sensitive information, (2) malicious changes that could interrupt data processing or destroy data files, or (3) disruption of critical operations. Further, weaknesses in the security structure do not ensure that EDP security controls are adequate and operating effectively.

During our review, we identified the following:

- Major Financial Application and General Support System Security Program – As identified in FY 2002, required certifications and accreditation statements have not been completed and risk assessments have not been performed.

- Monitoring of User Access – Periodic review of user access to financial applications, LAN and physical access to the FDA facilities is not documented

- Change Management – Configuration management tracking software is not utilized by OFM. A manual log is used instead to record change requests and resolutions.

- Testing and Approval of Changes – Users are not consistently involved in testing and approval of completed program changes and there is no requirement for a supervisory review, approval and sign-off on the changes prior to implementation into production.

- OFM Change Control Policies – OFM change control policies and procedures are not consistently applied to all changes.

- Business Continuity/Disaster Recovery – The business continuity plan for Network Control Center (NCC) was last tested in May 2002. Issues identified during the testing of the plan such as lack of detail in the plan and a lack of alternative processing location have not been resolved. The plan continues to be very broad in nature and, should a disaster occur, would not provide sufficient information to enable complete and timely recovery of the operations. FDA also has not identified a recovery/processing location should the main FDA facilities and NCC become unavailable due to a disaster.

Further, HHS' Office of Inspector General contracted with an independent auditor to perform a Statement of Auditing Standards No. 70 (SAS 70) review of central payroll operations. The Independent Service Auditor's Report for the period October 1, 2002 through June 30, 2003, determined that controls in the Enterprise Human Resource and Payroll System (EHRP) to prevent incompatible personnel action processing duties from being performed by one individual were not operating with sufficient effectiveness to achieve the control objective "Controls provide reasonable assurance that incompatible duties and critical stages of processes have been assigned to different organizational units or individuals."

Because certain financial reconciliation and report processes within FDA continue to evolve and require further improvement, the general and application controls related to access controls, systems software and application software development and change controls are critically important to FDA to ensure the integrity, confidentiality, and availability of sensitive data.

Recommendation

We recommend that:

- FDA complete the certification and accreditation statements and conduct risk assessments for all major financial applications.
- FDA document the policies and procedures related to periodic review of user access to financial applications, LAN and physical access to FDA facilities.
- OFM and OIRM should work together to implement configuration management tracking software.
- OFM and OIRM should work together to ensure that production changes are approved by management and users are consistently involved in testing and approving of completed program changes.
- OIRM should apply the OFM change control policies and procedures to all changes.
- OFM and OIRM should make the Business Continuity plan more detailed and select an alternative recovery/processing location.

* * * * * * * * *

In addition, we considered FDA's internal control over Required Supplementary Stewardship Information by obtaining an understanding of the agency's internal control, determined whether internal control had been placed in operation, assessed control risk, and performed tests of controls as required by OMB Bulletin No. 01-02 and not to provide assurance on internal control. Accordingly, we don not provide an opinion on such controls.

Finally, with respect to internal control related to performance measures reported in the Management's Discussion and Analysis, we obtained an understanding of the design of internal control relating to the existence and completeness assertions and determined whether they have been placed in operation, as required by OMB Bulletin No. 01-02. Our procedures were not designed to provide assurance on internal control over reported performance measures, and, accordingly, we do not provide an opinion on such controls.

We noted other matters involving internal control over financial reporting, which we have reported to management in a separate letter dated October 28, 2003.

This report is intended solely for the information and use of the management of FDA and the Department of Health and Human Services, OMB, and Congress, and is not intended to be and should not be used by anyone other than these specified parties.

Ernst & Young LLP

October 28, 2003

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Report on Compliance with Laws and Regulations

To the Inspector General of the
Department of Health and Human Services, and
the Commissioner of the Food and Drug Administration

We have audited the financial statements of the Food and Drug Administration (FDA), an operating division of the Department of Health and Human Services, as of and for the year ended September 30, 2003, and have issued our report thereon dated October 28, 2003. We conducted our audit in accordance with auditing standards generally accepted in the United States; the standards applicable to financial audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No.01-02, *Audit Requirements for Federal Financial Statements*.

The management of the FDA is responsible for complying with laws and regulations applicable to the FDA. As part of obtaining reasonable assurance about whether the FDA's financial statements are free of material misstatement, we performed tests of its compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of financial statement amounts and certain other laws and regulations specified in OMB Bulletin No. 01-02, including the requirements referred to in the Federal Financial Management Improvement Act (FFMIA) of 1996. We limited our tests of compliance to these provisions and we did not test compliance with all laws and regulations applicable to the FDA.

The results of our tests disclosed no instances of noncompliance with the laws and regulations discussed in the preceding paragraph exclusive of FFMIA that are required to be reported under *Government Auditing Standards* or OMB Bulletin No. 01-02.

Under FFMIA, we are required to report whether the FDA's financial management systems substantially comply with the Federal financial management systems requirements, applicable Federal accounting standards, and the United States Government Standard General Ledger at the transaction level. To meet this requirement, we performed tests of compliance with FFMIA section 803(a) requirements.

The results of our tests disclosed instances in which the FDA's financial management systems did not substantially comply with certain requirements discussed in the preceding paragraph. We have identified the following instances of noncompliance.

- FDA does not have an integrated accounting system to capture certain transactions, including accounts receivable and accounts payable, and certain aspects of the existing financial reporting system do not conform to the requirements currently specified by the Joint Financial Management Improvement Program.

- Weaknesses identified in FDA's financial management systems' access and application controls are significant departures from requirements specified in OMB Circulars A-127, *Financial Management Systems*, and A-130, *Management of Federal Information Resources.*

The Report on Internal Control and our separate management letter includes information related to the financial management systems that were found not to comply with FFMIA requirements, relevant facts pertaining to the noncompliance, and our recommendations related to the specific issues presented. It is our understanding that management agrees with the facts as presented, and that relevant comments from the FDA's management responsible for addressing the noncompliance are provided as an attachment to this report.

Providing an opinion on compliance with certain provisions of laws and regulations was not an objective of our audit and, accordingly, we do not express such an opinion.

This report is intended solely for the information and use of the management of FDA and the Department of Health and Human Services, OMB, and Congress, and is not intended to be and should not be used by anyone other than these specified parties.

Ernst & Young LLP

October 28, 2003

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 4, 2003

To: Joseph E. Vengrin
Assistant Inspector General for Financial Management Audits
Office of Inspector General

From: Associate Commissioner for Management
and Chief Financial Officer

Subject: FDA's Response to the FY 2003 Draft Audit Report

We appreciate the opportunity to review and comment on the draft audit report of the Food and Drug Administration's (FDA) consolidated financial statements, internal control structure, and compliance with laws and regulations as of and for the fiscal year ending September 30, 2003. We have reviewed the report and concur with the findings and recommendations.

We are pleased that your audit firm, Ernst & Young, LLP, has given us an unqualified opinion on our FY 2003 consolidated financial statements with no material weaknesses in our internal control reporting. This demonstrates the effort among FDA staffs working together to produce timely and accurate financial statements – all within the accelerated timeframe set forth by the Department.

FDA must still work to resolve its reportable conditions and address recommendations made in the Management Letter. We will continue our efforts to resolve the findings and will report our progress periodically to the Department. Our goal remains to continue to receive unqualified opinions on all of our future consolidated financial statements and meet the mandated accelerated year-end due dates.

We would like to thank the Ernst & Young, LLP audit team for the professional and cooperative manner in which they conducted their audit. We found their suggestions and recommendations to be useful and informative. We will put these recommendations in place as soon as possible as we continue to improve FDA's financial management.

Jeffrey M. Weber

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Appendix

FDA Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
CBER	Center for Biologic Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
DHHS	Department of Health and Human Services
EFT	Electronic Funds Transfer
ELA	Establishment License Application
FDA	Food and Drug Administration
FFMIA	Federal Financial Management Improvement Act
FMFIA	Financial Managers' Financial Integrity Act
FDAMA	Food and Drug Administration Modernization Act
FSI	Food Safety Initiative
FTE	Full-Time Equivalency
FY	Fiscal Year
GAO	General Accounting Office
GLAS	General Ledger Accounting System
GMRA	Government Management Reform Act
GPRA	Government Performance and Results Act
GSA	General Services Administration
HACCP	Hazard Analysis and Critical Control Point
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
INAD	Investigational New Animal Drug
IDE	Investigational Device Exemption
IND	Investigational New Drug
IMPAC	International Merchant Purchase Authorization Card
JINAD	Generic Investigational New Animal Drug
MQSA	Mammography Quality Standards Act
NADA	New Animal Drug Application
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NIH	National Institutes of Health
NME	New Molecular Entity
NPR	National Performance Review
OFACS	Office of Facilities, Acquisitions and Central Services
OFM	Office of Financial Management
OIG	Office of Inspector General
OIRM	Office of Information Resources Management
OMB	Office of Management and Budget
OMS	Office of Management and Systems
OPDIV	Operating Division
PDP	Product Development Protocol
PDUFA	Prescription Drug User Fee Act
PHS	Public Health Service
PLA	Product License Application

PMA	Premarket Approval Application
PMIS	Property Management Information System
PMS	Payment Management System
SFFAS	Statement of Federal Financial Accounting Standards
SGL	Standard General Ledger
USC	United States Code
USDA	United States Department of Agriculture
Y2K	Year 2000
510 (k)	Premarket Notification

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Key FDA Financial Management Officials

Jeffrey M. Weber
Associate Commissioner for Management and
Chief Financial Officer

Helen S. Horn
Director, Office of Financial Management and
Deputy Chief Financial Officer

William R. Harris
Director, Division of Accounting

Peter M. Kelchner
Chief, CFO Liaison Branch

Food and Drug Administration (HFA-120), 5600 Fishers Lane, Rockville, Maryland 20857

For more information about the Food and Drug Administration,
visit our Web site at www.fda.gov