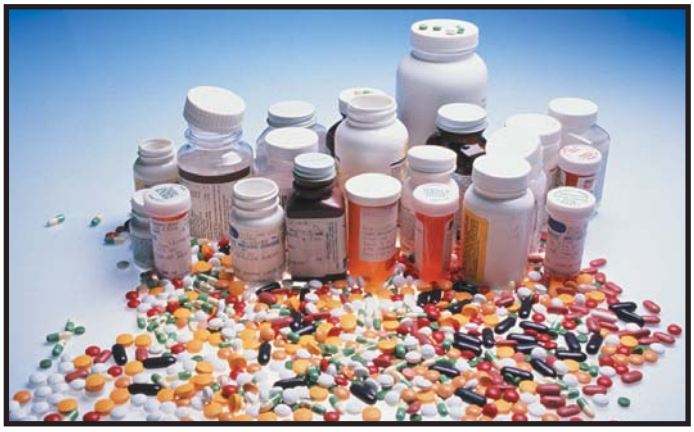
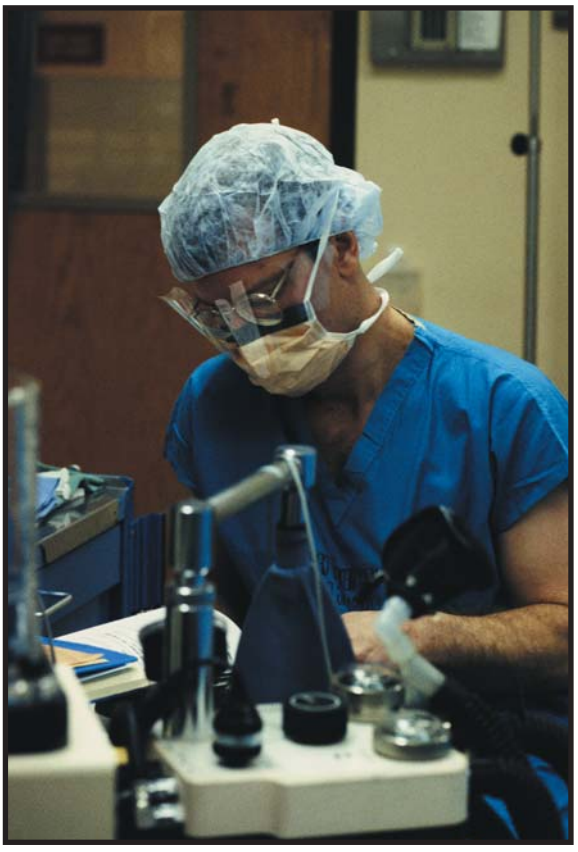
FDA's Annual Financial Report

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

FISCAL YEAR 2002





U.S. Department of Health and Human Services

Food and Drug Administration
Annual Financial Report
Fiscal Year 2002

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December 16, 2002

Deputy Commissioner's Message

I present to you the Food and Drug Administration's (FDA) Annual Financial Report for fiscal year (FY) 2002. I am pleased to report that FDA has earned its fifth 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.

After the events of September 11, 2001, protecting our homeland has become more important than ever before. As the nation's foremost consumer safety organization, FDA strives to assure a safe food supply through critical science-based prevention strategies; ensures medical product safety and their use by millions of Americans; brings safe and effective new technologies to a world-wide market; and monitors emerging hazards through surveillance systems and monitors about eight million import shipments that enter the United States. Additional FY 2002 resources allowed FDA to facilitate the availability of new bioterrorism tools accelerating the availability of medical products necessary for public health preparedness and to strengthen its surveillance, investigational, and laboratory support for detection and management of product contamination for foods, medical products, and blood.

The President's Management Agenda (PMA) lays out the framework for an effective Federal government that is citizen centered and results-oriented. During FY 2002, FDA made progress in accomplishing the PMA and the Department of Health and Human Services (DHHS) Secretarial goal of becoming "one HHS." The PMA includes five government-wide initiatives: Strategic Management of Human Capital, Competitive Sourcing, Improved Financial Performance, Expanded Electronic Government, and Budget and Performance Integration

The Secretary is promoting changes to consolidate, streamline, and standardize administrative programs throughout DHHS. In line with his plan, in FY 2002, FDA took the first steps toward consolidating its administrative functions. A few FDA PMA activities include the first phase of de-layering the organization; the development of plans to implement a new financial system in conjunction with the DHHS initiative; the study of the creation of a "shared service" organization; and continued preparation for the consolidation of the agency at the White Oak Federal Center.

The Reports Consolidation Act of 2000 requires that I, as the Agency Head, give an assertion on the information in this report. So, as acting 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 Plans and Reports of HHS components will include descriptions of the means HHS 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.

Lester M. Crawford, D.V.M., Ph.D.

December 16, 2002

Message from the Chief Financial Officer

I am pleased to present you with the Food and Drug Administration's Annual Financial Report for fiscal year (FY) 2002. 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 fifth consecutive year FDA has received an unqualified opinion on our financial statements. It is also the fifth consecutive year that our auditors did not identify and report material weaknesses in FDA's internal controls. The FY 2002 financial statements have been prepared in accordance with all new accounting standards that were effective for FY 2002 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.

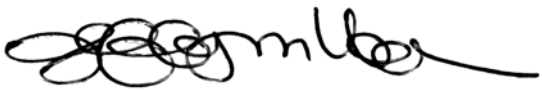
FDA is making progress in implementing the President's Management Agenda (PMA) and the Department of Health and Human Services' Secretarial goal of becoming "one HHS." The PMA lays out a framework for an effective Federal government accomplished through five Executive Branch-wide initiatives addressing human capital, financial management, electronic government, competitive sourcing, and budget and performance integration. The "one HHS" initiative is the Secretary's goal to consolidate, streamline, and standardize administrative programs throughout HHS.

In FY 2002, our progress included the completion of the first phase of de-layering the organization; the development of plans to implement a new financial system in conjunction with the DHHS initiative; and the study of the creation of a "shared service" organization. This is an opportune time for FDA as we continue the process of consolidating many decentralized headquarters operations into one location at the White Oak Federal Center.

In response to the terrorist attack of September 11, 2001, and with additional FY 2002 resources provided by Congress, FDA quickly hired a substantial number of field staff that will increase our ability to ensure the safety of the national food supply and other regulated products. Other investments were made to strengthen our surveillance, investigational, and laboratory support capabilities for detection and management of product contamination of foods, medical products, and blood.

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 CFO, 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, Division of Accounting's CFO Liaison Branch at Pkelchne@oc.fda.gov or 301-827-4792.



Jeffrey M. Weber

Preface

As an operating division of the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA) is required to produce an annual financial report covering the previous fiscal year.

The FDA's Annual Financial Report contains five sections (management discussion and analysis, principal consolidated financial statements and notes, required supplementary information, required supplementary stewardship information, and the Inspector General audit reports) and two appendices.

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. FDA has organized its MD&A into eight chapters containing the following:

- Agency Overview Chapter - Reviews the major events and cross-cutting issues in the Fiscal Year 2002. Provides an overview of the mission, strategic direction, organizational structure, governing laws, and resources. Discusses the Agency's compliance to systems, laws and controls including Integrity Act assurances, performance data reliability, and use of net costs. Presents the challenges and future trends facing FDA.

- Six Program Chapters - Provides mission description, major accomplishments, and key performance goals and results. The six programs are: Foods, Human Drugs, Biologics, Animal Drugs and Feeds, Devices and Radiological Health, and National Center for Toxicological Research.

- Financial Performance Chapter – Highlights progress made under the President's Management Agenda and Secretarial Management Goal. Reports on key administrative accomplishments and financial performance goals. Analyzes FDA's financial statements and discusses the Agency's financial condition.

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 2002 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 – Provides explanatory information on FDA's user fee programs and defines a list of FDA acronyms used in the report.

Acknowledgements

We would like to recognize the following people among the many, for their contribution to the FY 2002 FDA Annual Financial Report:

Patricia Arnwine, Dave Beranek, Butch Bosin, Robin Brooks, John Ford, Walt Goetz, Jay Graff, Michelle Hawley, Donna Page, Jerry Paull, Deborah Price, Rixie Scott, Roxanne Schweitzer, Chet Trybus, and Keith Valentine.

A special acknowledgement goes to Angela Freeman and Linda App, Office of Finance, Assistant Secretary for Budget, Technology, and Finance; Cathy Cox of the DHHS Office of Inspector General; and to Cathy Supernaw, Elizabeth Hacquard, Jack Reagan, and Mark Schwartz of KPMG, independent auditors, for all of their efforts.

The report could not have been produced without the help of the many of staff from FDA's Office of Financial Management.

Report Availability and Contact Information:

The FDA Annual Financial Report for FY 2002 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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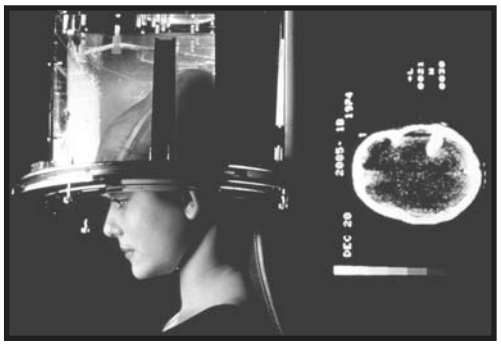
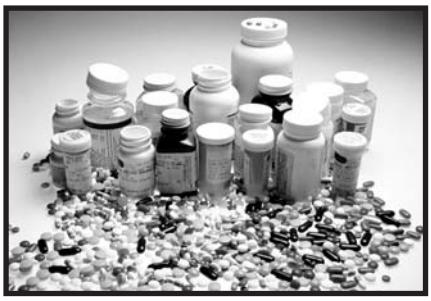
Management Discussion & Analysis



Management Discussion & Analysis



Agency Overview

Mission

The FDA Modernization Act of 1997 (PL 105-115) affirmed FDA's public health protection role and defined the Agency's mission:

- Promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
- Protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled, and; public health and safety are protected from electronic product radiation;
- Participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
- Carry out the above in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

Background

The U. S. Food and Drug Administration is a scientific, regulatory, and public health agency that oversees items accounting for over 20 cents of every dollar spent by consumers. Its jurisdiction encompasses most food products (except meat and poultry), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumer, medical, and occupational use, cosmetics, and animal feed.[1]

The Agency grew from a single chemist in the U.S. Department of Agriculture in 1862 to a staff of over 10,000 employees and a budget of $1.551 billion[2] in FY 2002 comprising of chemists, pharmacologists, physicians, microbiologists, veterinarians, pharmacists, statisticians, lawyers, and many others. About a third of the Agency's employees are in 176 field offices and laboratories, including five regional offices and 19 district offices.

Agency scientists evaluate applications for new human drugs and biologics, complex medical devices, food and color additives, infant formulas, and animal drugs. FDA also monitors the manufacture, import, transport, storage, and sale of about $1 trillion worth of products at an annual cost to taxpayers of about $4 for each person. Agency investigators and inspectors visit more than 16,000 facilities a year.

FDA has a mandate to protect the public health by ensuring the availability of safe and effective drugs, vaccines, blood products, medical devices, and animal health products, and by ensuring a safe food supply. Whether responding to contaminated products or natural disasters (such as, floods, hurricanes, or tornadoes), the public has trusted FDA to guard them from sickness or injury arising from the use of regulated products.

In recent years, FDA sought to increase its readiness in responding to a new threat – the deliberate use of biological, chemical, or radiological agents on the American public. FDA funded several activities to strengthen its capacity to respond. Some of the activities included hiring additional front-line staff; developing procedures and protocols to fast track the use of investigational new drug applications in treating exposure to these harmful agents; coordinating with other Federal agencies in the review of their emergency response plans; working with the Centers for Disease Control and Prevention (CDC) to identify medical products that could be added to the National Pharmaceutical Stockpile Program; and developing other methods and strategies to respond to this threat.

The terrorist attacks of September 11, 2001, and the subsequent incidents of anthrax contamination elevated the threat into a mission critical responsibility. The events of the past year have given FDA an awareness that the products it regulates--foods, drugs, biologics, animal feeds, and medical devices--could be used intentionally to cause widespread harm. To meet this challenge, the Congress provided more resources to FDA in the FY 2002 Emergency Supplemental Appropriation (see section entitled, “Year in Review”). This appropriation provided the resources to better equip FDA to prepare for, and respond to,

[1] Source: John P. Swann, Ph.D., FDA History Office [adapted from George Kurian, ed., A Historical Guide to the U.S. Government (New York: Oxford University Press, 1998)]

[2] The amount includes the salaries and expenses account ($1.368 billion) and user fees ($183.487 million). This amount does not include the budget authority of $151 million supplemental related to Counter Terrorism activities.

a terrorist attack. With the additional 832 staff including 655 field investigators, FDA has strengthened its security infrastructure to enhance the safety of food entering this country.

Besides the supplemental appropriation, new legislation, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Law), was passed to protect the safety and security of the drug and food supply, enhance controls on dangerous biological agents and toxins, and strengthen the national preparedness for bioterrorism and other public health emergencies.

In summary, FDA is more prepared than it was a year ago to address the broad range of its responsibilities. FDA is a part of the cadre of emergency preparedness agencies working collaboratively. These coordinated emergency response activities span key areas (for example, blood and vaccine supplies, diagnostic tests, human and veterinary drugs, and food security). Protecting and promoting the public health of the American public remains the highest priority for FDA in the 21st Century.

The Year In Review – Major Events

FDA selected several areas to highlight some of its accomplishments. These are discussed below.

FDA's Response to Bioterrorism and Emergency Preparedness

The September 11th attacks brought a heightened sense of awareness to the FDA of its mission and responsibilities to the American public, as it was thrusted into the front lines of defenses against terrorism. Some of these actions are captured below.

FDA performed many actions on the day of the attack and during the period of the incidents of the anthrax contamination that addressed public health issues arising from the attack that included:

- Issued a statement that authorized several measures to help emergency collections, transportation, and release of blood for transfusion;
- Provided regulatory guidance to the CDC for acquiring a new smallpox vaccine through a government contract;
- Eased potential medication shortage for the victims that were presumed to come in contact with anthrax powder by clarifying that the antibiotics doxycycline and penicillin G procaine are effective for the treatment of all forms of anthrax infections;
- Inspected renovated facilities for producing the anthrax vaccine; and
- Worked closely with the pharmaceutical industry, the National Institutes of Health (NIH), the CDC, and other agencies to improve the availability of medications and medical devices in a terrorist attack, such as testing dosing levels for smallpox vaccine.

Concurrently, FDA accelerated its response preparation in assessing its needs. Additionally, the Agency developed a "counter terrorism" strategic plan with four strategies. These strategies and highlights of activities include:

Strategy One -- Protect regulated products: Deter, detect, investigate, and interdict terrorist threats before they become a reality.

- Hired and began training 832 new investigators, analysts, and other support personnel which will improve the Agency's capacity to respond to terrorist threats and attacks, and augment domestic food safety and security;

- Conducted threat assessments of risks of different products and agents that could be used for a terrorist attack involving intentional contamination during various stages of food production and distribution; and

- Published guidance for domestic food producers and importers on preventive measures to increase their preparedness and enhance the security of their products (67 FR 1224; January 2, 2002).

Strategy Two -- Develop medical counter measures to lower the impact of attacks on the population.

- Published a rule on May 31, 2002, which allows approval of new drug and biological products for the treatment of chemical, biological, radiological, or nuclear substances based on animal efficacy studies when adequate and well-controlled studies in humans cannot be ethically conducted and field studies are not feasible;

- Engaged, before the events of September 11, 2001, in developing new regulatory models to support preparedness for the possibility of an emergency attack – for example, anthrax; and

- Took the initiative to clarify that antibiotics, doxycycline and penicillin G procaine, are effective and approved for use in treating all forms of anthrax infections.

Strategy Three -- Sharpen the Agency's emergency preparedness and response capability so that FDA is poised to protect the Nation and itself in the event of an attack.

- Develop the Agency's laboratory accreditation program to ensure that laboratory results are universally accepted, and develop uniform scientific practices by accrediting the Field's eight general purpose and five specialty labs to the international standard for regulatory sample analysis; and

- Expand federal/state/local involvement in FDA's Electronic Laboratory Exchange Network (eLEXNET), a part of the CDC's Public Health Information Network, by having 79 laboratories around the country participate in a common, shared microbial agent electronic data system, while assuring coordination with other members of the Public Health Information Network.

Strategy Four -- Ensure that radiation devices used to diagnose or treat terrorist-related incidents are safe and effective.

- Collaborate with the NIH in developing a guidance document on the use of potassium iodide to reduce the risk of thyroid cancer in radiation emergencies.

Ensuring Safe Food Supply

Special attention was given to the safety of the food supply because of its potential susceptibility to deliberate contamination. Several actions have taken place:

- Two industry security guidances that outline measures that firms can take to reduce the potential risk of a terrorist attack on food under their control were developed. One for domestic food producers, processors, transporters, and retailers, and the other one for importers, brokers, and others involved in importing to this country; and

- The hiring of 832 employees, of which 635 were assigned to food safety activities in FDA's field force. The majority of these employees will be assigned to monitor imports. This will permit FDA to conduct nearly 24,000 import inspections a year, nearly double the present amount. Other employees hired will perform risk assessments and develop rapid methods for detecting pathogens in various types of products.

FDA also monitored other ongoing initiatives including the threat of bovine spongiform encephalopathy[3] (BSE) and the growing antimicrobial resistance challenge.

The goal of the BSE program is to prevent the introduction and spread of BSE into the U.S. herd and human food chain. There is strong scientific evidence (epidemiological and laboratory) that the agent that causes BSE in cattle is the agent that causes the variant Creutzfeldt-Jakob Disease (vCJD) in people. If BSE emerged in the U.S., it could pose a serious health risk to humans and be financially devastating to the U.S. beef industry. FDA developed a three prong approach in its efforts to realize 100 percent compliance with the FDA's ruminant feed (BSE) regulations, Code of Federal Regulations, Title 21, Part 589.2000 – education, strong and visible inspection presence, and enforcement action. FY 2002 activities included:

- Revising the BSE Response Plan that is designed to prepare and guide FDA personnel, DHHS and other Federal agencies for emergencies involving BSE;

- Holding a public hearing to solicit information and views on whether and how to strengthen a regulation designed to help prevent the occurrence, through animal feed, of BSE in U.S. cattle herds;

- Issuing a revised BSE inspection checklist for use by all Federal and State inspectors;

- Developing a new database module that will record the results of all inspections conducted under BSE regulation; and

[3] BSE, or "Mad Cow Disease," is a deadly chronic degenerative disorder affecting the central nervous system. BSE and Chronic Wasting Disease (CWD) both belong to a group of progressive degenerative neurological diseases that are always fatal, known as transmissible spongiform encephalopathies (TSEs). There are several TSE diseases that affect humans and the best known is Creutzfeldt-Jakob Disease.

• Continuing inspections to maintain a 100 percent compliance with regulations. The latest update showed that 1 percent of nearly 10,000 firms was found out of compliance. Where firms are out of compliance, enforcement actions are being pursued.

Antibiotic resistance is a growing problem that has recently been identified as a major public health threat and a priority by FDA. The problem involves the increasing resistance of disease-causing microbes to drug therapies. Tuberculosis, gonorrhea, malaria, and childhood ear infections are just a few of the diseases that have become hard to treat with antibiotic drugs. The use of antimicrobial drugs in food-producing animals may lead to the emergence of bacterial pathogens (disease-causing organisms) that may be harmful to humans and that are resistant to drugs used to treat human illness.

Besides working with the agriculture and medical communities in FY 2002, FDA produced or participated in the following activities:

• Held a public hearing on the FDA proposed action to withdraw poultry antimicrobial approval for enrofloxacin, a veterinary drug for treating chickens and turkeys for certain bacterial infections;

• Published a revised draft guidance for assessing the microbiological safety of antimicrobial drug residues in food; and

• Published a new draft guidance[4] for evaluating the safety of antimicrobial new animal drugs that focuses on the microbiological effects on bacteria of human health concern.

FDA is also participating with the CDC and U.S. Department of Agriculture (USDA) in the National Antimicrobial Resistance Monitoring System (NARMS) that detects emerging antibiotic resistance among food borne pathogens and the possible associated health hazards through systematic collection, analysis, and interpretation of antimicrobial susceptibility surveillance data. NARMS is adding to FDA's knowledge base of drug susceptibility and is helping ensure that continued effectiveness of human and veterinary drugs.

Strengthening Medical Products Oversight

Another major effort is improving FDA's oversight of approved medical products; such as, human drugs, veterinary drugs, vaccines, medical devices, or food additives. During FY 2002, this has been expressed through three major areas: strengthening human subject protections, reducing medical errors, and improving pharmaceutical manufacturing practices. Some of the accomplishments include:

• Creating a new office of Good Clinical Practice in the Office of the Commissioner whose mission is to improve the conduct and oversight of clinical research and to ensure protecting participants in FDA-regulated clinical research;

• Establishing a new advisory subcommittee on drug safety and risk management to the Advisory Committee for Pharmaceutical Science whose purpose is to provide expert advice on complex drug-specific issues and methods of risk assessment, management, and communication;

[4] For an explanation on the draft guidance, see the Animal Drugs and Feeds Program's section on "other accomplishments."

- Meeting its statutory requirements by inspecting 50 percent of registered blood banks, source plasma operations, and biologics manufacturing establishments to reduce the risk of product contamination;

- Holding a public meeting to discuss the application of bar coding of human pharmaceutical products, biological products, and medical devices because bar coding can help ensure that the right patient gets the right drug, and the right dose of it, at the right time; and

- Launching a new initiative to enhance pharmaceutical good manufacturing practices by focusing on risk management strategies, product quality standards, and manufacturing technologies.

Mission and Strategic Direction

The FDA mission[5] of protecting the public health was strengthened with the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act improves FDA's ability to prepare for and respond to bioterrorism and other public health emergencies.[6] The Act gives broad authority to FDA to protect the national food supply and drug supply. It also reauthorizes the Prescription Drug User Fee Act. FDA is implementing the law and will be issuing regulations, guidance, and changing its operations to adapt to the law.

To successfully accomplish its mission, FDA leadership identified four strategic goals based on the importance of "prevention" as the Agency's primary line of attack on the Nation's health and safety concern. Prevention, to FDA, means that we use all means available to reduce health or safety risks facing the American people by correctly assessing the risks and managing them.

These four strategic goals provide direction for the annual performance goals and are grouped in seven major areas in the FY 2002 Final Revised Performance Plan.[7] These areas are: Administrative Management (later changed to Agency-wide); Foods; Human Drugs; Biologics; Animal Drugs and Feeds; Medical Devices and Radiological Health; and National Center for Toxicological Research.[8]

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[5] See page I-1 for listing of FDA's statutory mission.

[6] For more information pertaining to FDA's implementation of this Act, see FDA's Bioterrorism Web Page at: http://www.fda.gov/oc/bioterrorism/bioact.html

[7] Source: The FY 2002 Revised Final Performance Report is available on FDA's web-site at: www.fda.gov/ope/fy02plan/default.htm. FDA's Performance Report for FY 2002 will be available on FDA's web site by Spring 2003.

[8] For the annual financial report, the select performance goals from the seven areas are found in the six program chapters (Foods, Human Drugs, Biologics, Animal Drugs and Feeds, Medical Devices and Radiological Health, and National Toxicological Research Center) and the Financial Performance chapter (addressing administrative management).

FDA's strategic goals fit into the larger strategic framework envisioned by DHHS. During FY 2002, the DHHS strategic plan was revised for the next five year period. There are eight goals covering DHHS; four of which include FDA participation.[9] A summary of DHHS and FDA strategic goals and their desired outcomes are listed in Table 1.

Table 1

DHHS STRATEGIC GOALS*	FDA STRATEGIC GOALS	DESIRED OUTCOMES
Reduce the Major Threats to the Health and Well-Being of Americans	Counter the Terrorist Threat	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	Bring New Technologies to a World-Wide Market	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	Assure Medical Product 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.
Achieve Excellence in Management Practices	Maintain a Strong and Effective FDA	State-of-the-art scientists and health professionals make critical risk management decisions.
		Streamlined Agency optimally organized to support mission-critical activities.
		Cost-effective performance of operations.
		Citizen-centered agency accountable for results.

* Source: DHHS strategic Plan for Fiscal Year 2003 through 2008 (Draft), July 29, 2002.

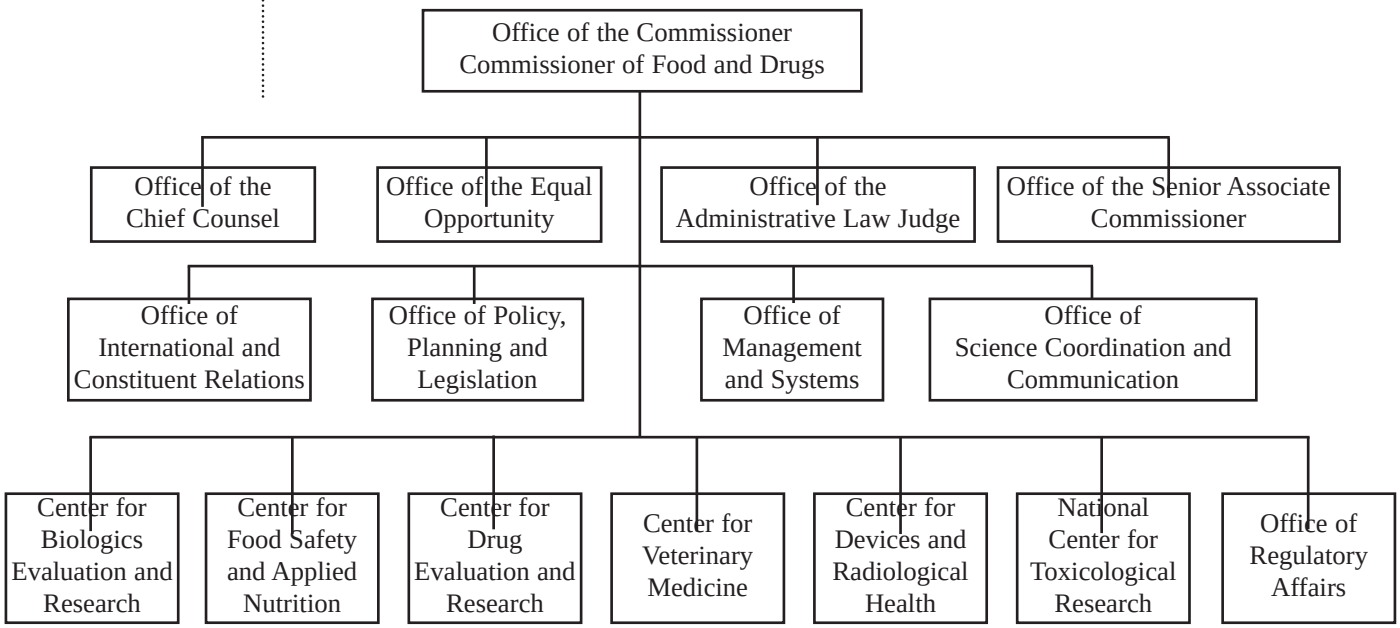
[9] See the FY 2002 DHHS Performance and Accountability Report, which will be issued in February 2003, for examples of FDA performance goals achieving the intent of the DHHS Strategic Goals.

Organizational Structure

FDA is organized into eight major components consisting of the Office of the Commissioner, the Office of Regulatory Affairs (ORA) (which is responsible for the FDA field force), and the following 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 eight subordinate offices that provide legal guidance, develop plans and policies, direct public and consumer affairs programs, promote the Agency's international relationships among foreign governments, and deliver administrative services.

The Office of Human Resources and Management Services, Office of Management and Systems (OMS), Office of the Commissioner (OC) reorganized its operations to prepare for administrative consolidation in line with the Secretary's vision of "one-HHS." Its five divisions were reduced to three addressing personnel operations, human resources policy and programs, and management programs (dockets management, ethics, and management analysis).

The Office of Facilities, Acquisition, and Central Services, OMS, OC reported that it had created the division of security operations, policy, and planning to better coordinate and prepare FDA's physical and personnel security requirements.

The Centers

Five of the six centers are product centers that are equipped to perform premarket review, conduct postmarket assurance, take enforcement actions, and provide scientific and administrative support. The sixth center, NCTR, performs regulatory research for the other product centers. Except for NCTR, which is headquartered in Jefferson, Arkansas, the Office of the Commissioner, the Centers, and the ORA are headquartered in the Washington, DC metropolitan area.

The Centers provide oversight of the Programs that are described in six individual chapters in the annual financial report. Five of the six programs receive substantial 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 has 3,492 full-time equivalents. The mission of the ORA is to:

- Achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection;
- Conduct investigational and laboratory functions of all of FDA's major product areas: Foods and Cosmetics, Human Drugs, Biologics and Blood, Animal Drugs and Feeds, and Medical Devices and Radiological Health, both before and after marketing;
- Respond rapidly to various types of emergencies, and redirect field efforts during the year among FDA's different programs to respond to unforeseen emergencies;
- Monitor clinical research and conduct in-plant pre-approval inspections to ensure that manufactured products are safe and effective;
- Determine whether import entries comply with FDA regulations and take enforcement actions; and
- Perform outreach to consumer groups, health professionals, States, and industry to encourage compliance and safe use of FDA-regulated products.

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 foreign or domestic establishments, include bioresearch monitoring inspections of clinical research. Other premarket inspections are conducted in manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in the application. Laboratory method validations are conducted to confirm that the methods described in the premarket application work as described.

Field investigators and laboratory analysts conduct foreign inspections for premarket approval and postmarket compliance purposes. Postmarket foreign inspections in the human drug, biologic, animal drug and feeds, and medical device and radiological health programs are conducted to assess Good Manufacturing Practices. This is consistent with the biennial inspection requirement that Congress requires of domestic manufacturers in these programs.

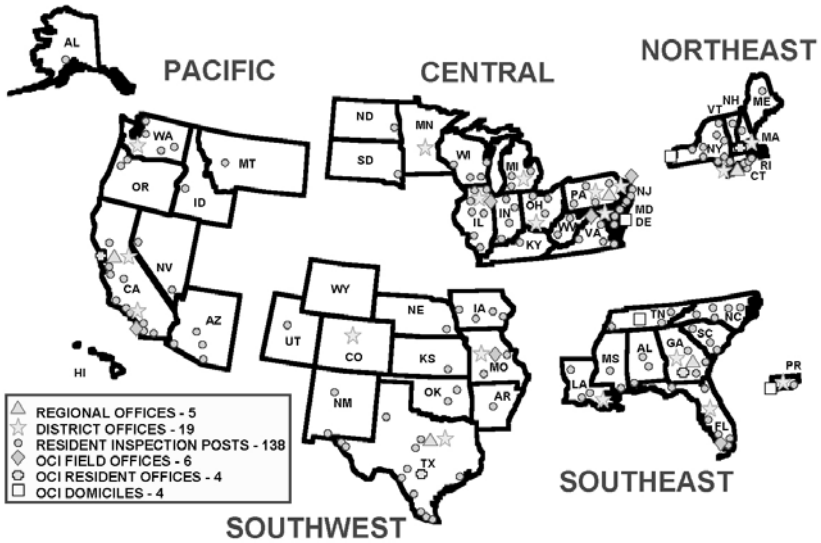
Besides conducting regular surveillance over regulated products, the field workforce also responds to emergencies by immediately mobilizing to investigate reports of product problems including tampering incidents, food borne illness, those caused by natural disasters, and those which may be the result 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 are staff offices that coordinate FDA activities and coordinate with state authorities. The 19 District Offices serve as offices for investigators and compliance action staff, and are the main control points for day-to-day operations in their assigned areas. Thirteen laboratories provide for FDA's basic field product testing capability. Fourteen OCI offices are located across the country to include resident offices and domiciles. There are 138 resident posts distributed widely across the country. These are smaller offices that serve mainly as a base for investigators so that FDA can have investigative staff widely dispersed to respond to emergencies whenever they occur, as quickly as possible to lower a potential harm. FDA maintains offices and staff in 49 of the States, and in the District of Columbia and Puerto Rico. See Figure 2 below for a map of ORA's field locations.

Figure 2

OFFICE OF REGULATORY AFFAIRS



Governing Laws and Regulations[10]

The basic governing laws for FDA are the Federal Food, Drug and Cosmetic Act (FD&C) Act, as amended (21 U.S. Code 321 - 394), the Fair Packaging and Labeling Act (15 USC 1451 to 1461), and the Public Health Service Act, as amended (42 U.S.C. 262 to 263, 263b, and 264): [For a compilation of laws and related statutes enforced by FDA, see web page: www.fda.gov\opacom\laws\lawstoc.htm.]

- **FD&C Act**, as amended, applies to foods, drugs, cosmetics, animal drugs and feeds, medical devices for humans or animals, and electronic products that emit radiation (such as, X-ray devices, lasers, microwave ovens, and televisions).

- **The Fair Packaging and Labeling Act** affects the contents and placement of information required on the package.

- **The Public Health Service Act**, as amended, applies to biological products for human use, mammography, and control of communicable diseases.

Resources

The FDA resource level for FY 2002 was $ 1.752 billion.[11] This number includes: appropriations for salaries and expenses (S&E), building and facilities (B&F), user fees; offsetting collections (reimbursables); carry-over balances from earlier years; and adjustments. For a complete analysis of FDA's resources in FY 2002, please read the Financial Analysis section in the Financial Performance Chapter on Page I-75.

Systems, Controls, and Legal Compliance

The Federal Accounting Standards Advisory Board requires the Management Discussion and Analysis to address the systems, controls, and legal compliance[12] that support preparing financial statements and financial documentation. This is achieved through the annual reporting of Federal Managers' Financial Integrity Act (FMFIA) 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 implement proper safeguards to prevent waste, fraud, and mismanagement of Agency resources.

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10 21 CFR Part 1 - 1299 interprets these and other laws and provides explanation on Agency's requirements.

11 Source: The amount is from the FY 2002 Combined Statements of Budgetary Resources. Please note this total includes accounts that are not available either permanently or temporarily pursuant to PL 107-188.

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

The only material weakness that FDA continues to report is an item that has been reported every year since 1989. It relates to how few imported food inspections we conduct each year. FDA is not ready to declare this weakness resolved until the results are achieved by the recently authorized staff for imported foods inspections have been hired and fully trained.

Management Controls Review

During FY 2002, FDA assessed its management controls using a variety of means and each major FDA component submitted an assurance statement signed by their component head. No new material weaknesses were identified during the FY 2002 FMFIA reporting cycle.

Financial Management Systems Review

FMFIA Section IV requires a "conformance statement" whether the Agency's financial management systems conform to Executive Branch requirements. FDA reported that its financial systems do not conform to these requirements because the earlier year's Chief Financial Officer's (CFO) Act audit findings show several instances of non-compliance to the FFMIA. The findings focused on three financial applications: Accounts receivable, cost management, and property. Additionally, FDA is working with DHHS and DHHS components to develop the Department's Unified Financial Management System. This is long term project and FDA is preparing its financial management systems and operations to be integrated with the Department's system.[13]

The Office of Financial Management developed a corrective action plan outlining the actions needed to remove the finding of non-compliance to FFMIA.

Performance Data Reliability and Net Program Costs

The Office of Management and Budget (OMB) requested that agencies explain the procedures management has designed and followed to provide reasonable assurance that reported performance information is relevant and reliable.

Each of the six programs has identified their information systems, data bases, and other management procedures used to track and report on performance information. Each program's data verification and validation section discusses how the program is providing reasonable assurance that the performance data in their systems are relevant and reliable. For further information, please see the FY 2002 Performance Report.

For the FY 2002 Annual Financial Report, we will continue to use net program costs displayed in a three year period. This information comes from the Statement of Net Cost found in the section on financial statements. Net program costs 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

[13] More explanation of the UFMS and FDA's preparation is found in the Financial Performance Chapter.

required to determine the full cost of their operations. The Government Performance and Results Act (GPRA) directs Executive Branch agencies to define their mission and set strategic and annual performance goals. The aligning of full cost of the program with performance objectives and results gives a clearer picture on the true cost of program performance. FDA is continuing its practice to display net program costs in the program's chapter.

The Statement of Net Cost has been prepared 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 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.

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

Food Safety – Bioterrorism

FDA has a limited capacity to monitor or control foods imported, inspect domestic manufacturers, and detect food borne pathogens before they cause human illness. When these limitations are combined with the possibility of deliberate attempts to contaminate the food supply at a point along the food production, processing, and distribution chain, the risks are greatly amplified. FDA managers and scientists must develop plans to coordinate a response network with various governments to identify and contain outbreaks associated with deliberate attempts to contaminate the food supply.

Biological, Chemical, and Radiological Terrorism

FDA must review and approve of products used in the diagnosis, treatment, and prevention of human exposure to biological, chemical, and radioactive agents. The anthrax incidents demonstrate the need for the Nation to be better prepared in responding to similar future events. The new fast track authority in the Bioterrorism Law will help FDA to review designated priority medical counter-measures. FDA must create the plans and protocols to respond to potential bioterrorist threats.

Foreign Imports of FDA-Regulated Products

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 commerce. Public safety and confidence could be jeopardized by a failure to increase surveillance activities. Products may enter the U.S. through one of about 300 U.S. Customs ports found throughout the country. The growth of international trade has lead to a tripling of imports during the past ten years. 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, the Agency takes every precaution, making 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 these products and track trends associated with them.

Prevent Outbreak of Bovine Spongiform Encephalopathy (BSE)

FDA must assure full compliance with the BSE regulation through inspection and compliance actions. FDA must also consider the risk of areas not covered by the USDA's ban. This includes ruminant protein-containing cosmetic products that are packaged and ready for sale; bovine-derived materials intended for human consumption (as either finished dietary supplements or for use as ingredients in dietary supplements, vaccines, blood and blood products, and human drugs); and human food other than meat, such as gelatins.

The Safety of Genetically Engineered Foods

FDA will continue to be tasked with evaluating the safety of foods developed using the tools of modern biotechnology--also called bioengineering. The Agency must continue to study the several variables in determining the safety of bioengineered foods, develop policies, inform and educate the public, and provide industry with the proper guidance. FDA's decisions can dramatically affect the economics of the food and agriculture community.

Office of Inspector General's Top Management Challenges[14]

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.

[14] A discussion on the President's Management Agenda is found in the Financial Performance Chapter.

Three of the FY 2002 DHHS management challenges affect FDA: bioterrorism preparedness, protection of critical infrastructure, and grants management. Grants management is a new challenge identified in FY 2002. The others are repeat findings. FDA has made progress with bioterrorism preparedness and protection of critical infrastructure.

During the past year, FDA has developed the means to better prepare for attacks from biological, chemical, and radiological incidents. The Agency has worked closely with DHHS components and other agencies to bolster the response to terrorist attacks. Through its supplemental funding, FDA has hired more investigators, inspectors, and scientists nationwide to protect the safety of the foods and other regulated products.

FDA has been strengthening its protection of critical infrastructure in response to a Presidential Decision Directive 63 and to the Government Information Security Reform Act. Through the annual audit process, OIG has identified areas for FDA to improve its information systems controls. FDA is correcting these findings so that the Agency will have a reliable and secure information technology environment.

Management Discussion & Analysis

Foods Program

Mission

The Foods Program is responsible for the safety of the nation's food supply, and the safety and proper labeling of cosmetics. The aim of the program is to:

- Ensure that the food supply, quality of foods, food ingredients, and dietary supplements are safe, nutritious, wholesome, and honestly labeled and that cosmetics are safe and properly labeled;
- Set standards and develop regulations for the food industry;
- Take timely and appropriate action on new food ingredients and dietary supplements before they go on the market to ensure their safety and effectiveness;
- Research ways to provide the necessary basis for regulatory decisions;
- Identify food-related health hazards;
- Take corrective action to reduce human exposure to food related hazards and the possibility of food-related illnesses and injuries and
- Educate and train consumers and industry on food safety.

Background

The Foods Program is administered by the CFSAN and supported by ORA.[15]

The FDA oversees a vast food industry that includes over 60,000 United States (U.S.) food processors and warehouses and comprises a significant segment of the nation's economy. Products regulated by FDA account for about two-thirds of consumer spending on food, with an annual retail value of about $430 billion. Every year, U.S. food processors spend $1.4 billion on research and development and introduce 10,000 to 15,000 new products. In addition, increasing amounts of foods are being imported each year from other countries, including third world countries, which tend to have less sophisticated food processing and regulatory systems.

Cost[16]

Fiscal Year	Net Program Cost (000s)
2002	$431,053
2001	$390,085
2000	$364,914

The Foods Program has experienced a 10.5 percent increase in net costs in FY 2002. This increase is attributed to the infusion of food safety "bioterrorism" funds from the FY 2002 supplemental appropriation. The net cost includes the expenses for a program, including the allocation of overhead expenses (such as, the Office of the Commissioner's costs for administrative and policy direction, ORA's field operations' costs, rent, and other overhead), less exchange revenue.

Program Goals and Accomplishments

Highlights of Product Approvals

New Non-Nutritive Sugar Substitute

Neotame, a general purpose sweetener, was approved by CFSAN. This sweetener may be used in a wide variety of food products, other than meat and poultry. Depending on its food applications, neotame is approximately 7,000 to 13,000 times sweeter than sugar. It is a free-flowing, water soluble, white crystalline powder that is heat stable and can be used as a tabletop sweetener as well as in cooking applications. Examples of uses for which neotame has been approved include baked goods, non-alcoholic beverages (including soft drinks), chewing gum, confections and frostings, frozen desserts, gelatins and puddings, jams and jellies, processed fruits and fruit juices, toppings and syrups.

[15] For a fuller discussion on the support provided by ORA to the Programs, see pages I-10 through I-12.

[16] Source: Statements of Net Costs for FYs 2000, 2001, and 2002. The source for the remaining programs' cost tables is the Statements of Net Costs for the three fiscal years.

Highlights of Product Safety Actions

Contaminated Honey Imports from China

The U.S. Customs Service and the FDA discovered bulk imports of Chinese honey that were contaminated with low levels of chloramphenicol, a potentially harmful antibiotic and unapproved food additive. The contaminated honey was detected during an investigation into a widespread scheme to evade payment of U.S. anti-dumping duties on bulk imports of Chinese honey. The investigation has resulted in the detention of more than 50 containers of bulk Chinese honey at U.S. ports. In an effort to evade U.S. anti-dumping duties, this honey had allegedly been illegally transshipped through third-party countries on its way from China to America.

Konjac Min-Cup Gel Candies That Pose Choking Risk – Two FDA Warnings

FDA issued two warnings and announced an import alert concerning mini-cup gel candies that contain the ingredient "konjac" (also known as conjac, konnyaku, yam flour, or glucomannan). FDA decided a second warning was warranted (the first was issued on August 17, 2001) after consultation with experts on choking from the Consumer Product Safety Commission (CPSC). CPSC staff confirmed that these candies pose a serious choking risk, particularly to infants, children and the elderly. In addition, the agency has issued an import alert to address the importation of these candies from other countries.

These multi-fruit-flavored candies are typically packaged as individual, mouth-sized servings, and often feature an embedded piece of preserved fruit. Unlike gelatin products commonly found in the U.S., these candies do not readily dissolve when placed in the mouth. For more specific information, see the Import Alert #33-15 at http://www.fda.gov/ora/fiars/ora_import_ia3315.html.

Nationwide Health Risk Alert About Spokane Produce Brand Romaine Lettuce

FDA warned consumers not to consume Spokane Produce brand romaine lettuce because this product has been associated with an outbreak of *E. coli O157:H7* in a cheerleading camp in Washington State in mid July 2002. FDA urged consumers to dispose of this product. *E. coli O157:H7* causes a diarrheal illness often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called Hemolytic Uremic Syndrome (HUS). HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death.

Kava: FDA Consumer Advisory And Letter To Health Professionals

FDA advised consumers of the potential risk of severe liver injury associated with the use of kava-containing dietary supplements. Kava (*Piper methysticum*) is a plant indigenous to the islands in the South Pacific where it is commonly used to prepare a traditional beverage. Supplements containing the herbal ingredient kava are promoted for relaxation (e.g., to relieve stress, anxiety, and tension), sleeplessness, menopausal symptoms and other uses. Liver-related risks associated with the use of kava have prompted regulatory agencies in other countries to take actions to protect consumers. FDA has not made a determination about the ability of kava dietary supplements to provide such benefits.

Other Accomplishments

Hiring of New Inspectors for the Foods Program

As result of the emergency supplemental appropriation, six hundred new field employees were authorized for the Foods Program and over 400 of them will be either stationed at border locations or working specifically on imports. These additional resources will enable FDA to conduct nearly 24,000 import inspections a year, nearly double the present amount.

CFSAN Adverse Events Reporting System (CAERS)

As a result of receiving funding in FY 2002, CFSAN developed a new, comprehensive system for tracking and analyzing adverse event reports involving foods, cosmetics, and dietary supplements. The new CAERS will replace the patchwork of adverse event systems that are maintained by individual CFSAN Offices. FDA will use the CAERS system as a monitoring tool to identify potential public health issues that may be associated with the use of a marketed product. Information gathered in CAERS will also be used to formulate and disseminate CFSAN's post-marketing policies and procedures.

Food Contact Substances

In April, CFSAN made available two final technical guidance documents to assist industry in preparing notifications for new uses of food contact substances. The toxicology guidance document recommendations represents the first such document FDA has developed for such substances. A final rule was published in May in the Federal Register codifying regulations implementing the food contact notification program.

Listeria and Shellfish Research

FDA worked with industry to conduct research on the prevalence and levels of Listeria monocytogenes in ready-to-eat foods. FDA and industry collected and sampled over 30,000 samples. The results will be used to update the draft Listeria assessment of risks to public health.

FDA conducted ten comprehensive domestic and international shellfish laboratory evaluations to ensure adequate monitoring of shellfish in interstate commerce for microbiological contaminants and marine biotoxins.

Improving Safety of Milk

FDA participated in the National Conference of Interstate Milk Shippers Hazard Analysis Critical Control Points (HACCP) Evaluation team. They evaluated a pilot process for the Grade A milk industry to monitor and control milk safety nationwide as an alternative to the Pasteurized Milk Ordinance.

Model Food Code

The 2001 FDA Model Code was published, representing FDA's best advice for a uniform system of regulation to ensure that food at the one million U.S. restaurants and supermar-

kets is safe and properly protected. The FDA Food Code is offered for adoption by local, State, and Federal governmental jurisdictions for administration by the various departments, agencies, bureaus, divisions, and other units within each jurisdiction that have been delegated compliance responsibilities for food service, retail food stores, or food vending operations.

Electronic Inspection System (EIS)

FDA upgraded the EIS for regulatory agencies in their FDA Food Code implementation and regulatory program management. The EIS is an inspection and food safety database management tool to aid federal, state, and local regulatory agencies. The Minnesota Department of Agriculture has implemented EIS as their inspection system and personnel were provided a one-week training course in system setup and customization.

Voluntary National Food Regulatory Program Standards

FDA issued the Voluntary National Retail Food Regulatory Program Standards, a benchmark document detailing the operational and administrative criteria necessary for all retail food regulatory programs to monitor and improve retail food safety. Sixty state or local jurisdictions were assisted in implementation of the standards.

Performance Plan Goals

Food Safety: Premarket Review of Food Ingredients

The first strategic goal of the Foods Program was to provide consumers quicker access to new food ingredients, bioengineered foods, and dietary supplements, while assuring their safety and effectiveness.

The Food Program's key challenge in the premarket area is to expedite review of new food products without jeopardizing public safety. The performance goal below reflects the agency's commitment to completing work on the "backlog" of overdue food and color additive petitions.

Performance Goal[17]

Complete the safety evaluation of fifty percent of the number of food and color additive petitions that were under review for more than 360 days at the beginning of the Fiscal Year.

Results

The Foods Program met this goal. It had completed the safety evaluation of nine of seventeen food and color additive petitions that were under review for more than 360 days on October 1, 2001.

[17] Because FY 2002 data is not currently available, we are using FY 2001 performance goal and results.

The food and color additives review program has concentrated on reaching timely decisions on newly submitted petitions, as well as effectively eliminating the backlog of overdue petitions. A few years ago, there was an inventory of more than 150 pending food and color additive petitions, most of which had been under review for more than a year. Significant progress has been made, so that on October 1, 2001, fewer than 20 petitions had been under review for more than a year.

One factor that contributed to this progress was the implementation of the food contact notification program that was established by the FDA Modernization Act. Following establishment of this program, a number of petitions in the overdue inventory were converted to notifications; these tended to be the most straightforward of the pending petitions. Many of the remaining petitions were those that have raised particularly difficult scientific or policy issues. The backlog of overdue petitions should be completed by next year.

Food Safety: Postmarket Surveillance

The second strategic goal was to reduce the health risks associated with food and cosmetic products by preventing human exposure to hazards, monitoring product quality, and correcting problems that are identified.

Compliance monitoring is a critical component of food safety assurance during and after production and through the commercial distribution stage. FDA has the statutory authority to inspect establishments, examine or analyze samples, and conduct investigations to determine whether product safety and quality standards are met at each stage of commercial food production and distribution. The Agency accomplishes its safety assurance for domestic foods and cosmetics through compliance programs that guide surveillance and enforcement activities.

The greatest challenge the Foods Program faces is how to cope with the growth of the regulated industry and the growth and changes in health risks. FDA has increased the number of domestic establishment inspections to improve the coverage for the entire food supply. These inspections are performed by the ORA's Field force or by State governments under contract with FDA. Other partnership arrangements are used to leverage inspectional resources. The ORA provides laboratory analysis of food samples and initiates regulatory action on adultered or misbranded products. The Field force also responds to emergencies by immediately mobilizing to investigate reports of product problems including tampering incidents, those due to natural disasters, and those which may be the result of terrorist activities.

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.

Performance Goal[18]

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

[18] Because FY 2002 data is not currently available, we are using FY 2001 performance goal and results.

Result

The Foods Program met this goal. ORA reported that its Field force had inspected nearly 80 percent of domestic firms producing foods at "high risk" of microbiological contamination (i.e. approximately 5300 of 6800 "high risk" establishments) in FY 2001. Overall, FDA and the states (under FDA auspices) conducted approximately 14,000 domestic food inspections.[19]

High-risk establishments are those establishments that produce foods with the greatest risk for microbial contamination and those foods requiring specific components for a safe and nutritious product. Examples include establishments that produce infant formula, ready-to-eat food, heat and serve, seafood products or low acid canned and acidified foods. See Table 2 below for further explanation.

Table 2

Type of Food	Explanation	Examples
Ready-to-Eat Food	Products that will undergo no or minimal processing (such as, heating, freezing, washing, that would eliminate a pathogenic organism on the food).	Fresh fruits and vegetables, bakery goods, cheeses, and cooked pasta dishes.
Heat and Serve Food	Products which normally receive a heat treatment (such as, microwave) prior to final consumption by the consumer. Such products are hazardous if the recommended heat treatment is insufficient to eliminate pathogenic organisms which may be in the product.	Frozen foods.
Seafood Products	Particular types of seafood susceptible to cigueterra or scrombotoxics. Also, uncooked molluscan shellfish is high risk. Seafood not considered high risk would be raw fish, not of the scromboid species, which require cooking before consumption, such as trout, catfish and shrimp.	Mahi mahi, pompano, tuna, salmon, swordfish.
Low Acid Canned or Acidified Foods	Products not properly processed may present a potential hazard to health in the form of botulism. Examples of low acid canned food include not only the traditional tin and aluminum cans, but glass jars and hermetically sealed pouches. Acidified foods are low acid food products to which an acid, such as vinegar, is added for preservation.	Products which normally receive a heat

[19] Please note that domestic travel was curtailed from September 11, 2001 to October 2001, reducing the number of inspections.

Management Discussion & Analysis

Human Drugs Program

Mission

The Human Drugs program promotes the public health by assuring that safe and effective drugs are available to the American people. The aim of the program is to:

- Ensure the safety and effectiveness of all drug products used for the prevention, diagnosis, and treatment of disease;
- Ensure the prompt approval of safe and effective new drugs so that patients can enjoy the benefits provided by therapies to treat and prevent illness and disease;
- Review premarket applications for new and generic drugs in a timely and quality manner, as well as new and generic drug supplemental applications;
- Evaluate reports of adverse events, medication errors, and product defects associated with drug products;
- Enhance DHHS' ability to react to terrorist attacks and assure public health;
- Use postmarket surveillance reporting and the collection and analysis of drug product samples in evaluating compliance with quality standards and labeling requirements; and
- Conduct inspections to determine if fraudulent drugs are marketed in commercial channels, and evaluate foreign and domestic compliance with good manufacturing practices.

Background

The Human Drugs Program (Program) is administered by CDER and supported by ORA.

The Program promotes and protects the health of Americans by assuring that all prescription and over-the-counter drugs are safe and effective. It evaluates all new drugs before they are sold, and serves as a consumer watchdog for the more than 10,000 drugs on the market to be sure they continue to meet the highest standards. The Program routinely monitors TV, radio, and print drug ads to ensure they are truthful and balanced. It also plays a critical role in providing health professionals and consumers information to use drugs appropriately and safely. Recent drug approvals represent important advances for children, women, elderly persons, and patients with heart disease and cancer, the leading cause of death in the United States. The Program priorities include:

Assuring that safe and effective new and generic drugs are available to the American public

- The Program's multidisciplinary scientific staff conducts thorough reviews of all new and generic drugs;
- FDA has reduced the average review time for new drugs covered under the Prescription Drug User Fee Act (PDUFA) from more than 2.5 years to less than one year;
- Patients with life-threatening illnesses gain access to treatments sooner;
- FDA requires many drug manufacturers to provide information on how children can take their drugs safely and effectively; and
- As part of the Nation's bio-terrorism efforts, FDA is encouraging the development and expediting the review of medications for the prevention or treatment of injuries that could be caused by terrorists using biological, chemical, or nuclear agents.

Improving drug safety

- After approval, the Program identifies drug safety concerns through voluntary reports submitted to the FDA's Med Watch program and CDER's adverse event reporting system, which together receives more than 250,000 reports each year;
- The Program's scientists analyze adverse event reports and take actions that best protect the public's health, ranging from providing more information to patients to withdrawing drugs from the marketplace;
- The Program instituted a comprehensive program to communicate with consumers and improve patient safety. For example, 6 million consumers received FDA's brochure on proper medication use; and
- The Program works with industry to reduce errors related to confusing packaging and/or drug names; and has proposed a regulation to make prescription drug labeling easier for health-care providers to use.

Cost

Fiscal Year	Net Program Cost (000s)
2002	$280,402
2001	$255,316
2000	$251,243

The Human Drugs Program experienced a 9.8 percent increase in net costs in FY 2002. This increase may be attributed to the following: funding the application review goals of the PDUFA; enhancing the generic drug program to provide a steady supply of more affordable drugs; and for increasing enhancements of the drug safety program. The net cost includes the expenses for a program, including the allocation of overhead expenses (such as, the Office of the Commissioner's costs for administrative and policy direction, ORA's field operations' costs, rent, and other overhead), less exchange revenue.

Program Goals and Accomplishments

Highlights of Product Approvals

Eloxatin for Colorectal Cancer

Eloxatin (oxaliplatin) injection for use in combination with infusional 5-fluorouracil (5-FU) and leucovorin was approved for the treatment of patients with colorectal cancer whose disease has recurred or become worse following initial therapy with a combination of irinotecan with bolus 5-FU and leucovorin. The combination including Eloxatin was shown to shrink tumors in some patients and delay resumed tumor growth. CDER reviewed the marketing application for Eloxatin in seven weeks, the fastest review to date for a cancer drug. Cancers of the colon and rectum (colorectal) are the fourth most commonly diagnosed cancers and rank second among cancer deaths in the United States. About 150,000 new cases of these cancers occur each year, and they cause approximately 56,000 deaths.

New Anti-Clotting Drug

ARIXTRA™ (fondaparinux sodium) injection was approved for reducing the risk of blood clots after orthopedic surgery for hip fracture, hip replacement, and knee replacement. ARIXTRA™ is the first synthetic anticoagulant indicated for use in these types of surgeries. The formation of clots in the deep veins of the legs is common after these surgeries and can lead to serious and potentially fatal consequences, such as when the clots break off and travel to the lungs.

Viread for HIV-1 Infection

Viread (tenofovir disoproxil fumarate) is a new antiviral drug indicated for treatment of HIV-1 infection in combination with other antiretroviral medicines. Tenofovir disoproxil fumarate is the first nucleotide analog approved for HIV-1 treatment. Nucleotides are

similar to nucleoside analogs, and block HIV replication in the same manner. The introduction of potent antiviral drugs and the combined use of these drugs have markedly reduced replication of HIV in many patients and have improved survival rates. Yet because HIV mutates rapidly, resistance to one or more of these potent drugs may develop over time, necessitating the development of new drugs to treat these resistant virus strains.

Other Accomplishments

Reauthorization of PDUFA

The Congress reauthorized PDUFA for another five year period. FDA worked with its stakeholders to strengthen the program and improve the financial model on which fees are based. Major changes include increased revenues that should cover FDA's anticipated PDUFA fee expenditures every year; a more stable revenue model that is focused on total fee revenue levels that increase each year and allowed volatility in total application, product, and establishment fee revenues; a totally new workload adjustment provision that takes into consideration all aspects of review workload, including investigational new drug and manufacturing supplement submissions that do not generate fee revenue; and a change in the critical trigger that sets a minimum level of spending from appropriations for the drug review process, allowing a tolerance of five percent.

New OTC Drug Facts Label Promoting the Safe Use of OTC Medicines

May 16, 2002, marked the date that most OTC drug manufacturers must display FDA's new easier-to-read drug facts label on their products. The OTC regulation FDA finalized in March 1999 requires a standardized format for the labeling of the drugs Americans use most often - OTC drugs. Many manufacturers voluntarily adapted the new OTC label even before the May 16th implementation date. In recent surveys, randomly selected categories of OTC drugs at a retail chain showed that nearly 75 percent of labels examined already displayed the drug facts label. Although in many cases the new label began appearing on the shelves within the last two years, most of the more than 100,000 OTC products marketed will now be required to display the new labeling.

Changes to the Risk Management Program to Prevent Birth Defects Caused by Accutane

FDA advised consumers and health care providers about significant changes to the Accutane risk management program for pregnancy prevention. The new program is called S.M.A.R.T. (System to Manage Accutane Related Teratogenicity). S.M.A.R.T. was developed in consultation with FDA by Accutane's manufacturer, Roche Laboratories. The program is designed to enhance the safe and appropriate use of Accutane by strengthening the existing Accutane Pregnancy Prevention Program, a comprehensive patient education program.

Accutane is approved to treat the most serious form of acne. This form of acne is painful, permanently disfiguring, and does not respond to other acne treatments. Accutane is very effective, but its use carries significant potential risks, including birth defects and even fetal death. In recent years, as more women have been receiving prescriptions for Accutane, the risk that pregnant women may be inappropriately using the drug has increased.

Establishment of a Drug Safety and Risk Management Advisory Committee

Drug safety, risk management, risk communications, medication errors, and patient safety are all issues which have gained prominence over the past few years. In part, this is due to publication of the Institute of Medicine report, "To Err is Human," as well as a greater awareness that medications are not safe in an absolute sense. The safety of medications depends on the manner in which the healthcare community uses them. These issues play a significant role in CDER's overall evaluation of the risk benefit of drugs, and are common topics of discussion at Agency advisory committee meetings.

In general, however, these advisory committee meetings tend to be comprised of disease and medical subspecialty experts, rather than experts in risk related issues. CDER was able to supplement some meetings with risk management experts in an ad hoc manner. In addition, the Center designed and established a drug safety and risk management advisory committee. This committee includes experts in the areas of medication errors, risk communication, risk perception, risk management, clinical trial methodology, evidence based medicine, biometrics, and pharmacoepidemiology.

Performance Plan Goals[20]

Information is provided on two premarket goals: one pertaining to NDAs and the other to ANDAs. For the NDA goal, FY 2000 results are shown. For the ANDA goal, FY 2001 results are shown.

Premarket Review: New Drugs

A major objective of the Program is to reduce the time required for FDA's review process of all drugs. Emphasis is given to the review of new drugs intended to treat serious or life-threatening diseases (such as, AIDS, AIDS-related diseases, cancer, and heart disease); and those products that demonstrate the potential to address unmet medical needs. Applications for drugs similar to those already marketed are designated standard, while priority applications represent drugs offering significant advances over existing treatments. The reauthorization of PDUFA assures that commitments by FDA and the drug industry will continue to meet or exceed its demanding performance goals. It is also essential to retain FDA's skilled employees, who play a significant role in the outstanding effectiveness of the drug review process.

Performance Goal

Review and act on 90 percent of standard original NDA submissions within 12 months of receipt (50 percent within 10 months); and 90 percent of priority original NDA submissions within 10 months.

Results

CDER met its FY 2000 performance goal (see Table 3 on next page).

[20] CDER is reporting on FY 2000 and FY 2001 performance goals since this is the most recent final performance data available for certain measurements. Final performance data for FY 2002 will not be available until January 2004.

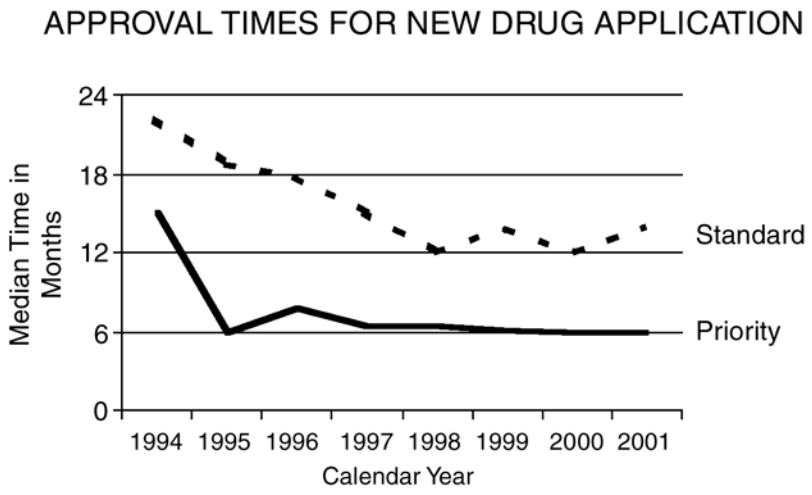
Table 3

Fiscal Year 2000 Cohort (as of 12/31/01)

Submission Type	Number of Submissions Filed	Goal (months)	Number of Reviews "On Time"	Percent of Reviews "On Time"
NDAs - Priority	29	90% in 6 mo.	28	97%
NDAs - Standard	92	90% in 12 mo.	89	97%
		50% in 10 mo.	73	79%

The chart below (Figure 3) illustrates that median approval time in months for priority applications has decreased from 15 months in 1994 to 6 months in 2001, and median approval time for standard applications has decreased from 22.1 months to 14 months. Approval time represents the total review time at the Agency plus industry response time to the Agency's requests for additional information.

Figure 3



Premarket Review: Generic Drugs

Generic Drugs are known for their cost-effectiveness. According to the Congressional Budget Office, they save consumers an estimated $8 billion to $10 billion a year compared with the price of brand-name products. FDA continues to support an active generic drugs program with a focus on expanding the availability of high-quality generic drug products to the public. The basic requirements for approval of generic and brand-name drugs are the same as new drug approvals, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of the original product. The generic version must have the same dosage form, safety, strength, route of administration, and conditions of use as the trade-name product.

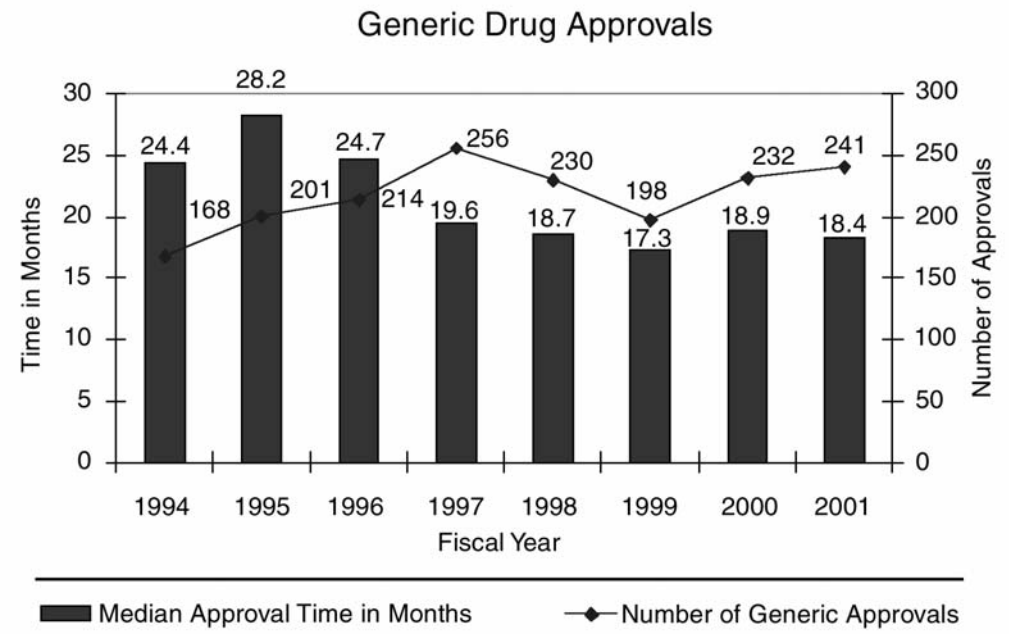
Performance Goal

Review and act upon 50 percent of fileable original generic drug applications within six months after submission date.

Results

FDA met its goal for FY 2001 acting on 84 percent of original applications within six months after the submission date. This is an increase of more than 27 percent over FY 2000. The FY 2001 18.4-month median approval time compares to 18.9-months in FY 2000 and 17.3-months in FY 1999 (see Figure 4 below).

Figure 4



The Office of Generic Drugs utilized an increase of $2.5 million in FY 2002 to improve the efficiency of the generic drug review process thereby decreasing the average approval time. The increase was also used to conduct research that will allow CDER to address specific scientific questions regarding bioequivalence and chemistry of generic products. This research is directed at evaluating ways to enable approval of generic drugs in areas that currently lack generic alternatives, such as inhalational or topical drug products.

Postmarket Assurance

CDER uses a number of postmarketing risk assessment approaches to ensure the continued safe use of drug products. Still, approximately 1.3 million patients each year are injured from medical therapy with up to two-thirds of these events due to medical management errors. Costs from these medical errors range from $37 to $50 billion annually. The Institute of Medicine estimates that as many as 100,000 Americans die annually as a result of preventable medical errors and the proliferation of new products may increase this number. CDER maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events such as adverse reactions, drug-drug interactions, and poisonings.

FDA puts substantial effort into reviewing adverse event and medication error reports to identify serious or potentially serious outcomes that might be avoided. The Adverse Event Reporting System (AERS) is a powerful, state-of-the-art tool for detecting signals: this

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. AERS offers paper and electronic submission options, international compatibility, and pharmacovigilance screening. As CDER discovers new information about a drug's safety profile, FDA may decide to disseminate risk information, such as "*Dear Health Care Practitioner*" letters, and may initiate regulatory action.

Performance Goal

The FY 2002 performance goal 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.

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 5 below).

Figure 5

Electronic submissions provide CDER, FDA, and the public with several tangible benefits. Specifically, automating the receipt and processing of safety reports will allow CDER to be more responsive to public health issues, reduce resources associated with data management, and apply better data and better science to the drug regulatory process. Electronic submissions also result in substantial cost savings. It is estimated that the cost of receiving a report is cut from $18 to $5 per report for those submitted electronically.

Management Discussion & Analysis

Biologics Program

Mission

The Biologics Program is responsible for ensuring that biological products, including whole blood and blood products, vaccines, and therapeutic products including cells, gene therapies, and tissues, are safe and effective. The aim of the program is to:

- Ensure the safety, efficacy, potency, and purity of biological products including vaccines, therapeutics, and related drugs and devices intended for use in the treatment, prevention, or cure of diseases in humans;
- Ensure the safety of the nation's supply of blood and blood products;
- Evaluate the safety and effectiveness of biological products before marketing, and monitor the pre-clinical and clinical testing of new biological products;
- License biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine, and biotechnology manufacturers;
- Conduct regulatory research to establish product standards and develop improved testing methods; and
- Assure the safety of marketed biological products through monitoring adverse experiences, lot release testing and postmarket surveillance.

Background

The Biologics Program (Program) is administered by CBER and supported by ORA.

Biologics are medical products derived from living sources. They include vaccines, blood and blood derivatives, allergenic patch tests and extracts, tests to detect HIV and hepatitis, gene therapy products, cells and tissues for transplantation, and new treatments for cancers, arthritis, and other serious diseases. The products that the Program regulates are on the leading edge of technology. Rapid scientific advances in biochemistry, molecular biology, cell biology, immunology, genetics, and information technology are transforming drug discovery and development, paving the way for unprecedented progress in developing new medicines to conquer disease.

The Program is also responsible for ensuring the safety of the nation's blood supply by reducing the risk of infectious disease transmission and other hazards, while maintaining an adequate supply of whole blood and blood products.

Costs

Fiscal Year	Net Program Cost (000s)
2002	**$187,416**
2001	**$160,889**
2000	**$132,860**

The Biologics Program has experienced a 16.5 percent increase in net program costs. This increase is attributed to funding for counter-bioterrorism activities, for premarket activities, and for inspections. The net cost includes the expenses for the program, including the allocation of overhead expenses (such as, the Office of the Commissioner's costs for administrative and policy direction, ORA's field operations' costs, rent, and other overhead), less exchange revenue.

Program Goals and Accomplishments

Highlights of Product Approvals

CBER approved biological products used to diagnose and treat a wide variety of medical conditions.

First Biological Treatment for Sepsis

The first biological treatment for sepsis, a life-threatening illness caused by severe infection, is a genetically engineered version of a human protein, Activated Protein C. This protein interferes with some of the body's harmful responses to severe infection, including the formation of blood clots that can lead to organ failure and death.

Treatment for Gastrointestinal Stromal Cancer

This cancer drug is for the treatment of gastrointestinal stromal tumor (GIST), which is an uncommon tumor, affecting about 5,000 people in the United States. It is a tumor that occurs in the stomach or intestinal tract and metastasizes in the abdomen or the pelvis. In GIST, the cancer drug blocks a different abnormal enzyme found on the tumor cells. As these abnormal enzymes are largely confined to cancer cells, there is little damage to normal cells while cancer cells are killed.

First Nucleic Acid Test (NAT) System

The NAT system is used to screen whole blood donors for infections with Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV). This test system can simultaneously detect HIV and HCV in blood using a semi-automated system and is expected to further ensure the safety of whole blood and blood components, including fresh plasma, red cells, and platelets, by permitting earlier detection of HIV and HCV infections in donors.

Other Accomplishment Information

One Hundred Years of Biologics Regulation

On July 1, 2002, the Biologics Program commemorated 100 years of biologics regulation, the Biologics Control Act of 1902. This milestone was marked by a series of events, including a scientific symposium (presentations are displayed at www.fda.gov/cber/inside/centennial.htm.) and an exhibit at the Smithsonian National Museum of American History. The symposium honored the past contribution of CBER scientists and regulators, underscored the role of biologics in modern medicine, and provided a glimpse into the exciting future of biologic innovations and CBER's role in shepherding these products to market. Among the many significant scientific and regulatory contributions made by CBER staff is:

- pioneering research on vaccines, including development and licensing of the first Rubella (German measles) vaccine and the first licensed bacterial conjugate vaccine for Haemophilus influenzae;
- groundbreaking research on Hepatitis B, viral transmission and viral inactivation, leading to new regulatory requirements to protect recipients of blood and blood plasma, and licensing of diagnostic tests for Hepatitis B;
- licensing of the first HIV test kit to protect the blood supply and new-generation tests for HIV, including nucleic-acid based tests;
- using of state-of-the-art DNA microarray technology to study genes (genomics), research that could lead to a better understanding of infectious diseases, to a better standardization of biologics and to new improved medicines and vaccines;
- collaborating with NIH on proteomics research, the study of all proteins in living cells, which potentially could revolutionize cancer detection and care; and
- licensing of many new biotechnology-derived products for severe and life-threatening illnesses.

The CBER exhibit at the National Museum of American History contains a video and book that trace the Center's history and highlight its contributions to advancements in public health.

Gene Therapy Patient Tracking System

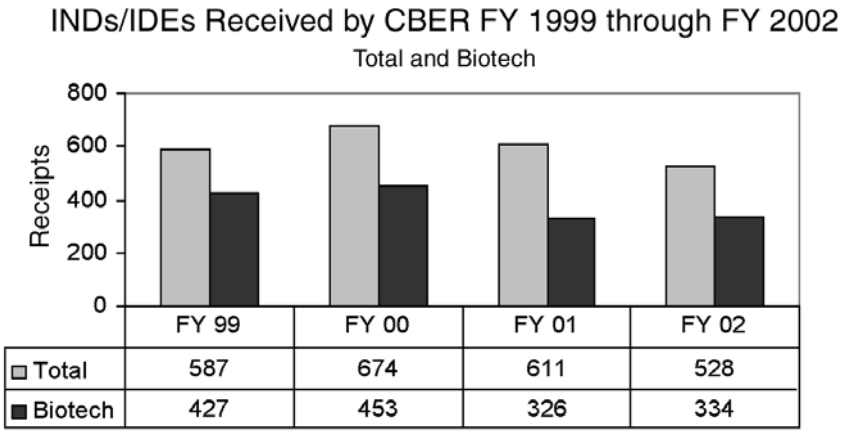
CBER developed a comprehensive Gene Therapy Patient Tracking System (GTPTS) to help ensure the proper oversight for gene therapy products. The GTPTS is a system for the collection and analysis of information pertinent to the safety of recipients of gene therapy. Far more than an adverse event database, it represents a comprehensive, integrated collection of procedures, policies, programs, databases, and report structures pertinent to the conduct of studies, the collection of short-term and long-term outcomes information from recipients, the transmission of information to FDA, the storage of information in electronic databases in an accessible and analyzable format, and the analysis and use of the information to make informed regulatory decisions and to increase the understanding of researchers, subjects, and the public.

Critical to this system is an evaluation of the specific needs of gene therapy oversight with regard to what information should be collected; how best to collect that information; and how to best store, analyze, report, and use the data. One component of the GTPTS involves information technology and the need for adequate informative databases. No current database satisfies the needs of the GTPTS. FDA and NIH are developing a database application, the Genetic Modification Clinical Research Information System (GeMCRIS), to assist in the evaluation and analysis of human gene therapy clinical information. GeMCRIS will be one of the databases used for the GTPTS.

Growth of Biotechnology-Produced Products

The below chart (Figure 6) shows trend of INDs/IDEs for a four year period. INDs/IDEs are submitted by sponsors, before beginning clinical trials, to determine their safety and efficacy, and to request FDA authorization to administer an investigational drug or biological product to humans.

Figure 6



Biotechnology-produced products have increased dramatically in recent years. The number of biotechnology INDs received by CBER rose from five in FY 1980, to 334 in FY 2002. During FY 2002, FDA received 16,484 investigational amendments for INDs. Much of this growth has been in somatic cell, gene therapy, and xenotransplantation products for which there were nine INDs in FY 1989, increasing to 113 INDs in FY 2002. Adjunct procedures used in gene therapy, such as stem cell isolation, are also rapidly increasing, and leading to a secondary rise in device and biological submissions on this area.

Performance Plan Goals[21]

Premarket Review

The first strategic goal of the Biologics Program was to ensure the expeditious availability of safe and effective human drugs, including biologics, for the prevention, diagnosis, and treatment of disease.

CBER is responsible for reviewing and approving biologics covered by PDUFA[22] that are vaccines and therapeutics. CBER also has responsibility for reviewing and approving biologic products not covered by PDUFA. The non-PDUFA biological products are blood and blood products, human tissue for transplantation, allergenic products, and devices associated with their manufacture.

PDUFA established performance goals for the evaluation of applications for marketing drug and certain biological products. Review performance monitoring is being done in cohorts. For example, the FY 2001 cohort includes applications received from October 1, 2000, through September 30, 2001.[23]

Performance Goal

The FY 2001 cohort review performance goals covered under PDUFA for priority original New Drug Applications (NDA), Product License Application (PLA), and Biologics License Application (BLA) are:

- Review and act on 90 percent of priority original PDUFA NDA/PLA/BLA submissions within six months of receipt; and

- Review and act on 90 percent of priority PDUFA efficacy supplements within six months of receipt.

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21 The Biologics Program reports on two premarket performance goals that have a time delay in reporting performance results due to the design of the performance measure. DHHS requires FDA to report final data results only and no partial data are allowed. Because of the time delay and DHHS policy, we are using FY 2001 performance data since the FY 2002 results are not available until 6 months after the cohort year.

22 Please note that the PDUFA program excludes various process activities that normally are associated with the regulation of biological products. These include: enforcement policy development; post-approval compliance and surveillance activities, including review of adverse drug reports and annual reports; advertising review activities once marketing of the product has begun; and inspections unrelated to the review of covered applications and research.

23 Accomplishment of the cohort-year performance goals is not immediately measurable at the close of the fiscal year. The outcome can be measured either 6 or 10 months after the last submission received in FY 2002, depending upon the category of submission (for 10-month standard applications – July 2003, and for priority original applications – April 2003). The FY 2001 performance data is used.

Results

For the two performance goals, CBER exceeded its performance goal. Table 4 shows CBER's performance for the two performance goals. The data provided are as of September 30, 2002.

Table 4

Biologics Program FY 2001 PDUFA Cohort as of 9/30/02

Application Type	Number Submitted	Number Filed	RTF, UN or WF	First Action w/in Goal (%)	Submissions Overdue (%)
New Product Priority	3	3	0	100%	0%
Efficacy Supplement Priority	2	2	0	100%	0%

RTF = Refuse to File; UN = Unacceptable for filing (User Fee not paid); WF = Withdrawn before filing;

Post-Market Quality Assurance

The second strategic goal of the Biologics Program is to reduce the risk of biologics products on the market through assuring product quality and correcting problems associated with their production and use.

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.

Performance Goal

For FY 2001, meet the biennial inspection statutory requirement by inspecting 50 percent of registered blood banks, source plasma operations, and biologics manufacturing establishments.[24]

[24] The FY 2001 performance measure is used for this goal because final performance results for FY 2002 are not available.

Results

CBER reported that it had exceeded its performance measure. Fifty-seven 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 2,790 establishments in the Biologics Program inventory.

Management Discussion & Analysis

Animal Drugs and Feeds Program

Mission

The Animal Drugs and Feeds Program is responsible for ensuring that animal drugs and medicated feeds are safe and effective for intended uses and that food from treated animals is safe for human consumption. The aim of the program is to:

- Foster public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act, and other authorities;
- Process premarket applications as quickly as possible to increase the availability and diversity of safe and effective veterinary products that relieve animal pain and suffering; and
- Monitor marketed products for all animal drugs and feeds to minimize harm to humans or animals that might arise from the use of these products.

Background

The Animal Drugs and Feeds Program (Program) is administered by the CVM and supported by ORA.

The average American consumes nearly 200 pounds of meat and fish, 30 pounds of eggs, and 600 pounds of dairy products each year. Although 80 percent of the Program's work is devoted to human health protection through the safety of animals used to produce human food, the Program is also responsible for food additive and animal drug review for companion and other non-food animals. CVM's top priorities are animal drug review, antibiotic resistance, prevention of BSE or "mad cow disease," and the safety of food derived from genetically modified animals.

Cost

Fiscal Year	Net Program Cost (000s)
2002	$112,736
2001	$ 83,106
2000	$ 63,591

The Animal Drugs and Feeds Program experienced a 35.7 percent increase in net costs in FY 2002. This increase is attributed to funding for: food safety, BSE, imports and inspections, antibiotic drug review, and pay raises. The net cost includes the expenses for the program, including the allocation of overhead expenses (such as, the Office of the Commissioner's costs for administrative and policy direction, ORA's field operations' costs, rent, and other overhead), less exchange revenue.

Program Goals and Accomplishments

Highlights of Product Approvals

New Dosage Form Drug Approved for Horses

FDA approved, *Torpex*, the first metered-dose inhaler product for respiratory disease in horses. The active ingredient, albuterol, is a new chemical entity never before approved for veterinary use, and is administered to horses intranasally by a metered-dose inhaler for the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction (also known as chronic obstructive pulmonary disease in horses). Aerosol albuterol provides relief to affected horses within minutes allowing the horse to breath easier.

New Pain Medications

Deracoxib is an original approval of a new chemical entity, a nonsteroidal anti-inflammatory drug, for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

Carpofen received a supplemental approval which adds the indication for the control of postoperative pain associated with soft tissue and orthopedic surgery in dogs.

Highlights of Product Safety Actions

Nationwide Recall of Product Containing Mercury

CVM received notices of adverse drug events from Alabama and Louisiana concerning the death of horses following application of a mercuric chloride blistering agent to their legs. The use of mercury blistering agents to treat lameness in horses is outdated, unsafe for animals and humans, and outside the scope of modern veterinary medicine. The product, administered topically on horses for the treatment of lameness, shin bucks, bows, chips, splints, and other horse leg ailments, was distributed nationwide to veterinarians, dealers, and consumers. On May 30, 2002, the company agreed to a nationwide voluntary Class I Recall[25] of the product and agreed to stop manufacturing the product. All products remaining on the market are subject to this recall.

Animal Feed Supplements Contaminated with Dioxin Recalled

On March 22, 2002, FDA announced the voluntary recall of several animal feed products that contained high levels of dioxin.[26] The products, chelated minerals and mineral premixes, are added to feed to provide cattle, pigs, and other livestock with needed micronutrients. The action was taken as a response to a joint investigation conducted by FDA and the Minnesota Departments of Agriculture and Health, and the Minnesota Pollution Control Agency.

Recalling these chelated minerals and mineral premixes is an important part of the overall effort to reduce dioxin levels in the food chain and environment. Dioxin compounds are commonly found, at very low levels, in food, particularly in foods containing meat or animal fat. FDA continues to survey for dioxin in the Agency's Market Basket survey and through a directed survey of animal products.

Other Accomplishments

Improved BSE Inspection Database

Preventing BSE remains a top priority for the FDA. The Agency conducted annual targeted inspections of 100 percent of all known renderers and feed mills handling prohibited feed material. During FY 2002, FDA designed, developed, and implemented a new BSE inspection tracking module in the Field Accomplishment Compliance Tracking System (FACTS) database, allowing FDA to record inspection results and track compliance more effectively.

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[25] A Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

[26] Dioxin is a broad family of chemical compounds that accumulate in the fat of humans and animals and can produce a broad range of adverse effects. The effects include, but are not limited to, enhanced tumorigenicity, enzyme induction, immune suppression and a wasting syndrome.

Legacy data from the first round of BSE inspections was integrated with the new database to ensure that all known firms were included in the FACTS inventory. Several online error checking features to prevent entering incorrect or illogical responses to the BSE Checklist database information were incorporated into the new module. BSE inspection information is available through search-generated reports under the FACTS menu, for use by FDA personnel. The information from each BSE inspection is now:

- Entered directly in the FACTS database by ORA personnel;
- Entered under specific BSE FACTS inspection codes (requiring the entry of a BSE checklist for successful inspection completion); and
- Contained in one central database which is directly available to all FDA personnel.

These improvements give greater and immediate control, and ensure high quality, meaningful, and timely recording of detailed inspection findings and compliance status with the Ruminant Feed Ban Rule.

Draft Guidance Document on Antimicrobial Resistance in New Animal Drugs

CVM published a Federal Register notice in September 2002, announcing the availability of a draft guidance document entitled, "Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern." This document describes an approach for drug sponsors to implement concepts from the framework document[27] for assessing the antimicrobial resistance concerns as part of the overall preapproval safety evaluation of new animal drugs.

The draft guidance document represents the Agency's current thinking on a recommended approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern. An alternative approach may be used as long as it satisfies the requirements of applicable statutes and regulations. The guidance outlines a possible process for evaluating new animal antimicrobial drugs before approval and a strategy for re-evaluating the safety of antimicrobial drug products currently approved for use in food-producing animals.

Performance Plan Goals[28]

Premarket Review

The first CVM strategic goal is to increase the availability and diversity of safe and effective animal drugs and feeds. To help achieve this goal, a staff college has been developed as a means of continuously building the scientific-based knowledge and capability of the

[27] FDA published a framework document in January 1999 that outlined possible strategies for managing the potential risks associated with the use of antimicrobial drugs in food producing animals.

[28] The final results for the FY 2002 performance goals are not available for reporting in the annual financial report. FY 2001 performance goals and results will be used.

CVM staff. The CVM Staff College will allow the review staff to increase and maintain a level of scientific knowledge that is critical in order for CVM to address developing animal science and veterinary medicine issues, such as antimicrobial resistance and biotechnology.

Performance Goal

Begin to design and implement a staff college.

Results

CVM reported it had met its goal for FY 2001. CVM started Phase I of the Staff College. The following actions were performed:

- Awarded a contract to perform needs assessment and begin building the staff college infrastructure needed for a competency based learning management system to enhance the science-base;

- Awarded a facility and equipment contract and began construction of a new training center; and

- Reviewed 130 candidates applying for staff college directorship.

Postmarket Review

The second strategic goal of the Animal Drugs and Feeds Program Performance Plan is to reduce the risks associated with marketed animal products. Once animal drugs and feeds are marketed, FDA continues to manage public health risks through post-market activities (such as, inspections, monitoring, and research) to identify potential human and animal health hazards.

CVM participates in the NARMS.[29] One of the NARMS program goals has been to provide information on antibiotic resistance to veterinarians, physicians, and public health authorities so that timely action can be taken to protect the public health and allow them to make informed decisions on treatment options for their patients. For example, a multi-drug resistant variant of Salmonella Newport has emerged in humans and animals and was detected in the NARMS data. The participating NARMS agencies have alerted the human and veterinary medical communities to this emergence so that they may be aware and take proper actions in treating infections with this organism.

Performance Goal

Maintain isolate testing rate for Salmonella in the National Antimicrobial Resistance Monitoring System at 12,000.[30]

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[29] NARMS is briefly described in the Agency Chapter on Page I-6.

[30] An isolate is defined in the bacteriology context as to grow a pure culture of a specific bacterium.

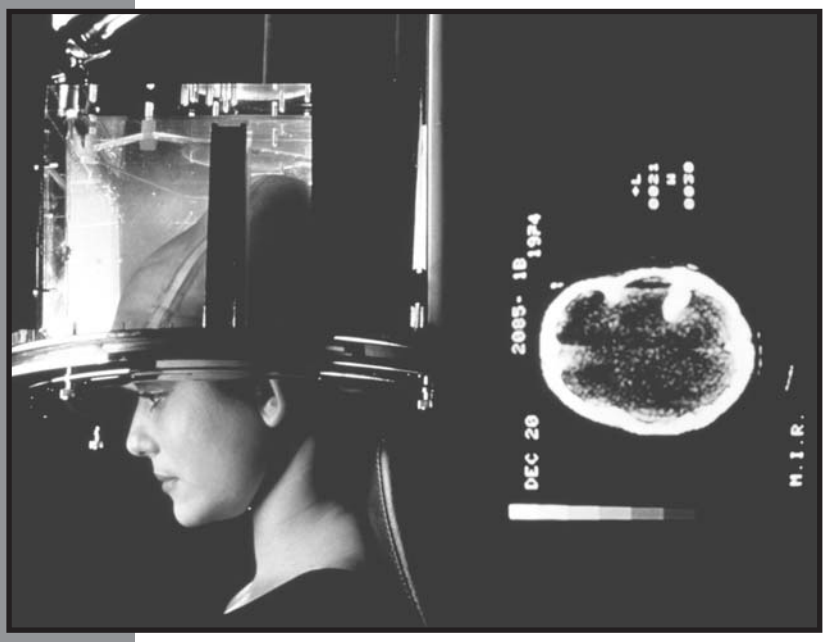
Results

The goal was not met in FY 2001. During the year, 8,899 isolates were collected (6,795 animal, 1,671 human, and 433 retail meat isolates). Although NARMS testing was expanded in FY 2001 by adding retail meats sampling, fewer veterinary isolates were available for study. Salmonella sampling was not a part of the FY 2001 USDA's Animal and Plant Health Inspection Service's National Animal Health Monitoring System program; thus, isolates were not received from that program for NARMS antimicrobial susceptibility testing in FY 2001.

NARMS is a cooperative agreement with other agencies and unfortunately the FY 2001 performance was out of FDA's control. The goal shows dependence on factors beyond FDA's control such as the number of humans contracting a food borne disease and the sampling issue mentioned above.

The goal has been revised for FY 2002 to show how CVM will use NARMS data to communicate with the public on antibiotic resistance. Although the performance goal was not met, NARMS is still a fully functional program and the public health has already and will continue to benefit from this program.

Management Discussion & Analysis



Devices and Radiological Health Program

Mission

The Devices and Radiological Health Program is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products. The aim of the program is to:

- Meet all statutory responsibilities for review of new medical devices;
- Assure medical product safety by monitoring the use of all medical devices, and the function and use of radiological health;
- Manage emerging hazards to prevent widespread health and safety threat and ensure safe and effective new technologies;
- Apply the Total Product Life Cycle model across the range of Devices and Radiological Health activities, by covering products from concept to obsolescence;
- Connect to the global public health community, and partner with stakeholders;
- Use science in the regulatory process to the maximum extent;
- Attract and retain a diverse and high quality workforce; and
- Measure and set targets to program's impact on public health.

Background

The Devices and Radiological Health Program is administered by CDRH and supported by ORA.

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products. There are thousands of types of medical devices, from heart pacemakers to contact lenses. Radiation-emitting products regulated by CDRH include microwave ovens, video display terminals, medical ultrasound equipment, and x-ray machines.

CDRH faces an increasing challenge to regulate a changing and rapidly growing device industry. The number of domestic and international device firms has increased from 9,061 in FY 1997 to approximately 14,250 in FY 2002.

The medical device industry of the 21st century is developing increasing numbers of more complex devices based on emerging technologies (such as, computer-related technology, molecular medicine, home-care and self-care devices, minimally invasive technology, device-drug combination products, and pioneering organ replacement and patient assist devices). All add to the increasing review workload and projected increases in device review times. FDA uses risk management to maximize the impact of limited resources by concentrating on high-risk, high-impact products and work areas that benefit consumers and health care workers the most.

CDRH also regulates 10,000 mammography facilities under the Mammography Quality Standards Act (MQSA) and over 4,000 radiological health firms under Radiation Control and Health Safety Act.

Medical devices, including those which are radiation-emitting products, are regulated by FDA under the FD&C Act. The certification of mammography facilities is regulated under the Public Health Service Act.

Costs

Fiscal Year	Net Program Cost (000s)
2002	**$240,885**
2001	**$223,320**
2000	**$203,773**

The Device and Radiological Health Program experienced 7.9 percent increase in net costs in FY 2002. This increase is attributed to premarket review activities and inspections. The net cost includes the expenses for a program, including the allocation of overhead expenses (such as the Office of the Commissioner's costs for administrative and policy direction, ORA's field operations' costs, rent, and other overhead), less exchange revenue.

Program Goals and Accomplishments

Highlights of Product Approvals

During FY 2002, CDRH's Office of Device Evaluation approved and cleared thousands of devices used to diagnose and treat a wide variety of medical conditions. A new Premarket Approval Application (PMA) website describing recently approved devices with patient information is now available at http://www.fda.gov/cdrh/mda/index.html. Highlighted below are several examples of medical devices approved during the past year that will have a major impact on patient care.

Prosthetic Endograft

This blood vessel graft, called an endovascular graft, is used to repair an abdominal aneurysm. The device consists of a woven polyester graft attached to the wall of the aorta with tiny metal hooks. Once in place, the device can prevent further growth and possible rupture of the aneurysm.

Self-Expanding Peripheral Stent

This device is a flexible coil-shaped metallic device that is used in the formal and popliteal arteries in the leg to hold open areas that were blocked by atherosclerotic disease. Blocked arteries can cause leg pain by preventing adequate blood flow from reaching the lower leg and foot.

Arterial Closure System

The QuickSeal Arterial Closure System stops bleeding in the formal artery after cardiac catheterization. The device helps the body to produce a blood clot to seal the hole in the femoral artery. Without this device, the doctor would have to apply pressure manually to the puncture site to stop bleeding. The device may reduce the time a patient spends in the hospital.

Glucowatch for Children with Diabetes

The new glucose test product is a wristwatch device that provides children and adolescents with diabetes more information to manage their disease. The device is used with finger-prick blood tests to monitor glucose. The adult version of "GlucoWatch" was approved last year. This device extracts fluid through the skin by sending out tiny electric currents. Glucose levels are measured using this fluid every twenty minutes for twelve hours even during sleep. The device sounds an alarm if the patient's glucose reaches dangerous levels.

Pocket-Sized ECG Machine

This device is a miniature version of a standard ECG machine, which is used by doctors to monitor the heart's health by recording its electrical signals. It performs the same functions as a standard size ECG machine. The device consists of a pocket-sized ECG and twelve leads that are placed on the patient's body to record the ECG information. The recorded data can be viewed on the device or transmitted using special software by mobile phone or other wireless networks to a computer for viewing by other medical personnel.

Other Accomplishments

FDA increased its surveillance of medical devices by requiring a manufacturer of certain critical medical devices to conduct post-market surveillance on those products. When needed, firms will be required to gather data on the product's performance for up to three years to identify and evaluate, as early as possible, rare but potentially dangerous events that could endanger public health.

The new rule, published in the Federal Register, will affect up to thirty medical devices a year. These include devices where failure would be likely to have severe adverse health consequences; devices implanted into the body for more than one year; and devices that sustain or support life and are used outside a medical facility.

"Many problems or risks associated with a medical device cannot be predicted before the device enters commerce, even with clinical studies," said Dr. Lester Crawford, FDA Deputy Commissioner. "Post-market surveillance will allow FDA and manufacturers to identify less common, but potentially serious, problems that were not evident during product development or to address problems that were not seen as serious enough to warrant keeping the product from reaching the market." It will provide a way to evaluate these problems early and identify ways to reduce the risk to patients (such as, physician training, device labeling, or design modification).

Manufacturers will be notified by FDA whenever the Agency determines that post-market surveillance is necessary for a given device. This may occur during the review of a firm's marketing application, as the device goes to market, or after the device has been marketed for a period of time. Companies will be required to submit a post-market surveillance plan within thirty days of receiving an order.

When Congress first instituted post-market surveillance of certain medical devices with the enactment of the Safe Medical Devices Act in 1990, it was modified by the FDA Modernization Act of 1997, giving the FDA more discretion in imposing post-market surveillance and establishing a time limit.

Performance Plan Goals[31]

Premarket Review

The first strategic goal of the Devices and Radiological Health Program is to provide quicker access to important, life-saving, and health-enhancing medical devices, while assuring their safety and effectiveness.

CDRH uses a wide variety of regulatory mechanisms to ensure the safety and effectiveness of medical devices. A major activity associated with this goal is the premarket review of device applications. Table 5 (on the next page) displays the type of applications that CDRH reviews.

[31] The premarket goals of the Devices and Radiological Health program have a time delay in reporting performance results due to the design of the performance measure. DHHS requires FDA to report final results only. Because of the time delay and DHHS policy, we are using FY 2001 performance data since the FY 2002 results are not available.

Premarket approval applications involve new products that represent the highest potential risk and benefit to consumers. FDA has redirected its available resources to reviewing these high-impact products where direct intervention helps consumers and health care professionals most. To accomplish its premarket responsibility, FDA is charged with review of submissions within statutory timeframes. FDA strives to support a stable and predictable review process and meet new FDA Modernization Act requirements for reduced review times for PMAs and increased interaction with sponsors.

CDRH is reporting on two premarket performance goals: premarket approval applications (PMAs) and premarket notifications (510ks).

Table 5

Type of Food	Type of Food
Premarket Approval Application (PMA) and PMA supplement	CDRH ensures the data submitted by the manufacturer shows the device is safe and effective. Also included are Humanitarian Device Exemption (HDE) applications, which are similar to PMAs, but are exempt from PMA effectiveness requirements.*
Product Development Protocol (PDP)	An alternative to PMAs in which the manufacturer makes a mutual and binding agreement with CDRH in advance. The protocol spells out the criteria that will be used in determining safety and effectiveness, and the pass-fail parameters for each area. PDPs are the easiest to construct for products whose safety and effectiveness is well enough understood so that pass-fail criteria can be readily established in advance.
Premarket Notification [510(k)]	CDRH ensures the data submitted demonstrate that the device is substantially equivalent to an eligible product already on the market.
Investigational Device Exemption (IDE) application	CDRH ensures proposed investigational studies will be well controlled and will safeguard the rights and safety of human subjects.

* An approved HDE authorizes marketing of a Humanitarian Use Device (HUD), which is defined by the FD&C Act, as a device that is "intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year."

Performance Goal

The FY 2001[32] performance goal was to review and complete 90 percent of PMA first actions within 180 days.

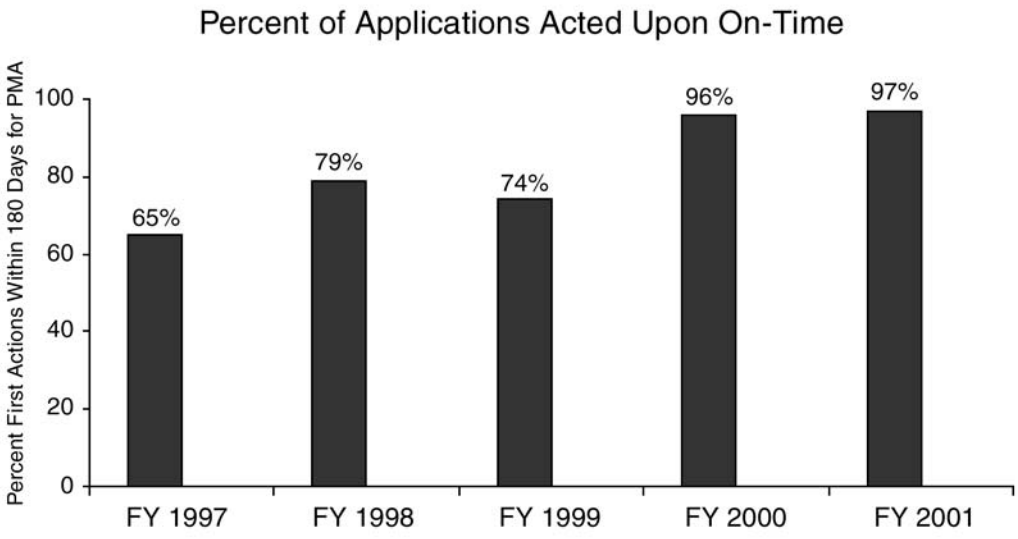
Results

CDRH achieved its goal by completing 97 percent of the first actions on 70 PMAs received in FY 2001. In FY 2000, FDA performance was 96 percent of 67 PMA first

[32] Please note that since FY 2002 performance data is not available, FY 2001 data will be used.

actions. FDA improved its performance considerably from FY 1999 when the on-time percentage was 74 percent of 43 PMA first actions. Figure 7 (below) presents CDRH's improving performance over the past five years.

Figure 7



Also, there were no backlogs for new product submissions and turnaround times for processing these submissions improved for all. PMA average total review time from filing to approval was 140 days for FY 2001.

Performance Goal

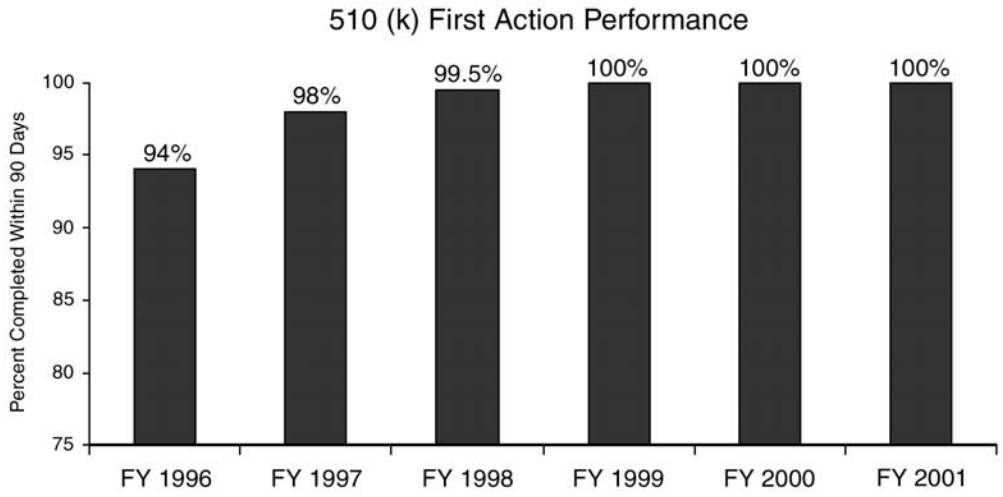
The FY 2001[33] performance goal was to review and complete 95 percent of 510(k) (Premarket Notification) first actions within 90 days.

Results

CDRH achieved its FY 2001 performance goal with a 100 percent rate of completion within this timeframe. This performance has resulted from CDRH changing the way premarket notifications are reviewed. CDRH is exempting more low-risk products from the 510(k) requirement, using more consensus standards in its reviews, and using more third party reviews. As a result, devices are available more quickly to patients and resource savings area available for high-impact devices. Figure 8 (on next page) shows FDA's improved timeliness in completing 510(k) first actions.

[33] Please note that since FY 2002 performance data is not available, FY 2001 data will be used.

Figure 8



Mammography

The second strategic goal of the Devices and Radiological Health Program is to reduce the risk of medical devices and radiation-emitting products on the market by assuring product quality and correcting problems associated with their production and use. CDRH has chosen to report on its mammography performance goal which is under this strategic goal.

The MQSA of 1992

Breast Cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among American women. Experts estimate that one in eight American women will contract breast cancer during their lifetime. MQSA was signed into law on October 27, 1992, to address the public health need for safe and reliable mammography, and was amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998.

The MQSA Program certifies mammography facilities and performs annual inspections to ensure that they remain in compliance with established quality standards. Through the authorities delegated to FDA to implement MQSA, FDA ensures that women have access to safe and effective mammography services. The Act requires all mammography facilities to be certified by the Secretary of DHHS as meeting quality standards in equipment, personnel, quality assurance, record keeping, and reporting. It is unlawful for a facility to perform mammography without a certificate.

MQSRA extends MQSA authorization through FY 2002 and makes substantive changes, such as:

- Requiring all mammography facilities to send reports written in lay person's terms to all patients receiving mammography services;

- Clarifying the responsibility of the mammography facility to retain mammogram records so women have the ability to obtain the original record of their mammogram;

- Mandating direct written notification to all patients of their exam results in lay person's terms; and

- Permitting FDA to conduct a limited demonstration project to determine the feasibility of inspecting mammography centers of excellence on a less than annual basis.

MQSA requires all of the approximate 10,000 mammography facilities in the U.S. to be inspected annually to ensure that they remain in compliance with quality standards. FDA estimates that a third of such facilities will need re-certification annually.

Performance Goal

The FY 2001 performance goal is that 97 percent of mammography facilities achieve compliance with inspection standards, with less than three percent with Level 1 (serious) findings. This goal helps ensure that mammography facilities remain in compliance with established quality standards and improve the quality of mammography in the U.S.

Result

CDRH achieved this goal. It marked the third consecutive year of achieving the 97 percent goal for certified mammography facilities complying with inspection standards. During FY 2001, FDA inspected 9,262 domestic mammography facilities compared to 9,443 in FY 2000.

Management Discussion & Analysis

National Center for Toxicological Research

Mission

The National Center for Toxicological Research (NCTR) Program conducts FDA mission-critical, peer-reviewed research to develop a more scientifically sound basis for regulatory decisions and reduce risks associated with FDA-regulated products. The aim of the program is to:

- Conduct peer-reviewed scientific research that provides the basis for FDA to make sound, science-based regulatory decisions, and to promote the health of the American people through the Agency's core activities of pre-market review and post-market surveillance;
- Conduct fundamental and applied research aimed at understanding critical biological events, to determine how people are adversely affected by exposure to products regulated by FDA;
- Develop methods to measure human exposure to products that have been adulterated or to assess effectiveness and/or the safety of a product; and
- Provide the scientific findings used by the FDA product centers for pre-market application review and produce safety assurance to the scientific community for the betterment of public health.

Background

NCTR's research program involves basic and applied research specifically designed to define biological mechanisms of action underlying the toxicity of products regulated by the FDA. This research is aimed at understanding critical biological events in the expression of toxicity and at developing methods to improve assessment of human exposure, susceptibility, and risk.

NCTR conducts research through the dedicated efforts of staff in eight divisions. The NCTR research divisions are committed to the study of biochemical and molecular markers of cancer, nutritional modulation of risk and toxicity, developmental toxicity, neurotoxicity, quantitative risk assessment, transgenics, applied and environmental microbiology, and solid-state toxicity. Each division works closely with the others in a seamless effort to support the FDA's mission to bring safe and efficacious products to the market rapidly and to reduce the risk of adverse health effects from products on the market.

Costs

Fiscal Year	Net Program Cost (000s)
2002	$45,681
2001	$43,033
2000	$43,347

NCTR's net costs increased by 6.2 percent in FY 2002. The net cost includes the expenses for the program, including the allocation of overhead expenses (such as, the Office of the Commissioner's costs for administrative and policy direction and other overhead), less exchange revenue.

Program Goals and Accomplishments

Other Accomplishments

Internet Journal to Foster Regulatory Research

NCTR continued its publication of the Internet journal entitled, Regulatory Research Perspectives: Impact on Public Health. This journal provides FDA scientists with a means of communicating specific information to colleagues in the Agency and the scientific and public health community. Contributions are solicited from every FDA Center and the Office of the Commissioner. FY 2002 articles include: "Developing Methods of Genetic Analysis to Improve Cancer Risk Assessment," November 2001 and "Development of Quantitative Structure-Activity Relationships (QSARS) and Their Use for Priority Setting in the Testing Strategy of Endocrine Disruptors," May 2002. Articles published in the journal may be found at www.fda.gov/nctr/science/journals/Default.htm.

Explaining FDA's Research Efforts

In the September-October 2002 issue, FDA Consumer Magazine, Dr. Daniel A. Casciano, Director, NCTR, explained the difference between the types of research conducted by the NIH and the research conducted by NCTR and FDA's other Centers. He stated that NIH supports basic research, that is, new knowledge that may or may not have a direct impact on protecting public health.

Research performed by NCTR and FDA's other Centers is "translational" – meaning basic information derived from an NIH-sponsored study is further modified to apply to a specific question that is relevant to the FDA's mandate to protect the public health.

An example of this is the basic research developed to create a mutant mouse or rat. FDA scientists use this technology and apply it to specific rodent strains to help assess the safety of a human or animal drug, or to understand the mechanism of action of a food additive or medical device. Sometimes the conversion of basic research information to applied research information that would be useful to the FDA takes several years. Other "translational" research efforts ongoing at the NCTR include:

- development and modification of research standards by which those involved in toxicological research can identify cancer-causing agents in model animal systems;
- assessment of potential toxic reaction of sunlight and cosmetics or some dietary supplements on the skin of model animal systems;
- development of tools that will help identify populations at risk to products regulated by the FDA using technologies that were derived from the sequencing of the human genome (a process funded by the NIH); and
- evaluation of specific anti-viral strategies developed through NIH funding to prohibit the transmission of the HIV virus to offspring of infected females.

It is extremely important that the FDA maintain its ability to make quality decisions based on sound science. This is more important because of the quickened pace of discovery by FDA-regulated industries. To avoid becoming a bottleneck to moving these newly developed products to the consumer, a strong internal scientific presence is essential in the FDA.

Performance Plan Goals

Risk Assessment for Regulated Products

NCTR Strategic Goal 1 is to develop new strategies and methods to test and predict toxicity and detect and assess risk for FDA regulated products (new and those already on the market).

One of the Agency's and NCTR's highest priorities is to increase the ability of FDA reviewers to evaluate and predict rapidly and accurately the adverse effects of FDA-regulated products. This capability is critical to the Agency's ability to carry out its mission to analyze the safety and efficacy of products during the premarket application and postmarket review process. The human response to a toxic agent is a complex process. To adequately predict the adverse effects of human exposure to a toxic agent, a group of tests

must be developed, validated, and applied. NCTR uses a multidisciplinary approach to predict human toxicity and to evaluate the risk associated with regulated products, using appropriate animal and non-animal models.

Performance Goal

Introduce the knowledge of new genetic systems and computer-assisted toxicology (toxicoinformatics) into the application review process. The performance measure for FY 2002 is to conduct one biologically based mechanistic study combined with predictive modeling to improve extrapolation of animal data to the human condition.

Scientists are developing and using new technologies and tests to better understand chemical toxicity and strengthen the extrapolation from animal models to humans. Because of America's quest for good health, increasing evidence of adverse drug/chemical reactions in humans, point to a need to identify and protect susceptible subpopulations of people at higher risk from exposure to drugs, contaminated foods, or other regulated products.

The NCTR methods used in the identification and quantitative measurement of carcinogenic and mutagenic risk are essential to the FDA regulatory process. The systems developed and characterized in this performance goal can simulate human exposure, and increase the ability to detect weak carcinogens.

Results

NCTR scientists conducted a series of investigations to examine the genotoxic consequences of AIDS drugs in neonatal mice. Initial experiments showed that zidovudine, but not lamivudine, is mutagenic, and that lamivudine does not alter the responses induced by zidovudine. During the year, these studies were expanded to include other AIDS drugs (stavudine, didanosine, zalcitabine, and nevirapine).

Performance Goal

Develop, with other organizations, gene chip and gene array technology.[34] The performance measure for FY 2002 is to support at least two multi-disciplined DNA and RNA-based microarray technologies.

NCTR programs, through partnerships and collaborative projects with other federal agencies and academia, use human data they have collected to better understand the mechanisms of carcinogenesis and to provide new knowledge on the identification of subpopulations, particularly as they relate to individual susceptibility.

The importance of risk chip technology is that it allows researchers to screen large numbers of people simultaneously for different types of biomarkers. This will allow the identification of individuals at risk for adverse drug reactions and will help FDA review of individual susceptibility using profiles of agents with known toxicities and allow selection of a diverse group for clinical trials. For instance, the technology will allow scientists to identify people at high risk for various toxicities, including liver toxicity.

[34] Microchip arrays are small quantities of genetic material bound to computer chips that are used to do a large number of chemical reactions very quickly.

Results

NCTR scientists collaborated with Environmental Protection Agency (EPA) scientists and successfully used microarray gene expression analysis to identify several genes changed in rodents given dichloroacetic acid, a known rodent carcinogen, in their drinking water. They identified specific genes that are involved in cell growth, tissue remodeling, apoptosis (normal cell death), cancer progression, and foreign chemical metabolism. This study shows the potential utility of the new DNA microarray technology in evaluating the mechanisms by which chemicals exert their toxicity.

Working with scientists at the University of Arkansas for Medical Sciences, NCTR scientists have established a fully automated microarray printing process to screen known rodent and human genes. This technology has great promise in understanding mechanisms and prediction of toxicity.

The FDA, the pharmaceutical industry, and others are embracing this technology to understand the underlying changes in the genetic components in response to a human drug causing damage to the body. This technology allows the assessment of health risk compared with benefit to be more rationally determined. Once mechanisms are determined in animal model systems, extrapolation to humans can be tested.

Mechanisms of Toxicity

NCTR's Strategic Goal 3 is to conduct basic research to understand mechanisms of toxicity, assess new product technology, and provide methods for use in FDA standards development and product risk surveillance.

Most regulatory research begins as a precise exploration of a specific agent, a concept, or the use of a method. Once techniques are developed, these novel approaches can be applied to answer compelling questions about human risk.

The identification of carcinogens has depended classically on two approaches, epidemiological studies and lifetime animal exposure studies, each of which has its own strengths and weaknesses. Developing new techniques to assess carcinogenic risk provides the basis for alternative methods of assessing carcinogenic potential that can augment, or perhaps even replace, the need for expensive animal testing and human clinical trials.

Performance Goal

Use new technologies (bioinformatics[35] , proteomics[36], and metabonomics[37]) for diagnosis of toxicity. The performance measure is to publish at least one scientific paper describing one technology for use in reviewing regulated compounds.

Staying abreast of new technologies in science is important for the Agency to protect pub-

[35] Bioinformatics is the application of computational information and technology to a research study; an essential component of research activities utilizing structural and functional genomics approaches.

[36] Proteomics is the qualitative and quantitative comparison of all the proteins in the body under different conditions to further unravel biological processes; a study of the proteins expressed by an organism.

[37] Metabonomics is the comprehensive, high-throughput study of the metabolism of the cell; the complete complement of all the small molecule metabolites used or produced by a cell, tissue or organism.

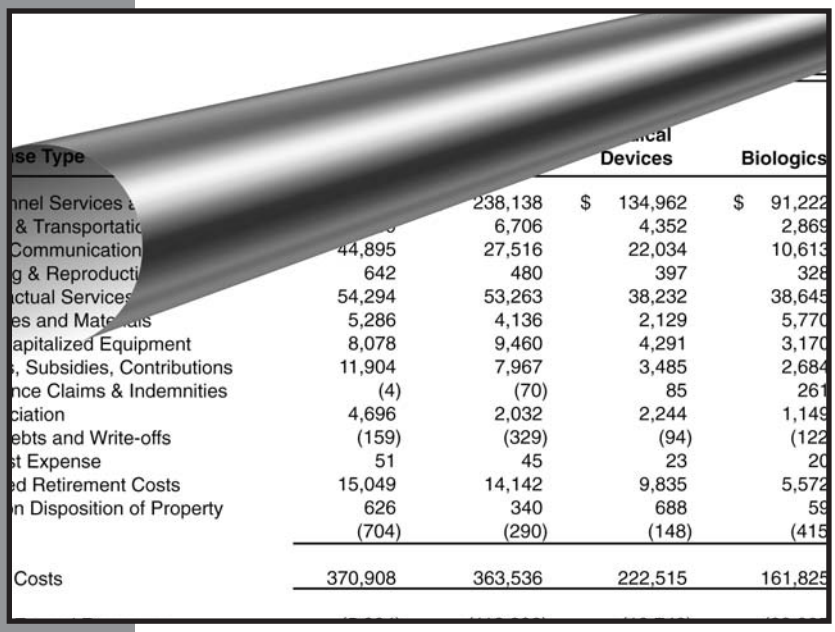
lic health. These new technologies have great promise on the mechanistic understanding of toxicity responses in the human. These will create core competencies in FDA that can form a foundation for future high technology science.

Results

The May 2002 issue, Regulatory Research Perspectives: Impact on Public Health, an Internet journal, featured a collaborative project between NCTR and EPA. Many potential estrogenic endocrine disrupting chemicals (EDCs) are associated with products regulated by the FDA (such as, food packaging, pharmaceuticals, and phytoestrogens). EPA has a legislative mandate to develop a screening and testing program for estrogenic EDCs in drinking water.

NCTR scientists have developed a quantitative structure-activity relationship (QSAR) approach that can be used to screen thousands of chemicals and determine the likelihood that they would be estrogenic. A series of QSAR models were developed and validated against experimental data. This QSAR approach was then applied to three environmental data sets identified by EPA and to a list of chemicals of concern identified by FDA's CFSAN and CDER. This QSAR screen provided a list of priority chemicals for further experimental evaluation and regulatory decision making.

Management Discussion & Analysis



se Type			Devices	Biologics
nnel Services a		238,138	$ 134,962	$ 91,222
& Transportatio		6,706	4,352	2,869
Communication	44,895	27,516	22,034	10,613
g & Reproducti	642	480	397	328
ctual Services	54,294	53,263	38,232	38,645
es and Mate ials	5,286	4,136	2,129	5,770
apitalized Equipment	8,078	9,460	4,291	3,170
, Subsidies, Contributions	11,904	7,967	3,485	2,684
nce Claims & Indemnities	(4)	(70)	85	261
ciation	4,696	2,032	2,244	1,149
ebts and Write-offs	(159)	(329)	(94)	(122
t Expense	51	45	23	20
d Retirement Costs	15,049	14,142	9,835	5,572
n Disposition of Property	626	340	688	59
	(704)	(290)	(148)	(415
Costs	370,908	363,536	222,515	161,825

Financial Performance

- Describes FDA's progress with the President's Management Agenda and the DHHS management initiatives;
- Highlights select administrative accomplishments;
- Reports on financial goals and results; and
- Analyses FDA's financial statements and financial condition.

President's Management Agenda

The goal of the President's Management Agenda (PMA) is to improve the management and performance of the Executive Branch.[38] The reform is far-reaching – transforming the Federal Government into a citizen-centered, results-orientated, 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. Each of the Executive Branch's departments is responsible for implementing the Agenda. As part of the DHHS, FDA is implementing the President's Management Agenda and Secretary's management improvement goals.[39] Table 6 below identifies the PMA's objectives.

Table 6

Goal	Objectives
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	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
	Automate internal processes to reduce costs internally in the federal government
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

[38] For purpose of this report, the Executive Branch of the Federal Government will be referred to as the Federal Government. The President's Management Agenda covers only agencies and departments in the Executive Branch.

[39] One of the Secretary's management goals is to centralize policy and support functions – known as the "One-DHHS" concept. An application of this policy is to create a centralized financial management system.

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

Strategic Management of Human Capital

The PMA calls for two major activities: delayering 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 global initiative, the DHHS and FDA are performing various consolidation initiatives. Organizational delayering addresses the Agenda's requirement to ensure that no more than four organizational levels exist between the citizen and the Agency decision-maker. Three organizational reviews were conducted for NCTR, CVM, and OC.

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 human resources (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 worklife 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.

DHHS decided to consolidate its 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. By year's end, FDA consolidated its seven separate HR components into one unit.

Because FDA will be consolidating its various headquarters components at the White Oak Campus, it 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. Final recommendations using the Shared Services concept for consolidating administrative services were presented to the Agency on September 12, 2002. A design phase is set to begin in FY 2003.

Competitive Sourcing

FDA conducted an analysis and prepared an Agency competition plan which was sent to the Department. Four outsourcing studies were conducted covering Graphic Design Services, Medical and Scientific Library Services, Television Studio Services and Web Design and Development Services. FDA conducted A-76 training for executives and employees. The Agency also participated in the Program Support Center's source selection for a DHHS-wide contract. FDA negotiated a Memorandum of Understanding with the National Treasury Employees Union (NTEU) concerning A-76 studies.

Improved Financial Performance

FDA is participating in the DHHS effort of designing the Unified Financial Management System (UFMS). In June 2002, a Global Design Team was formed that included detailed employees from various DHHS organizations. This team is working to develop a common budget and accounting classification structure, and systems architecture for DHHS and its components.

Implementing UFMS in FDA will be known as the Financial Enterprise Solution (FES). FDA's Office of Financial Management (OFM) is leading an agency-wide team with representatives from the offices and centers. The team will perform change management activities as well as business and technology analyses. These activities will determine and carry forward FDA's business requirements.

To prepare for the new financial system and to improve its financial management practices, FDA started three projects to standardize and centralize current financial operations:

- Agency Location Code Unification Project[40] – centralization of FDA's fifteen Agency location codes into one at Headquarters;
- Travel Manager – FDA's web-based travel authorizations and voucher payment system; and
- Automated Accounts Payable System – FDA's web-based commercial vendor invoice and payment system.

Preparation activities will continue in FY 2003 with data clean-up and developing requirements for a reporting architecture. The results will be streamlined financial processing and improved customer service.

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 FDA 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.

[40] For a status report on progress made during FY 2002 regarding these projects (Agency Location Code Unification Project, Travel Manager Project, and Automated Accounts Payable System Projects), please see pages I-66 and I-67.

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 financial management system and Property Management Information System was completed. This improvement will permit the timely reconciling of property and financial information and will contribute to the Agency meeting its accelerated financial reporting requirements.

Finally, OFM developed a cost allocation method used for predicting the FTE workload for various work activities. This is a first step in the process of integrating financial and performance management information for day-to-day operations. Specifically, the OFM cost method will enable the Agency's budget offices to build more accurate models for projecting the number of FTEs needed to perform work activities. This methodology will help program officials become aware of the cost implications for their work products and will contribute to improve financial reporting in the Agency's budget and performance documents.

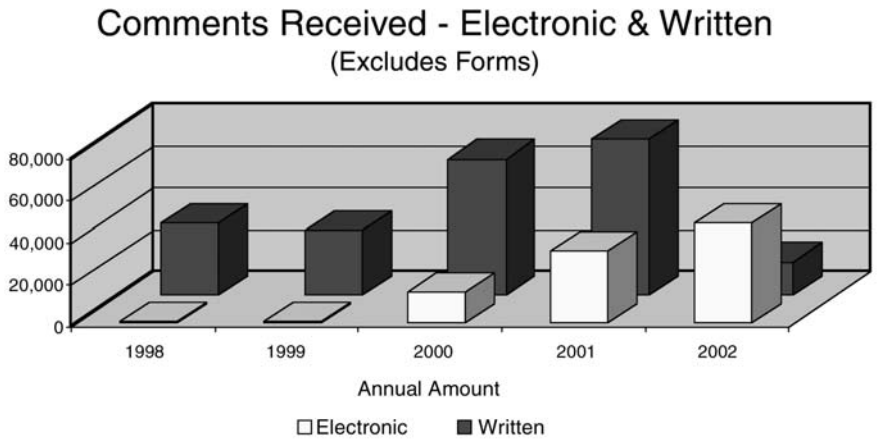
Expanded Electronic Government

FDA is providing leadership and support to the DHHS E-Rulemaking Team, chaired by the Department. E-Rulemaking is one of the 24 E-Government Initiatives on the President's Management Agenda that is on a fast-track for adoption government-wide in FY 2003. FDA provided demonstrations of its AIMS docket management system to the OMB, the DHHS Office of the Secretary, the Immigration and Naturalization Service, and the Center for Medicare and Medicaid Services

In 1998, OMS implemented its first online electronic submissions form that provided an easy way for the public to submit general comments on specific issues, specific comments on proposed rules, guidances, and notices of meetings. In 2001, FDA received over 385,000 public comments; ninety-seven percent were from individual citizens.

Electronic rulemaking at FDA reduces the processing time needed to receive and review comments. It increases comments received and the percentage of comments provided electronically has increased dramatically over the past five years. Figure 9 below displays the comments received in a four year period.

Figure 9



Budget and Performance Integration

FDA continues to integrate performance with budget decisions to help fulfill our mission, using several strategies. Both support FDA's public health mission and result in Agency decisions that provide improved public health.

The first strategy is to more effectively integrate the performance plan and budget, building organizational cultures that focus on outcomes and results. Integration increases the transparency between the performance plan and budget to allow for better understanding of the outputs produced by FDA's resource investment. This is accomplished through estimating costs and incremental improvements in performance goals; reducing the number of performance goals to a manageable level; improving the linkage between the performance plan and budget by using strategic planning teams to develop multi-year plans for top Agency priorities, including resource needs and performance levels; identifying high quality outcome measures; and incorporating performance measures and accountability into the management of the Agency. Over the past several years, the major strategic planning efforts have covered such diverse FDA mission areas as: Food Safety-Bioterrorism, Bovine Spongiform Encephalopathy, Imports and Inspections, Blood Safety, Patient Safety/Medical Errors, and Information Technology.

The second strategy is to improve the accountability of FDA managers for achieving performance and management goals by linking them to individual performance contracts. The contract requires the highest to lowest senior level manager to commit to a level of performance as articulated in specific performance goals. For example, one senior manager's goal was "to achieve the adoption of the Food Code in twenty-eight states."

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

Additionally, the administrative consolidation study currently underway at FDA is also examining the links between budget and planning to suggest, if appropriate, other means to further integrate the function.

Program Goals and Accomplishments[41]

Financial Management Accomplishments

Appropriation Increases

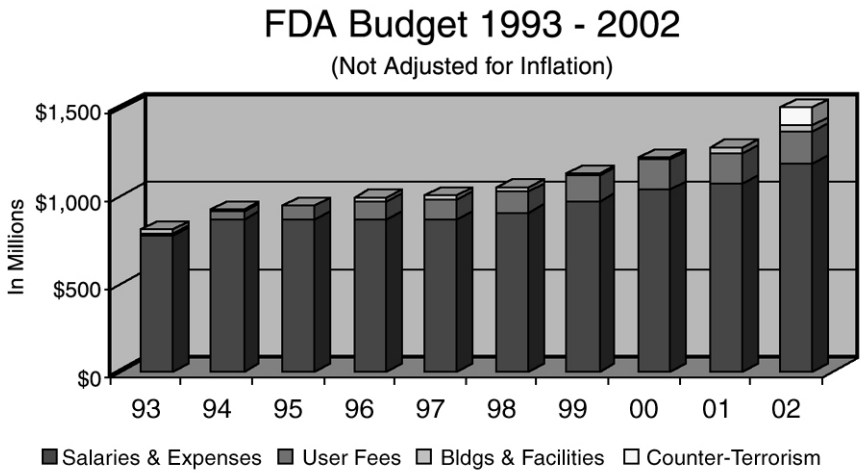
FDA realized a record appropriation for FY 2002. Congress for the first time in many years not only provided full funding of the 4.6 percent pay raise, but funding over and above the increases requested by the President for the Salaries and Expense account. FDA's program level is $1.6 billion, which includes full funding for the Buildings and

[41] The Department's Accounting Manual, Chapter 5-20, "DHHS Annual Financial Report, Section 5-20-20, sub-section "C", requires the Management Discussion and Analysis to include major program and financial management goals, objectives, and results. It also requires discussion of the financial statements and financial condition.

Facilities account, Prescription Drug User Fees, Mammography Quality Standards Act User Fees, and the Export Certification and Certification fund.

The Salaries and Expenses Appropriation totals $1.345 billion, comprising $1.2 billion for Salaries and Expenses, and $161.7 million for PDUFA.[42] This amount does not include the supplemental appropriation for bioterrorism. See Figure 10 below for ten year trend of funding.

Figure 10



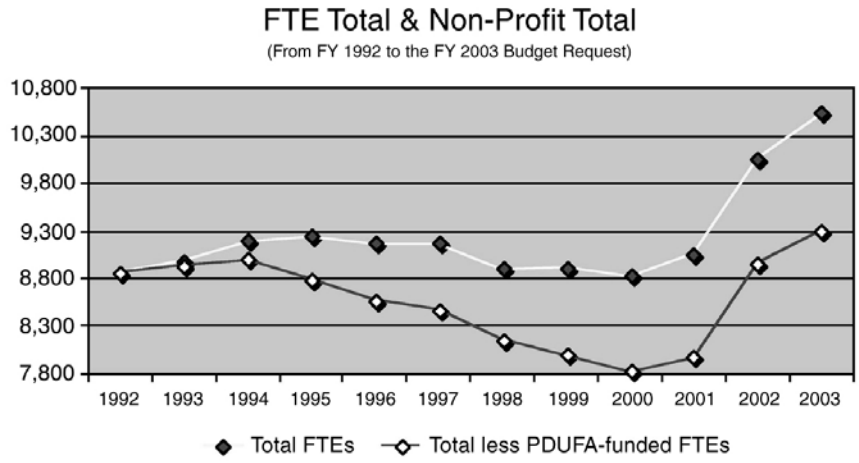
FY 2002 Supplemental Appropriations for Counter-Terrorism

The Congress identified a variety of programs needing increased resources to prevent possible terrorist threats through FDA-regulated products, and to develop products for the prevention or treatment of illness that could result from biological or chemical agents or radiological exposure following the events of September 11, 2001. It increased resources that had been requested, and in January 2002, a Supplemental Appropriation of $151.1 million was received by FDA. This increase has funded the hiring of over 800 new FDA staff and has also funded major improvements in lab equipment and information technology systems, especially for Field programs. Moreover, almost all of the increases included in the Supplemental were carried forward into the FY 2003 budget request, that at this time has been approved by the full appropriation committees of both chambers of Congress.

[42] Please note that the salaries and expenses appropriation does not include building and facilities, Mammography Quality Service Act user fees, or Export Certification User Fees.

Figure 11 below shows a ten year trend of human resources.

Figure 11



Agency Location Code Unification Project[43]

OFM began the Agency Location Code[44] (ALC) Unification Project as a key step in improving financial management processes. Goals of the ALC Unification Project are: consolidate 15 ALCs into one at Headquarters and consolidate FDA's accounting points from twenty-five to seven. To successfully accomplish this task, the ALC Unification Team performed the following:

- Reduced the number of open documents by 1,275 ($2.5 million);
- Reduced significantly the number of disbursement differences in the Field;
- Documented all the financial management operations and systems for all Field offices to identify possible gaps;
- Developed new standard operating procedures to be used by the entire Agency;
- Cleaned the Field's common accounting number (CAN) structure by purging all duplicate and invalid CANs;
- Improved communication by coordinating all ALC Unification efforts with ORA, OFM and NCTR; and
- Created the foundation for FDA's UFMS Implementation.

This effort began with unifying accounting operations that involved conducting symposiums with representatives from ORA regions, NCTR, ORA Headquarter, and OFM to discuss responsibilities and new standard operating procedures to prepare for UFMS. Beginning in FY 2003, all FDA receipts and disbursements will be processed through FDA Headquarters.

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43 For an explanation of the Unified Financial Management System Implementation Plan for FDA, see Page I-62.

44 An ALC designates federal agencies (or components within the agency) authorized by the U.S. Treasury to make federal disbursements and receive payments.

Travel Manager

OFM began Phase III of the Travel Manager project as part of the Financial Enterprise Solution Preparation Phase. This involves upgrading to version 8.0 and extending implementation to OC, CVM, CFSAN, NCTR, and ORA's Southeast Region. More than half the Agency uses OFM's Travel Manager. Travel Audit has developed and implemented post audit review requirements. Several audits were conducted this year with positive results. By using the audit feature of Travel Manager, vouchers are being processed faster and more accurately.

Automated Accounts Payable System

OFM implemented a web-based Automated Accounts Payable System (AAPS) throughout each ORA region and NCTR as part of the financial system standardization. AAPS, an Oracle-based system, pays invoices for commercial vendor goods and services. The system contains easy-to-use menu options, prompts, and editing functions that allow users to enter invoices directly into the system. Once invoices are verified, payment is scheduled and an electronic transmission is submitted to Treasury for electronic funds transfer or vendor check issuance.

Human Resources Management Accomplishments

Delegations of Authority

OHRMS completed Phase 2 of the reengineering of the Delegations of Authority by publishing FDA's delegations in Staff Manual Guides. These will be placed on the Internet website for all to see and replace the 2003 edition of the Code of Federal Regulations as the official source of this information for FDA. The web site will be easier to use and change, and less costly to the Agency.

Employee and Labor Relations Program

OHRMS provided advice and assistance to management officials concerning the Agency's A-76 initiative. This included working with the union to assure their participation in the activity. OHRMS negotiated a Memorandum of Understanding with NTEU about the A-76 studies.

It successfully administered representation election resulting in consolidation of all NTEU bargaining units in FDA.

Recruitment and Retention Programs

OHRMS established three group retention allowances for CDER "at risk" occupations (Mathematical Statisticians, Pharmacokeneticists, and Pharmacological-Toxicological Reviewers). It developed a Pay Flexibility Handbook for Managers and Recruiters. OHRMS also negotiated implementation of FDA Student Loan Repayment Program and the FDA Reasonable Accommodation Policy.

OHRMS provided advice, assistance, and quality control for hiring 30 aliens (non-citizens) mainly as part of FDA's counter-terrorism effort. It also established and implemented the FDA Recruitment Referral Award program.

Staffing Automation

OHRMS completed the first full year of using the Automated Candidate Evaluation System (ACES). Major benefits of ACES are the acceptance of online job applications by way of the Internet; improved applicant pool through exposure to the Internet; automated applicant ratings and rankings through applicant responses; automatic acknowledgement (by email) to all applicants; and through email, a fast and easy method for communicating with all applicants.

Besides expanding its library of rating questions from 20 to 65 occupations, ACES was an instrumental tool in helping FDA to meet its critical staffing needs because of the terrorist attacks of September 11, 2001. For ORA's Consumer Safety Officer hiring initiative, over 3,000 applications were handled for vacancies announced in 155 locations nationwide. The delegated examining unit issued hundreds of selection lists in a matter of weeks. It has been estimated that it would have taken six months to handle this workload under the manual process. About 500 applicants were selected for Consumer Safety Officers under this hiring initiative. The remaining 300 positions will be made available for a variety of other occupations in ORA.

Facilities and Administrative Management Accomplishments

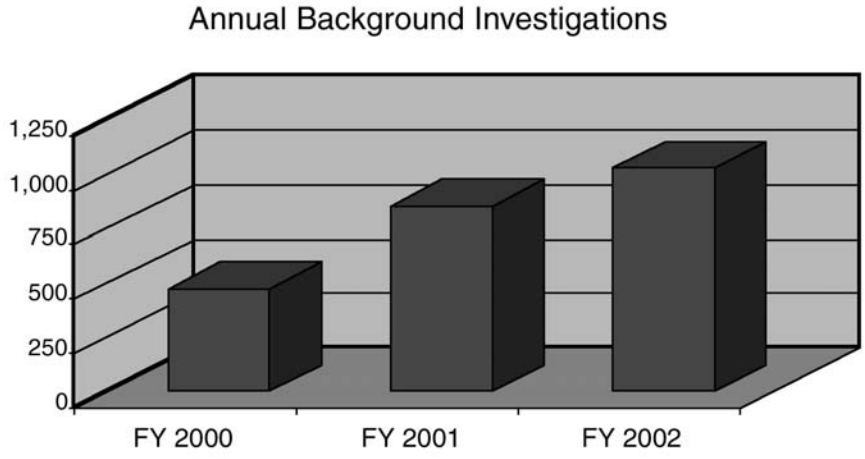
Facilities Plan

OFACS implemented a facilities plan that is designed to foster better communications among OFACS units, OMS, ORA, and the Centers. The primary aim of the facilities plan is to improve the quality and timeliness of the services provided to OFACS customers. One of the specific steps is to conduct on-going coordination meetings among OFACS' divisions to discuss all projects OFACS is performing for Centers and ORA, and to coordinate the delivery of timely services to their clients.

Personnel Security

OFACS purchased Livescan Fingerprint systems for Headquarters and NCTR, which will allow more timely response on this part of the background investigation. Figure 12 below shows the rise in background investigations requested in the past three years.

Figure 12



Employee Health at FDA Facilities

OFACS conducted environmental sampling at various locations for possible anthrax contamination. All results were negative. It coordinated responses to employee questions and answers on anthrax and posted them to the Environmental, Safety, and Health Intranet Page. OFACS continues to open suspicious mail at the screening facility.

Mail Management

OFACS established a new mailroom for screening mail and awarded a multi-year contract for mailroom screening services. This off-site mailroom services FDA's Headquarters components and the occupants of the Parklawn Building.

Information Resources Management Accomplishments

Enterprise Administrative Support Environment (EASE)

The Office of Information Resources Management (OIRM) implemented the web version of EASE for Agencywide use; thereby, drastically reducing the burden on Centers Technical Staffs for EASE software release installations. It also completed migration of the Administrative Resources Information Exchange (ARIES) historical data from 1985 to 2000 into the EASE's Reporting and Analysis Module (RAM) data warehouse.

Freedom of Information (FOI) Administration

OIRM implemented FOI Document Repository Application as a pilot for all major Agency components. FOI Act requests and responses are being distributed electronically by the FOI Document Repository. OIRM solicited feedback from components to streamline and improve application and process. It received, reviewed, logged, referred, and monitored processing of 17,895 FOI Act requests.

IT Investment Management

OIRM developed an IT Capital Investment Management Process that will make certain IT projects and resources are managed according to the requirements of the Clinger-Cohen Act. The process expanded the Chief Information Officer's requisition review process to make sure that all investments are linked to the Agency's IT Investment Portfolio and have FDA's standard project documentation (Investment Summary or OMB Exhibit 300, "Capital Asset Plan and Business Case").

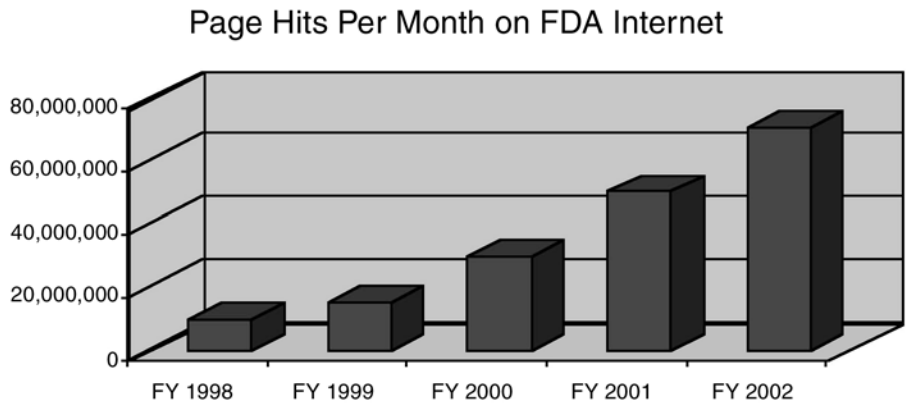
OIRM awarded a GSA contract to implement Agencywide project management for IT investments. This project addresses goals and objectives put forth by the Information Technology Management Work Group in FY 2001.

OIRM assisted the Agency's Information Technology Investment Review Board with a series of reviews and deliberations that focused on the allocation of FY 2002 Strategic System ($4.5 Million) and Operations & Maintenance ($7 Million) Reserves from the FDA Central Account.

Internet/Intranet Services and Support

OIRM supports the Agency's FDA public website that provides critical health information to the public. This site offers information of interest to health professionals, patients, consumers, industry, state and local officials, and many others. The Internet web infrastructure provides rich functionality, responds to changing needs and provides high performance scalability and reliability. In FY 2002, OMS supported a substantial increase in content on the FDA Internet website and traffic to this infrastructure, while continuing to remain within the budget. Also, increased storage capacity was added to the infrastructure. Figure 13 shows the number of pages requested for each month on the FDA Internet.

Figure 13



Financial Performance Goals and Results

Financial Statements Audit

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 contracted by the DHHS Office of Inspector General performs the financial statement audit. The firm issued the audit opinion and reports of findings and recommendations and compliance with laws and regulations. Several performance measures address the results of the financial statements audit. These are summarized in Table 7 for the past six years.

Table 7

Measures	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
Timely audit opinion	No	Yes	Yes	Yes	Yes	Yes
Clean (or unqualified) audit opinion	No	Yes	Yes	Yes	Yes	Yes
No. of material weaknesses	3	0	0	0	0	0
No. of reportable conditions	5	3	3	1	1	1
No. of instances of non-compliance with Federal Financial Management Improvement Act (FFMIA)	1	1	1	1	1	1

For the six reporting periods (FY 1997 through 2002), FDA earned five unqualified[45] or "clean" opinions from the independent audit firm that has audited its financial statements.

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,[46] and has received reportable conditions in each of the five periods. This was on FDA's information systems controls. In the FY 2002 audit report, FDA received one reportable condition, which is a repeat finding addressing FDA's information systems controls.

The finding of non-compliance with the FFMIA remains. The final resolution of the non-compliance with FFMIA will be the implementation of the new financial management system. FDA is making progress in addressing the prior information systems findings. The electronic integration of the Agency's property management and general ledger system was completed. This achievement will permit the general ledger system to capture capitalized property information that will be used to prepare FDA's financial statements. FDA is improving its planning and monitoring of hardware used to support its current financial management applications. FDA is designing a new accounts receivable application that is expected to be operational by the end of calendar year 2002.

Timely Payments, Reimbursements, and Collections

Measures were developed to track the timely payments of bills (to avoid late fees and interest penalties), to reduce paperwork and make the reconciliation process easier, and to improve collection procedures for monies that are owed to DHHS.

Compliance with Prompt Payment Act

FDA's FY 2002 target was 96 percent of commercial vendor payments made on time. FDA reported that it had exceeded its goal and achieved a timely payment rate of 97.04 percent.

Timeliness of Travel Payment

The Travel and Transportation Reform Act of 1998 and related Federal Travel Regulations require agencies to reimburse employees within 30 calendar days after submission of a proper travel claim to the Agency's designated approving office or pay a late payment fee. The performance targets set by DHHS are for timely temporary duty travel voucher and travel card payments to promote compliance with the law and to identify a problem area.

The FY 2002 target of timely payment of approved travel vouchers in 30 calendar days of submission to first-level reviewing officials is 97 percent. During FY 2002, 99 percent of approved travel vouchers were paid in 30 calendar days, which exceeded the goal.

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45 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 United States of America (GAAP) applicable to the entity.

46 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 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.

Improve collection of debt owed to FDA

The collection of debts owed to FDA is also an important aspect of sound financial management and business practice. FDA will continue to focus on increasing collections as part of its compliance with the Debt Collection Improvement Act of 1996.

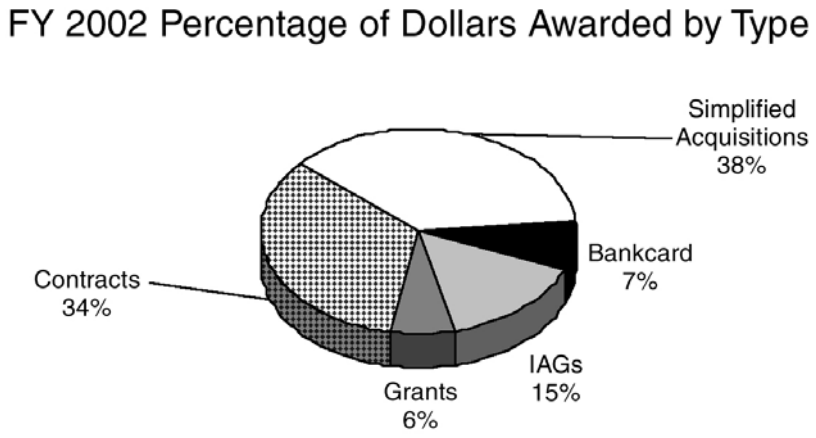
The FY 2002 target was to increase collections by ten percent over the prior year. FDA exceeded this target in FY 2002. Collections[47] doubled from the amount in FY 2001 from $153.7 million to $291.1 million.

In addition, FDA's delinquent debt was also reduced by half in FY 2002. The amount of debt in FY 2001 was $1.63 million. The FY 2002 amount was $.967 million.

Contracting Program

OFACS administers contracts, small purchases, the Bankcard (credit card) program, and grants. In FY 2002, the total of the contracting program was $159.8 million in contracts, $178.7 million in simplified acquisitions, and $35.5 million in Bankcard transactions, $72.7 million in interagency agreements, and $30.3 million in grants. See Figure 14 below for a graphic representation.

Figure 14

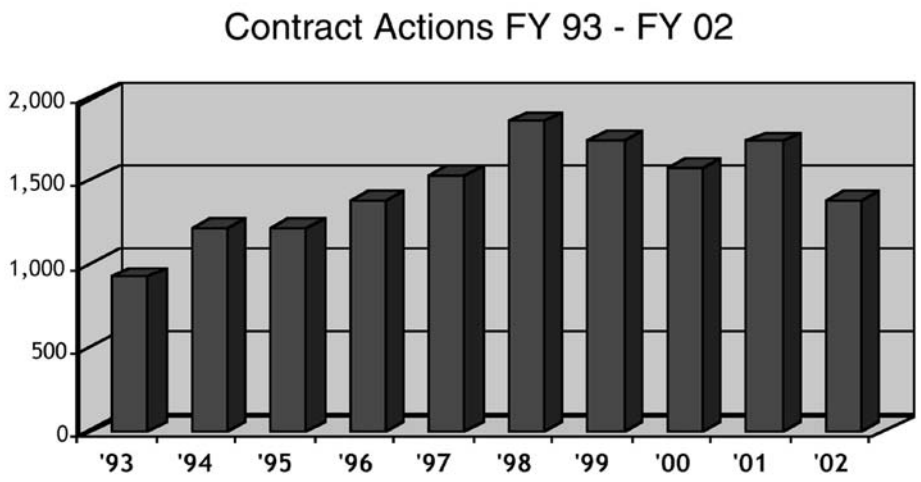


Performance-Based Contracting

OFACS reported that it had exceeded the OMB goal of 20 percent of contract dollars being issued in performance-based contracts. FDA's achievement was 24.6 percent. OFACS had encouraged and worked with project officers to convert contracts to performance based, especially the state contract program. Figure 15 on next page shows the ten year trend of contract actions. The number of contract actions declined in FY 2002 due to the fact that FDA is awarding more work through the GSA and Government-Wide Acquisition Contracts, also known as "simplified acquisitions".

[47] The size of the increase was affected by a change in the re-authorized Prescription Drug User Fee Act of 2002. This change allowed FDA to accelerate the FY 2003 billing and collection of advanced fees from the drug industry during FY 2002. The PDUFA fees collected in advance of FY 2003 cannot be used until the new fiscal year (October 1) and passage of an FDA appropriation.

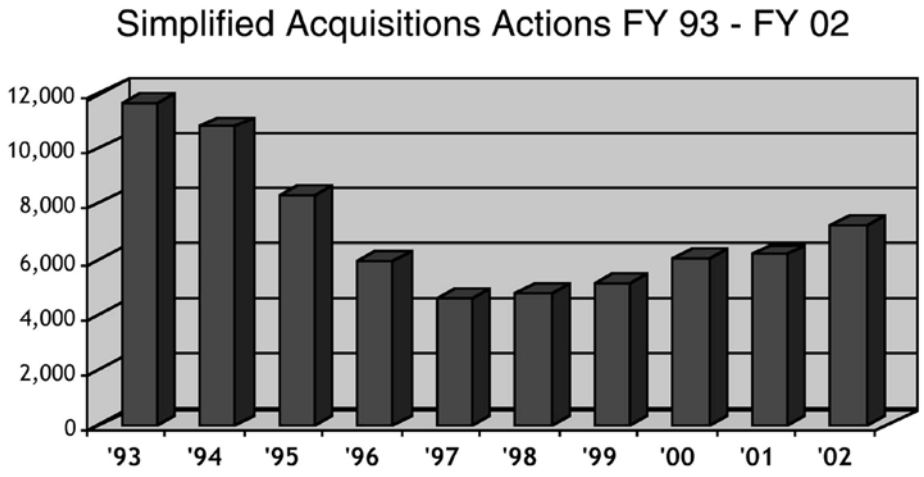
Figure 15



Simplified Acquisition Actions

The term, "Simplified Acquisitions" applies to purchases under $100,000. There are a variety of regulations that apply to Simplified Acquisitions depending on the dollar value and the source of procurement. The two basic types of Simplified Acquisitions are open market and GSA Schedule purchases. The open market procedures and thresholds are described below. Purchases from the GSA Schedule under $2,500 may be purchased without further competition; however, purchases over $2,500 must be competed among GSA Schedule vendors. In FY 2002, FDA experienced an increase in using this purchase type. See Figure 16 to display ten years of simplified acquisitions actions.

Figure 16



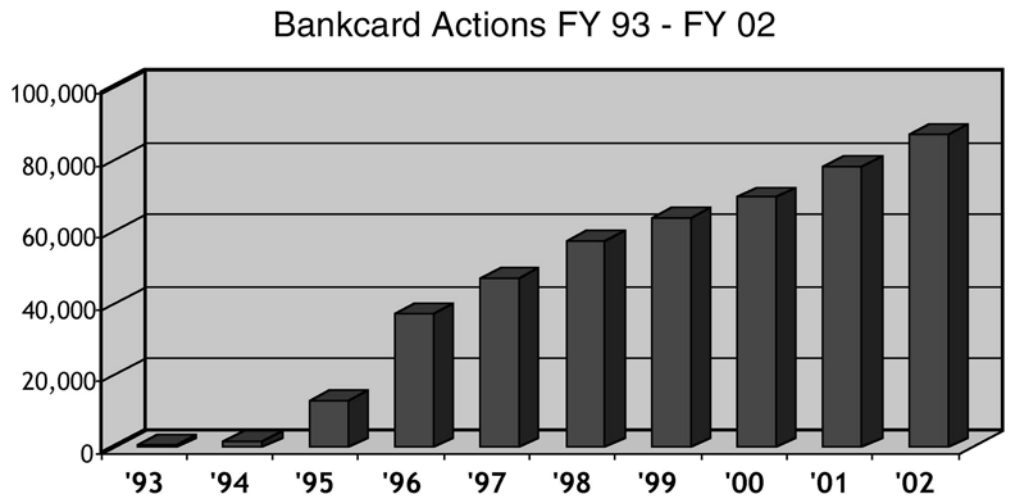
Bankcard Program

FDA has participated in the purchase card program since 1989. All FDA components are using the purchase cards. Cardholders are authorized for transactions of no more than $2,500 for each single purchase (with some exceptions), and are subject to monthly cumulative limits. Cardholders may obtain goods and services ordered over the phone, on the Internet, by mail order, or in person, using a special Government-wide VISA card known as the IMPAC card. FDA's use of IMPAC has grown dramatically since FY 1993, when 844 purchase card transactions occurred.

In FY 2002, FDA completed 86,972 purchase card transactions. The bankcard trend is shown graphically in Figure 17 below.

OFACS developed a web-based training for cardholders, approving officials and central control points. By using this program as opposed to the small purchase or blanket purchase agreement mechanisms, the Agency realized an administrative savings of $5.1 million this fiscal year.

Figure 17



Financial Analysis

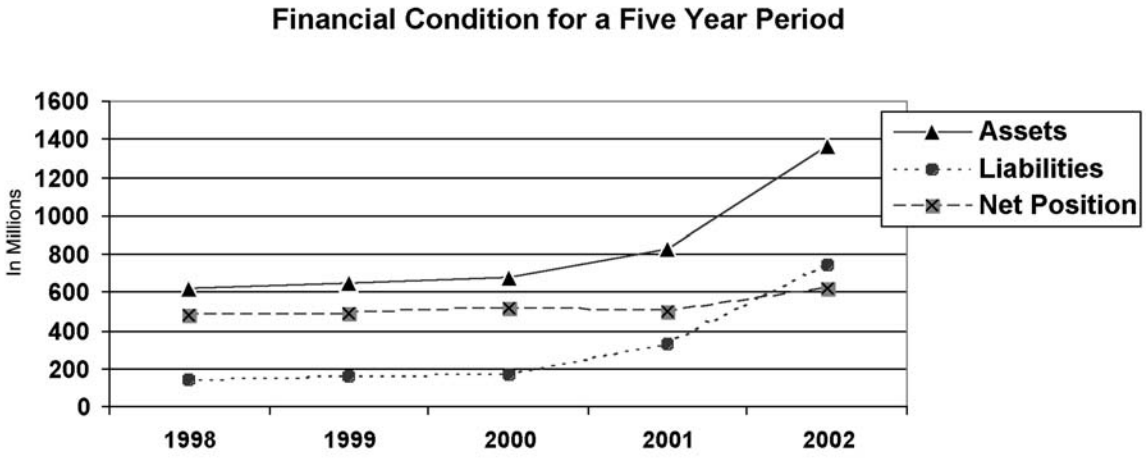
This section provides discussion on the principal financial statements highlighting important changes from the prior year conditions. For FY 2002, the research and development stewardship information is addressed. Financial statement reporting is required to be displayed in several formats as specified by the Federal Accounting Standards Advisory Board and OMB Bulletin 01-09, “Form and Content of Agency Financial Statements.”

Agency's Financial Condition

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 shows an increase in the net position (assets less liabilities). When compared with the past five fiscal years (FYs 1998 through 2002), the net position as shown in Figure 18, shows an increase due to two large increases: Fund Balances with Treasury as a result of deferred revenue collected under the newly authorized PDUFA III and the accounts receivable for the large amount of civil monetary penalties charged against private companies.

Figure 18



Costs

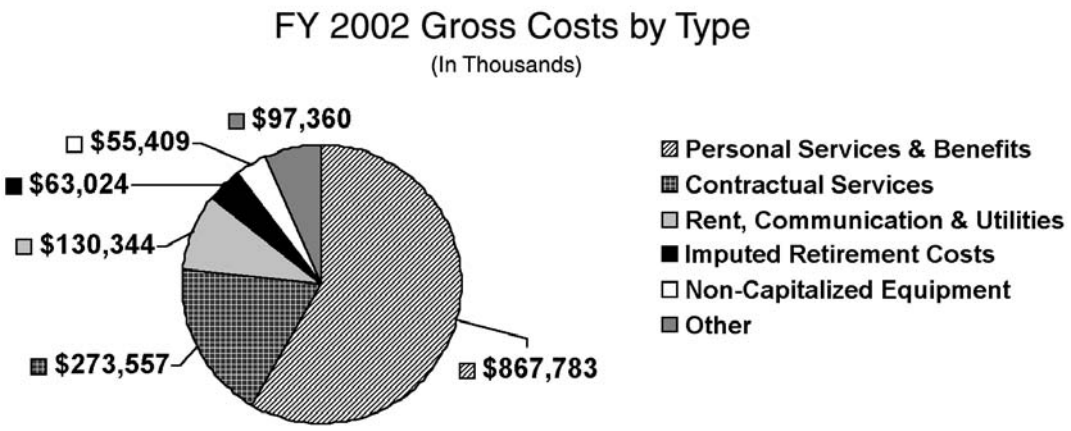
Net Cost	Breaks down total expenses by the six major programs of FDA's budget, net of exchange revenues and after allocation of indirect expenses such as administrative, field operations, rent, and other overhead.

Gross FY 2002 expenses were $1.487 billion, which includes projects funded by user fees. Deducting $189 million in earned revenues, FY 2002 net costs were $1.298 billion. This compares with gross expenses of $1.333 billion and net costs of $1.156 billion for FY 2001. Figure 19[48] and Figure 20[49] (both on next page) illustrate FDA's expenses by type and program. These are the budget programs reported under GPRA, which represent FDA's major responsibility segments. Amounts reported on the Consolidated Statements of Net Cost include allocation of expenses incurred by FDA's Office of Commissioner and ORA, both of which provide crosscutting services to the responsibility segments.

48 Source: Supplemental Statement of Net Cost by Expense Type and Program, FY 2002. Please note that some rounding differences may show a different total than the supplemental statement.

49 Source: Supplemental Statement of Net Cost by Program Costs by Appropriation, FY 2002.

Figure 19



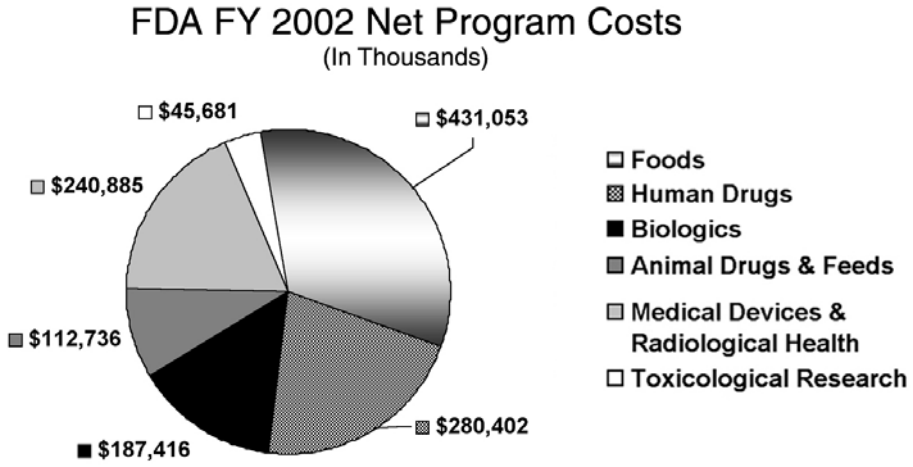
- Personal Services & Benefits rose by 10 percent from $789 million in FY 2001 to $867 million in FY 2002, caused by increases from the Congress on funding the food safety, imports and inspection activities, human subject protection, adverse reporting systems, and counter-bioterrorism activities.

- Contractual Services increased by 15.4 percent from $237 million in FY 2001 to $274 million in FY 2002, because of increases from the Congress on funding the orphan product grants and food safety.

- Rent, Communications, and Utilities increased by 9.3 percent from $119 million in FY 2001 to $130 million in FY 2002, because of increases from the Congress to hire 832 FTEs, improve the security of the Agency's facilities, and develop a state-of-the-art crisis management center.

- Non-capitalized equipment (formerly called expendable equipment) increased by 45.1 percent from $38 million in FY 2001 to $55 million in FY 2002. This increase is caused by the funding increases approved by the Congress.

Figure 20



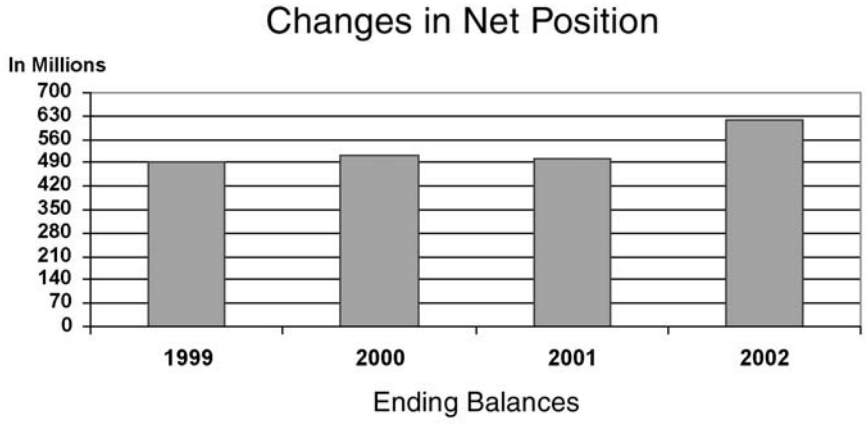
- The Foods Program's net costs increased by 10.5 percent caused by funding of the food safety activities, BSE-related activities, imports and inspectional activities, increases for dietary supplements, and the relocation of CFSAN to its new building in College Park, Maryland.
- The Human Drugs Program's net costs grew by 9.8 percent due to increases in user fees authorized by PDUFA II, and increases directed at imports and inspectional ctivities, patient safety and adverse events system, and human subject protection.
- The Biologics program's FY 2002 net costs increased by 16.5 percent due to funding increases for counter-bioterrorism initiative, patient safety, BSE-related activities, and human subject protections.
- The Animal Drugs and Feeds Program's FY 2002 net costs increased by 35.7 percent from FY 2001 because of funding increases for the BSE-related activities, antimicrobial resistance, and imports and inspections.
- The Devices and Radiological Health Program's net costs increased by 7.9 percent from FY 2001 due to a funding increase for the MeDSuN adverse event reporting system, patient safety, human subject protection, and import and inspectional activities.
- The National Center for Toxicological Research Program's net costs increased by 6.2 percent in FY 2002 due to funding increases for food safety activities.

Changes in Net Position

Changes in Net Position[50]	Provides information on the changes in financial position from year to year and the causes of the changes.

Unlike FY 2001, which experienced a decline in the net position, the Consolidated Statements of Changes in Net Position show an increase in FY 2002 due in part to the Bioterrorism supplemental appropriation. Figure 21 (below) shows the four year trend of ending balances.

Figure 21



[50] 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 or liquidation of liabilities, and resources that fund expenses recognized in earlier periods.

FDA's budgetary resources obligated but not yet provided was $115.5 million in FY 2002. This amount represents obligations recorded during FY 2002 for which expenses will not be incurred until a subsequent period. The acquisition of assets or liquidation of liabilities totals $70 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 $4.6 million, represent unfunded expenses recognized in prior periods but paid with FY 2002 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 $17.3 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.

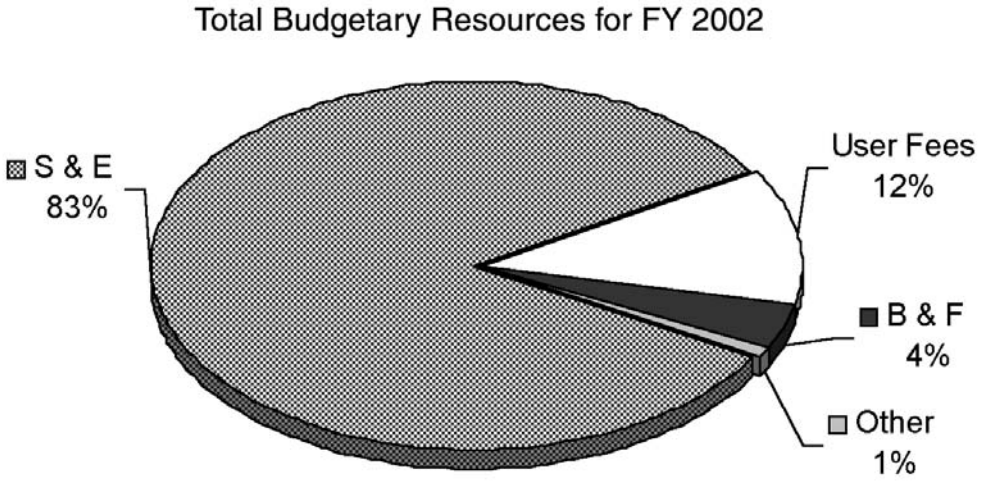
The costs of the federal government are not always funded in the period the costs are incurred. Costs of this nature are incurred in the current reporting period, but are normally funded through appropriations in subsequent years. Costs which are funded in future periods total $11.9 million, as of September 30, 2002, 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. Both categories experienced increases of $8.1 million and $4.0 million, respectively. 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 Resources[51]	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 2002 was $1.388 billion, not including spending authority of $342 million from user fee and reimbursable collections. Total budget authority, as of September 30, 2002, including offsetting collections, carry-over balances from earlier years and adjustments, was $1.752 billion. Of this amount, $1.658 billion had been obligated during FY 2002. Figure 22 below shows the total of budgetary resources[52] by major type -- salaries and expenses; user fees; buildings and facilities; and other small accounts, such as certification fund and royalties.

Figure 22



Total outlays were about $1.13 billion during FY 2002, which represents a 4.8 percent increase over FY 2001 total outlays of $1.07 million.

Figure 23[53] on next page shows FDA's outlay trend over the past five fiscal years. For FY 2002, FDA received budgetary increases to cover the import inspections, premarket review activities, inspections, counter-bioterrorism, dietary supplements, improving generic drugs' review, and improvements to FDA's post-approval surveillance to identify adverse events associated with products on the market.

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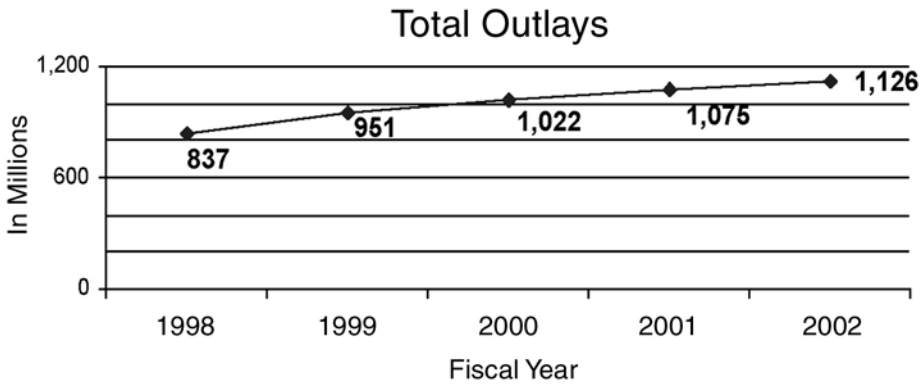
51 One must be careful to recognize the differences between expenses recorded on an accrual basis of accounting as compared to obligations reported on the Combined Statements of Budgetary Resources.

52 Source: Combining Statement of Budgetary Resources for the Year Ended September 30, 2002.

53 Source: Combined Statement of Budgetary Resources, FY 2002

Figure 23



Supplementary Stewardship Information

Stewardship Investments – Research and Development[54]	Provides information on research and development costs for a five year period and a description of major research and development programs that maintain or increase the national economic productive capacity or yield other future benefits.

Stewardship investments are substantial investments made by the Federal Government for the benefit of the nation. When these type of investments are made, Federal Accounting Standards require that they be treated as expenses in determining the net cost of operations.

FDA reports on two programs meeting the criteria of stewardship research and development investments[55] -- Orphan Products Development Program and Research Grants Program.

Orphan Products Development Program fosters the development of orphan products which may be a drug, biological product, medical device, or medical food that is intended to treat rare disease or condition.

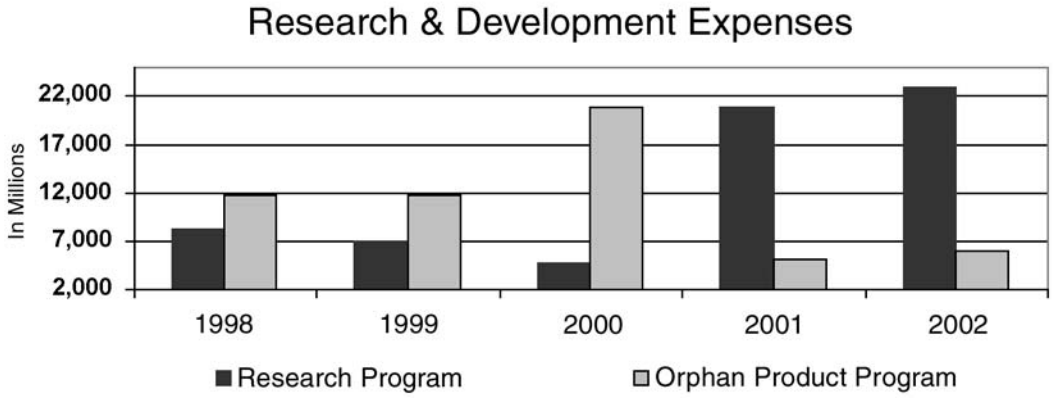
The Research Grants Program covers a broad array of programs – food safety, human drugs, biologics, veterinary medicine, and medical devices. Each of the product centers, NCTR, ORA, and OC uses the research grants program to focus research on a specific topic. The biggest increase in the past four years has been in the food safety area. More recently, research funding is being targeted at the Agency's bioterrorism preparedness posture.

[54] See the Required Supplementary Stewardship on Research and Development, page IV-2 through IV-4 for a complete explanation of stewardship financial reporting.

[55] See page IV-2 for a definition and description of research and development investments.

Figure 24 displays the four year trend of research and development expenses by the two major programs.

Figure 24



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.

Consolidated Principal Financial Statements

Consolidated Balance Sheets

Consolidated Statements of Net Costs

Consolidated Statements of Changes in Net Position

Consolidated Statements of Financing

Combined Statements of Budgetary Resources

Notes to Consolidated Principal Financial Statements

U.S. Department of Health and Human Services

Food and Drug Administration

CONSOLIDATED BALANCE SHEETS

As of September 30, 2002 and 2001

(In Thousands)

	2002	2001
ASSETS		
Intragovernmental:		
Fund Balances with Treasury (Note 2)	$710,703	$465,572
Accounts Receivable (Note 3)	11,330	104,410
Other Assets (Note 6)	13	14,060
Total Intragovernmental Assets	**722,046**	**584,042**
With the Public:		
Accounts Receivable, Net (Note 3)	379,134	39,177
Cash (Note 4)	155	155
General Property, Plant & Equipment, Net (Note 5)	260,982	208,004
Other Assets (Note 6)	292	252
Total Assets With the Public	**640,563**	**247,588**
TOTAL ASSETS	**$1,362,609**	**$831,630**
LIABILITIES		
Intragovernmental:		
Accounts Payable	$ 13,249	$ 10,107
Accrued Payroll and Benefits (Note 9)	11,819	10,249
Resources Payable to Treasury	373,027	122,378
Other Liabilities (Note 11 & 13)	1,229	4,130
Total Intragovernmental Liabilities	**399,324**	**146,864**
With the Public:		
Accounts Payable	80,208	56,115
Accrued Payroll and Benefits (Note 9)	109,658	95,669
Federal Employee and Veterans' Benefits (Note 8)	21,100	23,011
Environmental and Disposal Costs (Note 7)	4,218	4,987
Accrued Grant Liability, Net (Note 10)	97	3,215
Other Liabilities (Note 11 & 13)	128,488	1,285
Total Liabilities With the Public	**343,769**	**184,282**
TOTAL LIABILITIES	**743,093**	**331,146**
Commitments and Contingencies (Note 12)		
NET POSITION		
Unexpended Appropriations	414,490	329,498
Cumulative Results of Operations	205,026	170,986
TOTAL NET POSITION	**619,516**	**500,484**
TOTAL LIABILITIES AND NET POSITION	**$1,362,609**	**$831,630**

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, 2002 and 2001

(In Thousands)

	2002				
	Intragovernmental		With the Public		
Program/Activity	Gross Costs	Less: Exchange Revenue	Gross Costs	Less: Exchange Revenue	Net Program Costs
Foods	$ 121,589	$ 1,733	$ 319,274	$ 8,077	$ 431,053
Human Drugs	89,745	827	327,787	136,303	280,402
Biologics	47,490	6,170	158,030	11,934	187,416
Animal Drugs and Feeds	35,073	308	78,500	529	112,736
Devices & Radiological Health	63,587	2,149	188,649	9,202	240,885
National Center for Toxicological Research	8,134	12,072	49,619	-	45,681
Total	**$ 365,618**	**$ 23,259**	**$ 1,121,859**	**$ 166,045**	**$1,298,173**

	2001				
Foods	$ 105,900	$ 1,414	$ 290,216	$ 4,617	$ 390,085
Human Drugs	73,822	2,936	304,504	120,074	255,316
Biologics	42,001	2,216	136,563	15,459	160,889
Animal Drugs and Feeds	25,291	223	58,122	84	83,106
Devices & Radiological Health	62,225	2,525	176,466	12,846	223,320
National Center for Toxicological Research	7,800	14,821	50,063	9	43,033
Tobacco	159	-	138	-	297
Total	**$ 317,198**	**$ 24,135**	**$ 1,016,072**	**$ 153,089**	**$1,156,046**

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, 2002 and 2001

(In Thousands)

	2002		2001	
	Cumulative Results of Operations	**Unexpended Appropriations**	**Cumulative Results of Operations**	**Unexpended Appropriations**
Beginning Balances	$170,986	$329,498	$182,098	$329,795
Budgetary Financing Sources:				
Appropriations received	-	1,386,051	-	1,124.799
Appropriations transferred-in-out (+/-)	-	-	-	1,000
Other Adjustments (rescissions, etc) (+/-)	-	(32,096)	-	(40,626)
Appropriations Used	1,268,963	(1,268,963)	1,085,470	(1,085,470)
Other Financing Sources:				
Transfers-in/out without reimbursement (+/-)	226	-	(213)	-
Imputed financing from costs absorbed by others	63,024	-	59,677	-
Total Financing Sources	1,332,213	84,992	1,144,934	(297)
Net Cost of Operations	(1,298,173)		(1,156,046)	
Ending Balances	**$205,026**	**$414,490**	**$170,986**	**$329,498**

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, 2002 and 2001

(In Thousands)

	2002	2001
RESOURCES USED TO FINANCE ACTIVITIES:		
Budgetary Resources Obligated:		
Obligations Incurred	$1,657,502	$1,379,935
Less: Spending authority from offsetting collections and recoveries	(436,041)	(275,719)
Obligations net of offsetting collections and recoveries	1,221,461	1,104,216
Less: Offsetting receipts	(1,794)	(25)
Net Obligations	1,219,667	1,104,191
Non-budgetary Resources:		
Transfers in/out without reimbursement	226	(213)
Imputed financing from costs absorbed by others	63,024	59,677
Net non-budgetary resources used to finance activities	63,250	59,464
Total resources used to finance activities	**1,282,917**	**1,163,655**
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	(115,544)	(37,259)
Budgetary offsetting collections and receipts that do not affect cost of operations:		
Recoveries of prior-year authority	39,679	37,475
Decrease or (increase) in unfilled customer orders	139,092	3,177
Resources that fund expenses recognized in prior periods	(4,646)	(3,635)
Resources that finance the acquisition of assets or liquidation of liabilities	(70,415)	(35,433)
Total resources used to fund items not part of the net cost of operations	**(11,834)**	**(35,675)**
Total resources used to finance the net cost of operations	**1,271,083**	**1,127,980**
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	17,317	15,411
Losses or (gains) on disposition of assets	28	705
Other	(2,166)	-
Total components not requiring or generating resources	15,179	16,116
Components requiring or generating resources in future periods:		
Decrease or (increase) in exchange revenue receivable from public	3,984	1,827
Annual Leave expense from increase in annual leave liability	8,102	5,295
Other	(175)	4,828
Subtotal	11,911	11,950
Total components of net cost of operations that do not require or generate resources during the reporting period	**27,090**	**28,066**
Net cost of operations	**$1,298,173**	**$1,156,046**

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, 2002 and 2001

(In Thousands)

	2002	2001
BUDGETARY RESOURCES:		
Budget authority :		
Appropriations Received	$1,387,845	$1,124,823
Net Transers (+/-)	-	1,000
Unobligated balance:		
Beginning of Period	85,716	104,735
Spending authority from offsetting collections:		
Earned		
Collected	200,281	186,913
Receivable from Federal sources	3,110	545
Change in unfilled customer orders		
Advance Received	127,291	9
Without advance from Federal sources	11,800	2,652
Subtotal	342,482	190,119
Recoveries of prior year obligations	93,559	85,600
Temporarily not available pursuant to Public Law	(127,224)	-
Permanently not available	(29,930)	(40,626)
Total Budgetary Resources	**$1,752,448**	**$1,465,651**
STATUS OF BUDGETARY RESOURCES:		
Obligations incurred :		
Direct	$1,635,738	$1,354,992
Reimbursable	21,764	24,943
Subtotal	1,657,502	1,379,935
Unobligated balance:		
Apportioned	75,180	69,870
Unobligated balance not available	19,766	15,846
Total Status of Budgetary Resources	**$1,752,448**	**$1,465,651**
RELATIONSHIP OF OBLIGATIONS TO OUTLAYS:		
Obligated balance, net, beginning of period	$394,029	$365,057
Obligated balance, net, end of period:		
Accounts receivable	(9,430)	(6,321)
Unfilled customer orders from Federal sources	(21,719)	(9,918)
Undelivered Orders	369,330	296,595
Accounts payable	150,506	113,673
Outlays:		
Disbursements	1,454,375	1,262,166
Collections	(327,572)	(186,922)
Subtotal	1,126,803	1,075,244
Less: Offsetting receipts	(1,794)	(25)
Net Outlays	**$1,125,009**	**$1,075,219**

The accompanying notes are an integral part of these statements.

Notes to Consolidated Principal Financial Statements

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

NOTES TO FISCAL YEAR 2002
CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2002 and 2001
(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: Food and Cosmetics, Human Drugs, Medical Devices & Radiological Health, Biologics, Animal Drugs & Feeds, and Toxicological Research. The Tobacco program was terminated in FY 2000 after the U.S. Supreme Court declared that the FDA lacked authority to issue and enforce its tobacco regulations. Only incidental program expenses were incurred in FY 2001. In addition to its programs, FDA has separate budgets for buildings and facilities construction and administrative activities.

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

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2002 and 2001
(In Thousands)

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.

Due to new financial statement format requirements in OMB Bulletin 01-09, a comparative Balance Sheet and Statement of Net Cost are presented, but only single year format is required for the Statements of Changes in Net Position, Budgetary Resources, and Financing. Comparative financial statements for all required financial statements are required for FY 2003 and beyond.

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 and by Circular A-34, *Instructions on Budget Execution.*

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 2002, FDA received approximately $1,800 ($1,900 for FY 2001) 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 appropriated 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 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.

U.S. Department of Health and Human Services
Food and Drug Administration
NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2002 and 2001
(In Thousands)

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 and 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. On October 1, 2000, Statement of Federal Financial Accounting Standards No. 10, Accounting for Internal Use Software, became effective. 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.

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 billing and collection of advanced fees from the drug industry during FY 2002. The PDUFA fees collected in advance of FY 2003 cannot be used until the new fiscal year (October 1, 2002), 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.

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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 8.51 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 $275 and $270 as of September 30, 2002 and 2001, 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 and biologics, (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.

U. Reclassifications

Certain FY 2001 balances reported previously have been reclassified to conform to FY 2002 financial statement presentation.

V. Tax Status

FDA, as a Federal agency, is not subject to Federal, state, or local income taxes, and accordingly, no provision for income taxes is necessary.

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(In Thousands)

Note 2 – Fund Balances with Treasury

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

	2002	2001
Appropriated General Funds	$460,793	$432,230
Other Funds	244,851	28,649
Revolving Funds	5,059	4,693
Total Fund Balances with Treasury	**$710,703**	**$465,572**

Status of Fund Balances with Treasury

	2002	2001
(1) Unobligated Balance		
(a) Available	$ 75,180	$ 69,870
(b) Unavailable	146,836	1,673
(2) Obligated Balanced not yet Disbursed	488,687	394,029
Total	**$710,703**	**$465,572**

No restrictions on Fund Balances with Treasury exist at September 30, 2002 and 2001.

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Note 3 - Accounts Receivable, Net

Accounts Receivable, Net consist of the following:

	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**

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	2001		
	Gross Receivable	Allowance	Net Receivable
Intragovernmental			
Civil Monetary Penalties	$ 97,000	$ -	$ 97,000
Interagency Agreements	7,410	-	7,410
Total Intragovernmental	**104,410**	**-**	**104,410**
With the Public			
Civil Monetary Penalties	25,378	-	25,378
Prescription Drug User Fee Act	6,872	1,087	5,785
Mammography Quality Standards Act	2,765	223	2,542
Travel Refunds & Miscellaneous	5,046	125	4,921
Export Reform & Enhancement Act	544	22	522
Other	29	-	29
Total With the Public	**40,634**	**1,457**	**39,177**
Total	**$145,044**	**$ 1,457**	**$143,587**

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 2002 total $373,746 ($61,619 for FY 2001) net of DOJ fees of approximately $11,212 ($1,906 for FY 2001). Receivables arising from CMPs are recorded when the penalties are assessed by FDA/DOJ. FDA has recorded intragovernmental accounts receivable totaling $20 ($97,000 for FY 2001) 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 payable to the Department of Treasury is recorded for the same amount.

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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, 2002 and 2001, 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:

2002

Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulation Depreciation	Net Book Value
Personal Property:				
Laboratory & 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**

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2001

Classes of Fixed Assets	Service Life (Years)	Acquisition Value	Accumulation Depreciation	Net Book Value
Personal Property:				
Laboratory & Office Equipment	10	$ 72,278	$ 42,077	$ 30,201
ADP and Telecom Equipment	8	24,672	12,506	12,166
Internal Use Software	4	1,457	364	1,093
Capital Lease - Security System	20	1,380	132	1,248
Total Personal Property		99,787	55,079	44,708
Real Property:				
Buildings, Facilities, & Structures	5-50	214,742	87,118	127,624
Capital Lease - Structure	30	806	81	725
Land	N/A	8,957	-	8,957
Total Real Property		224,505	87,199	137,306
In Progress:				
Construction	N/A	20,505	-	20,505
Software	N/A	5,485	-	5,485
Total In Progress		25,990	-	25,990
Total		**$ 350,282**	**$ 142,278**	**$ 208,004**

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Note 6 - Other Assets

Other Assets is comprised of the following:

	2002		2001	
	Intra-governmental	With the Public	Intra-governmental	With the Public
Disputed Cash Advance - GSA Rent	$ -	$ -	$ 14,019	$ -
Travel and Employee Advances	-	292	-	252
Prepaid Subscriptions	13	-	41	-
Total Other Assets	$ **13**	$ **292**	$ **14,060**	$ **252**

In FY 2001, the majority of other assets consisted of funds held pending dispute resolution with GSA. The dispute concerned GSA rent charged to FDA that exceeded the cap imposed by Congress for annual GSA rent charges. GSA reimbursed the $14,019 to FDA in September 2002.

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

(In Thousands)

table presents FDA's estimated cleanup cost liability as of September 30, 2002 and 2001:

	2002	2001
Liabilities Covered By Budgetary Resources	$1,262	$1,533
Liabilities Not Covered By Budgetary Resources	2,956	3,454
Total Environmental and Disposal Costs	**$4,218**	**$4,987**

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 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 5.20 percent in the first year and thereafter for FY 2002 (5.21 percent in the first year and thereafter for FY 2001).

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, 2002 and 2001, amounted to $21,100 and $23,011, respectively, and is considered a liability not covered by budgetary resources.

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Note 9 - Accrued Payroll and Benefits

Accrued Payroll and Benefits consist of the following:

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**

2001

	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	$ -	$ -	$ -	$ 38,996	$ -	$ 38,996
Accrued Leave	-	-	-	118	56,555	56,673
Payroll Withholding	6,804	-	6,804	-	-	-
Accrued Workers' Compensation	-	3,445	3,445	-	-	-
Total	**$ 6,804**	**$ 3,445**	**$ 10,249**	**$ 39,114**	**$ 56,555**	**$ 95,669**

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(In Thousands)

Note 10 – Accrued Grant Liability, Net

	2002	2001
Grant Advances Outstanding (before year-end grant accrual)	$ 8,548	$ 5,674
Less: Estimated Accrual for Amounts Due to Grantees	8,645	8,889
Accrued Grant Liability, Net	**$ 97**	**$ 3,215**

Note 11 - Other Liabilities

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**

2001

	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	$ -	$ 967	$ 967	$ -	$ 670	$ 670
Contingent Liability	-	-	-	-	161	161
Deferred Revenue	3,163	-	3,163	417	-	417
Other				37	-	37
Total	**$ 3,163**	**$ 967**	**$ 4,130**	**$ 454**	**$ 831**	**$ 1,285**

(In Thousands)

All other liabilities are considered current except for the capital lease liability. The portion of the total capital lease liability of $1,546 ($1,637 for FY 2001) considered current is $86 ($91 for FY 2001), and the remaining balance, $1,460 ($1,546 for FY 2001), 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, 2002 and 2001, FDA's undelivered orders were $350,397 and $286,164, respectively. The entire balance has been funded with budgetary resources received in FY 2002 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
2003	$20,770
2004	18,782
2005	2,186
Total	**$41,738**

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, 2002, FDA has accrued $160 ($161 for FY 2001) for a legal contingent liability to be paid by the Treasury Judgment Fund. In this case, a judgment of as high as $20,000 could be awarded against FDA, but the final amount of this liability will be decided in future litigation.

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Note 13. Leases

Future lease payments are as follows:

Fiscal Year	Capital Leases	Operating Leases
2003	$ 223	$111,707
2004	222	121,065
2005	222	130,855
2006	222	142,292
2007	222	154,745
2008 and Thereafter	1,648	2,965 **
Total Future Lease Payments	2,759	$663,629
Less: Imputed Interest	(1,213)	
Total Capital Lease Liability (Note 11)	**$1,546**	

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

As of September 30, 2002 and 2001, FDA had one personal property capital lease for a security system used at its Jamaica, NY field office. The lease has 17 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, 2002 and 2001.

Operating leases for real property cover GSA and non-GSA leased assets. Operating leases comprise the majority of FDA's fiscal year 2002 and 2001 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 2002, FDA had five (five for FY 2001) 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, 2002 and 2001, FDA maintained approximately 975 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.

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NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
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(In Thousands)

Note 14 - Combined Statements of Budgetary Resources

The Statement of Budgetary Resources 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 79.2% or $1,387,845 (76.8%, or $1,125,823 for FY 2001), of its total FY 2002 budgetary resources of $1,752,448 ($1,465,651 for FY 2001) through appropriations. FDA's S&E account was appropriated $1,179,670 ($1,091,524 for FY 2001), which accounts for 85% (97% for FY 2001) 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 19.5% of total FY 2002 (13% for FY 2001) budgetary resources. Unobligated carryovers represent amounts of spending authority that have not been committed or earmarked for expenditure. Carryovers represent about 4.9% of FY 2002 (7.1% for FY 2001) budgetary resources.

FDA has both Category A (apportioned over a time period) and Category B (apportioned by activity/project) obligations. Category A obligations totaled $1,496,157 ($1,359,101 for FY 2001). Category B obligations totaled $161,345 ($20,834 for FY2001).

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 2002, FDA had funds of $1,160 temporarily not available for national public health emergencies.

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 in FY 2002 was $131,000.

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 2003 billing and collection of advanced fees from the drug industry during FY 2002. The PDUFA fees collected in advance of FY 2003 cannot be used until the new fiscal year (October 1, 2002) and passage of an FDA appropriation, and therefore, are considered unavailable until FY 2003.

The President's Budget is not expected to be published until February 3, 2003, therefore, FDA cannot, at this time, ascertain any differences between the actual figures from it to the Statement of Budgetary Resources. Once the President's Budget is published, the comparison will be made in the subsequent fiscal year. The President's Budget will be made available on the Office of Management and Budget (OMB) website.

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 2002 were $373,746 ($61,619 for FY 2001). CMP collections are immediately forwarded to the Department of Treasury when collected and cannot be used for FDA operations. Also see Note 3.

Required Supplementary Information (Unaudited)

Combining Statements of Budgetary Resources

Supplemental Consolidating Statements of Net Costs by Expense Type and Program

Deferred Maintenance

Intra Governmental Transactions

- *Intra-Governmental Assets*
- *Intra-Governmental Liabilities*
- *Intra-Governmental Revenues and Expenses*

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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 Bldg. 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

Combining Statement of Budgetary Resources

For the Year Ended September 30, 2001

(In Thousands)

(Unaudited)

	User Fees Account 75X0600	CRADAs 75X5148	Building & Facilities 75X0603	Certification Fund 75X4309	GSA Bldg. Delegation 75X0601	Salaries & Expenses 75_0600	Gift Fund 75x8247	White Oak 752.30600	Royalties 75_/_0600	Total
Budgetary Resources:										
Budget authority:										
Appropriations Received	-	1,924	31,350	-	-	1,091,524	25	-	-	1,124,823
Net Transfers	(103,345)	-	1,000	-	5,036	98,309	-	-	-	1,000
Unobligated balance:										
Beginning of Period	62,769	626	26,684	3,327	-	11,141	-	-	188	104,735
Net Transfers, actual	(57,368)	-	-	-	-	57,368	-	-	-	-
Spending authority from offsetting collections:										
Earned										
Collected	153,120	5	84	4,521	-	28,640	-	-	543	186,913
Receivable from Federal sources	-	-	-	-	-	545	-	-	-	545
Change in unfilled customer orders										
Advance Received	-	-	-	9	-	-	-	-	-	9
Without advance from Federal sources	-	-	-	-	-	2,652	-	-	-	2,652
Subtotal	153,120	5	84	4,530	-	31,837	-	-	543	190,119
Recoveries of prior year obligations	-	24	2,023	203	-	83,350	-	-	-	85,600
Permanently not available	-	-	(69)	-	-	(40,557)	-	-	-	(40,626)
Total Budgetary Resources	55,176	2,579	61,072	8,060	5,036	1,332,972	25	-	731	1,465,651
Status of Budgetary Resources:										
Obligations incurred :										
Direct	15,798	1,234	33,207	4,207	5,036	1,295,064	25	-	421	1,354,992
Reimbursable	-	-	-	-	-	24,943	-	-	-	24,943
Subtotal	15,798	1,234	33,207	4,207	5,036	1,320,007	25	-	421	1,379,935
Unobligated balance:										
Apportioned	38,219	1,345	27,865	2,062	-	69	-	-	310	69,870
Unobligated balance not available	1,159	-	-	1,791	-	12,896	-	-	-	15,846
Total Status of Budgetary Resources	55,176	2,579	61,072	8,060	5,036	1,332,972	25	-	731	1,465,651
Relationship of Obligations to Outlays:										
Obligated balance, net, beginning of period	-	433	10,283	739	-	353,602	-	-	-	365,057
Obligated balance, net, end of period:										
Accounts receivable	-	-	-	-	-	(6,321)	-	-	-	(6,321)
Unfilled customer orders from Federal sources	-	-	-	-	-	(9,918)	-	-	-	(9,918)
Undelivered Orders	791	821	24,371	557	0	270,055	-	-	-	296,595
Accounts payable	3	19	1,883	284	0	111,484	-	-	-	113,673
Outlays:										
Disbursements	15,004	803	15,213	3,901	5,036	1,221,763	25	-	421	1,262,166
Collections	(153,120)	(4)	(84)	(4,529)	-	(28,642)	-	-	(543)	(186,922)
Subtotal	(138,116)	799	15,129	(628)	5,036	1,193,121	25	-	(122)	1,075,244
Less: Offsetting receipts	-	-	-	-	-	-	(25)	-	-	(25)
Net Outlays	(138,116)	799	15,129	(628)	5,036	1,193,121	0	0	(122)	1,075,219

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

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, 2001

(In Thousands)

(Unaudited)

Expense Type	Foods	Human Drugs	Biologics	Animal Drugs and Feeds	Devices and Radiological Health	National Center for Toxicological Research	Tobacco	TOTALS
Personnel Services and Benefits	$ 229,099	$ 246,101	$ 102,381	$ 45,007	$ 144,760	$ 21,518	$ 42	$ 788,908
Travel & Transportation	11,441	6,692	2,938	1,880	4,234	698	-	27,883
Rent, Communication, and Utilities	42,473	28,879	11,378	10,312	22,853	3,355	9	119,259
Printing & Reproduction	1,389	608	349	149	491	62	2	3,050
Contractual Services	61,083	60,607	37,855	15,783	39,810	21,644	240	237,022
Supplies and Materials	6,409	4,565	7,132	1,655	2,363	3,132	-	25,256
Non-Capitalized Equipment	10,201	12,396	5,550	2,693	5,467	1,872	-	38,179
Grants, Subsidies, Contributions	9,588	4,034	849	1,816	2,040	289	1	18,617
Insurance Claims & Indemnities	118	137	98	14	90	28	-	485
Depreciation	5,132	2,295	1,303	536	2,540	3,605	-	15,411
Bad Debts and Write-offs	106	115	54	24	91	18	-	408
Interest Expense	21	18	10	5	9	147	-	210
Imputed Retirement Costs	19,468	12,468	8,741	3,545	13,935	1,517	3	59,677
Loss on Disposition of Property	217	173	10	35	268	2	-	705
Applied Overhead	(510)	(667)	(64)	(27)	(82)	(24)	-	(1,374)
Other	(119)	(95)	(20)	(14)	(178)	-	-	(426)
Gross Costs	396,116	378,326	178,564	83,413	238,691	57,863	297	1,333,270
Less: Earned Revenues	(6,031)	(123,010)	(17,675)	(307)	(15,371)	(14,830)	-	(177,224)
Net Cost	$ 390,085	$ 255,316	$ 160,889	$ 83,106	223,320	$ 43,033	$ 297	$ 1,156,046

U.S. Department of Health and Human Services

Food and Drug Administration

NOTES TO CONSOLIDATED PRINCIPAL FINANCIAL STATEMENTS
As of September 30, 2002 and 2001
(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. The following tables present FDA's real property for which deferred maintenance exists as of September 30, 2002 and 2001:

FY 2002

Category	Asset Condition	Cost to Return to Acceptable Condition	Critical Amount	Non-Critical Amount
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

FY 2001

Buildings	Poor	$29,356	$4,525	$24,831
Laboratories	Fair	$9,486	$3,090	$6,336
Utility Systems	Poor	$7,056	$1,940	$5,116
Total		$45,838	$9,555	$36,283

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
As of September 30, 2002 and 2001
(In Thousands)
(Unaudited)

Intragovernmental Assets

Agency	TFM Dept Code	Fund Balance w/ Treasury	Accounts Receivable	Other	Total
		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**
		2001			
Department of Agriculture	12		$ 816		$ 816
Department of Commerce	13		10	$ 41	51
Department of Defense	17, 21, 57, 97		1,662		1,662
Department of Energy	89		180		180
Department of Health and Human Services	75		1,155		1,155
Department of Justice	15		99,820		99,820
Department of Transportation	69		92		92
Department of the Treasury	20	$465,572	253		465,825
Department of Veterans Affairs	36		28		28
General Services Administration	47		47	14,019	14,066
National Aeronautics & Space Administration	80		14		14
All Other Federal Agencies			333		333
TOTAL		**$465,572**	**$104,410**	**$14,060**	**$584,042**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
As of September 30, 2002 and 2001
(In Thousands)
(Unaudited)

Intragovernmental Liabilities

Agency	TFM Dept Code	Accounts Payable	Accured Payroll and Benefits	Other	Total
		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**
		2001			
Department of Agriculture	12	$ 60			$ 60
Department of Energy	89	37			37
Department of Health and Human Services	75	2,818		$ 2,945	5,763
Department of Labor	16		$ 3,445		3,445
Department of the Treasury	20	2	1,695	122,378	124,075
General Services Administration	47	6,417		967	7,384
Office of Personnel Management	24	30	5,109		5,139
All Other Federal Agencies		743		218	961
TOTAL		**$10,107**	**$10,249**	**$126,508**	**$146,864**

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**

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY INFORMATION
INTRAGOVERNMENTAL TRANSACTIONS
For the Year Ended September 30, 2001
(In Thousands)
(Unaudited)

Intragovernmental Revenues and Expenses

Agency	TFM Dept Code	Revenues	Imputed Financing	Net Transfers	Expenses
Department of Agriculture	12				$ 2,101
Department of Commerce	13				193
Department of Defense	17, 21, 57, 97	$ 1,544			491
Department of Energy	89	172			4,900
Department of Health and Human Services	75	18,708	$17,137	$(263)	63,114
Department of the Interior	14	58			34
Department of Justice	15	2,260			48
Department of Labor	16				3,236
Department of State	19	23			88
Department of Transportation	69	344			15
Department of the Treasury	20	253	58		402
Department of Veterans Affairs	36	134			918
Environmental Protection Agency	68	576			54
General Services Administration	47	3			109,202
National Aeronautics & Space Administration	80	54			30
Nuclear Regulatory Commission	31				53
Office of Personnel Management	24		42,482		129,177
All Other Federal Agencies		6			3,142
TOTAL		**$24,135**	**$59,677**	**$(263)**	**$317,198**

Required Supplementary Stewardship Information (Unaudited)

Research and Development

U.S. Department of Health and Human Services

Food and Drug Administration

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION
As of September 30, 2002 and 2001
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 200 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 marketing exclusively incentives) 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 1998-2002 (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

REQUIRED SUPPLEMENTARY STEWARDSHIP INFORMATION
As of September 30, 2002 and 2001
Unaudited

Research and Development Expenses						
		Fiscal Year				
PROGRAM	**TYPE**	**02**	**01**	**00**	**99**	**98**
Orphan Product Development	Development	$5,961	$2,770	$3,070	$2,097	$11,687
Pilot Clinical Pharmacology	Development	--	--	--	--	285
Orphan Product Research Grants	Applied Research	--	2,273	17,794	9,605	--
Research Grants Program (excluding Orphan Product grants)	Applied Research	22,994	20,813	4,752	6,990	8,159
Toxicological Research	Applied Research	--	--	--	--	33,233
Total		**$28,955**	**$25,856**	**$25,616**	**$18,692**	**$53,364**

NOTE:
Pilot Clinical Pharmacology Program is excluded from FY 1999 through FY 2002 since it is used to "train" pharmacologists and does not meet the definition of research and development.

Toxicological Research is excluded from FY 1999 through FY 2002 because it is considered peer-review scientific research that supports FDA's current and future regulatory needs. This does not meet the definition of research and development.

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.

Reports on the Audit of FDA's FY 2002 Financial Statements

Office of Inspector General Transmittal Letter

Report on Consolidated Financial Statements

Report on Internal Control over Financial Reporting

Report on Compliance with Laws and Regulations

Agency's Response to Auditors' Reports

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

JAN 31 2003

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 2002 (A-17-02-00008)

The attached final report presents the results of the audit of Fiscal Year's (FY) 2002 financial statements of the Food and Drug Administration (FDA). We contracted with KPMG LLP, 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 Management 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 control 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 sheets as of September 30, 2002 and 2001, and the related consolidated statements of net cost for the FYs then ended, as well as the consolidated statements of changes in net position and financing, and the combined statement of budgetary resources for the FY ended September 30, 2002, 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.

We evaluated the nature, timing, and extent of the work, monitored progress throughout the audit, reviewed the documentation of KPMG, met with partners and staff members, evaluated the key judgments, met with officials of FDA, reviewed independent tests of the accounting records, and performed other procedures we deemed appropriate in the circumstances. We conducted our work in accordance with auditing standards generally accepted in the United States.

We concur with KPMG's report that indicated the financial statements referred to above present fairly, in all material respects, the financial position of FDA as of September 30, 2002 and 2001, and its net costs for the years then ended, as well as the changes in net position, budgetary

resources, and reconciliation of net costs to budgetary resources for the year ended September 30, 2002 in conformity with accounting principles generally accepted in the United States. The FDA is commended for sustaining its 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 information systems, which were considered to be a reportable condition.

Exclusive of the FFMIA, there were no reportable noncompliance with laws and regulations tested. The FDA's financial management systems (accounts receivable, cost management, and property) did not substantially comply with FFMIA Federal financial management systems requirements.

We would appreciate your views and information on the status of any action taken or contemplated on the recommendations within the next 60 days. If you have any questions or comments about this report, please do not hesitate to call me or David M. Long, Assistant Inspector General for Financial Management and Regional Operations, at (202) 619-1157 or through email at dlong@oig.hhs.gov. Please refer to report number A-17-02-00008 in all correspondence relating to this report.

Attachment

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Independent Auditors' Report on Consolidated Financial Statements

The Inspector General, U.S. Department of Health and Human Services and the Commissioner of the Food and Drug Administration:

We have audited the accompanying consolidated balance sheets of the Food and Drug Administration (FDA), an operating division of the U.S. Department of Health and Human Services (DHHS) as of September 30, 2002 and 2001, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the years then ended (collectively referred to as "consolidated financial statements"). These consolidated financial statements are the responsibility of the FDA's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America; 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*. Those standards and OMB Bulletin No. 01-02 require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the FDA, as of September 30, 2002 and 2001, and its net costs, changes in net position, budgetary resources, and reconciliation of net costs to budgetary obligations for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The information in the Management Discussion and Analysis, Required Supplementary Stewardship Information, and Required Supplementary Information sections is not a required part of the consolidated financial statements but is supplementary information required by accounting principles generally accepted in the United States of America or OMB Bulletin No. 01-09, *Form and Content of Agency Financial Statements*. We have applied certain limited procedures, which consisted principally of inquiries of management regarding the methods of measurement and presentation of this information. However, as part of our limited procedures applied to the Required Supplementary Information, we were unable to assess control risk relevant to FDA's intragovernmental transactions and balances with non-FDA trading partners, as required by OMB Bulletin 01-02. The FDA did not confirm intragovernmental transactions with most of its trading partners to enable the reconciliations of these transactions. Further, we did not audit this information and, accordingly, we express no opinion on it.

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In accordance with *Government Auditing Standards*, we have also issued reports dated December 9, 2002, on our consideration of the FDA's internal control over financial reporting and 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.

KPMG LLP

December 9, 2002

KPMG

2001 M Street, NW
Washington, DC 20036

Independent Auditors' Report on Internal Control over Financial Reporting

The Inspector General, U.S. 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 U.S. Department of Health and Human Services (DHHS), as of September 30, 2002, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the year then ended, (collectively referred to as the "consolidated financial statements"), and have issued our report thereon dated December 9, 2002. We conducted our audit in accordance with auditing standards generally accepted in the United States of America; 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 fiscal year 2002 audit, we considered the FDA's internal control over financial reporting by obtaining an understanding of the FDA's internal control, determining whether internal controls had been placed in operation, assessing control risk, and performing tests of controls in order to determine our auditing procedures for the purpose of expressing our opinion on the consolidated financial statements. We limited our internal control testing to those controls necessary to achieve the objectives described in OMB Bulletin No. 01-02 and *Government Auditing Standards*. We did not test all internal controls relevant to operating objectives as broadly defined by the Federal Managers' Financial Integrity Act of 1982. The objective of our audit was not to provide assurance on the FDA's internal control. Consequently, we do not provide an opinion on internal control over financial reporting.

Our consideration of 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 are matters coming to our attention relating to significant deficiencies in the design or operation of the internal control over financial reporting 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 consolidated financial statements. Material weaknesses are reportable conditions in which the design or operation of one or more of the 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 consolidated 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 any internal control, misstatements due to error or fraud may occur and not be detected.

We noted a matter, described below, involving the internal control over financial reporting and its operation that we reported in our report last year and that we again consider to be a reportable condition.

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Internal Controls Over Information Systems Should Be Enhanced

We reviewed the FDA's internal controls over information systems and noted the following:

Security Program. We assessed the FDA's security program and, although there was improvement in this area, we noted that the FDA has not prepared risk assessments for all major financial applications. We also noted improvements are needed in documenting and approving detailed incident response procedures and procedures should be developed to address compliance with security awareness training for delinquent users. Therefore, we recommend that the FDA's Office of Information Resource Management (OIRM) develop detailed guidance for the preparation of comprehensive risk assessments. With the guidance prepared, we recommend that the Office of Financial Management (OFM) conduct risk assessments and complete certification and accreditation statements for major financial applications. We further recommend that detailed incident response procedures be developed and approved by management. Last, we recommend that improvements be made to the FDA's security awareness training regarding delinquent users.

Access Controls. We assessed the FDA's management efforts related to financial systems and, although we noted continued improvement in this area, we believe that certain matters related to granting and monitoring of user access, adherence to the FDA-wide guidelines for remote access, database access configuration, local area network log settings, password assignment for servers, and restrictions surrounding network ports and services could be improved. Therefore, we recommend that OIRM improve the access control procedures, implement policies and procedures to reduce the potential for unauthorized access, and ensure adherence to the FDA standards.

Change Management. We assessed the FDA's management efforts related to financial systems to ensure that system integrity can be relied upon and, although we noted that controls have been established, improvements could be made. Detailed procedures should be included in the OFM's software development and change control policies and procedures, configuration management and change controls should be established on financial platforms, and management approval for production program changes should be improved. Therefore, we recommend that OFM and OIRM work together to develop, establish and implement detailed procedures, configuration management and change controls, and ensure production changes are approved by management.

Service Continuity. We assessed the FDA's business resumption efforts and noted that the Automated Information Systems Contingency Plan has not been completed in accordance with the FDA-wide policy. We further noted that financial system backup tapes should be rotated to an off-site location on a frequent basis. Last, the FDA needs to strengthen its disaster recovery planning activities and identify an alternate data processing facility. Therefore, we recommend OFM and OIRM make improvements to the FDA's disaster recovery plans, backup tape storage, disaster recovery planning, and recovering operations in the event of an unexpected business interruption.

Additional Required Procedures

As required by OMB Bulletin No. 01-02, we considered the FDA's internal control over Required Supplementary Stewardship Information by obtaining an understanding of the FDA's internal control, determining whether these internal controls had been placed in operation, assessing control risk, and performing tests of controls. Our procedures were not designed to provide assurance on internal control over Required Supplementary Stewardship Information, and, accordingly, we do not provide an opinion thereon.

As further required by OMB Bulletin No. 01-02, with respect to internal control related to performance measures determined by management to be key and reported in the Management's Discussion and Analysis section of the Annual Report, we obtained an understanding of the design of significant internal controls relating to the existence and completeness assertions. Our procedures were not designed to provide

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assurance on internal control over reported performance measures, and, accordingly, we do not provide an opinion on such controls.

We also noted other matters involving internal control and its operation that we have reported to the management of the FDA in a separate letter dated December 9, 2002.

This report is intended solely for the information and use of the FDA's management, the DHHS Office of the Inspector General, OMB, and Congress and is not intended to be and should not be used by anyone other than these specified parties.

KPMG LLP

December 9, 2002

2001 M Street, NW
Washington, DC 20036

Independent Auditors' Report on Compliance with Laws and Regulations

The Inspector General, U.S. 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 U.S. Department of Health and Human Services (DHHS), as of September 30, 2002, and the related consolidated statements of net cost, changes in net position, and financing, and the combined statement of budgetary resources for the year then ended (collectively referred to as the "consolidated financial statements"), and have issued our report thereon dated December 9, 2002. We conducted our audit in accordance with auditing standards generally accepted in the United States of America; 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 consolidated financial statements are free of material misstatement, we performed tests of the FDA's compliance with certain provisions of laws and regulations, noncompliance with which could have a direct and material effect on the determination of the consolidated financial statement amounts, and certain provisions of other laws and regulations specified in OMB Bulletin No. 01-02, including certain requirements referred to in the Federal Financial Management Improvement Act (FFMIA) of 1996. We limited our tests of compliance to the provisions described in the preceding sentence, and we did not test compliance with all laws and regulations applicable to the FDA. However, providing an opinion on compliance with laws and regulations was not an objective of our audit, and, accordingly, we do not express such an opinion.

The results of our tests of compliance disclosed no instances of noncompliance with other laws and regulations discussed in the second paragraph of this report, 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 (1) Federal financial management systems requirements, (2) applicable Federal accounting standards, and (3) 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, described below, in which the FDA's financial management systems did not substantially comply with the Federal financial management systems requirements discussed in the preceding paragraph.

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Federal financial management systems requirements noncompliance. Our tests revealed that the FDA's accounts receivable, cost management, and property systems are not in compliance with the Federal financial management system requirements as follows:

- The accounts receivable system does not support the calculation, generation and posting of billings under interagency agreements based on the billing source, event and/or time period.
- The core financial system does not assign indirect costs to interim and final cost objects, or allow for multilevel assignments and reassignments of cost.
- The interface between the Asset Management System (AMS) and the general ledger is not electronic. Although an electronic interface is not required under the guidelines, this condition results in a reconciliation process between the AMS and the general ledger that is cumbersome and leads to reconciling items not being posted timely. It should be noted that an electronic interface has been implemented between the AMS and the general ledger in October 2002.

The results of our tests disclosed no instances in which FDA's financial management systems did not substantially comply with federal accounting standards and the United States Government Standard General Ledger at the transaction level.

This report is intended solely for the information and use of the FDA's management, the DHHS Office of Inspector General, OMB, and Congress and is not intended to be and should not be used by anyone other than these specified parties.

KPMG LLP

December 9, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 18 2002

To: David M. Long
Assistant Inspector General for Financial Management
and Regional Operations
Office of Inspector General

From: Associate Commissioner for Management and Systems
and Chief Financial Officer

Subject: FDA's Response to the FY 2002 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, 2002. We have reviewed the report and concur with the findings and recommendations.

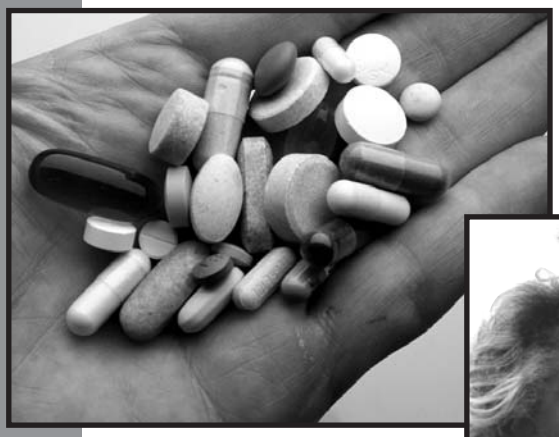
We are pleased that your audit firm, KPMG LLP, has given us another unqualified opinion on our FY 2002 consolidated financial statements with no material weaknesses in our internal control reporting. This accomplishment shows the continual progress that FDA has made in the past year in improving its financial systems and internal control structure. It also demonstrates the extensive effort among FDA staffs working together to produce timely and accurate financial statements.

FDA must still work to resolve the remaining reportable condition 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.

We would like to thank the KPMG 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 productive. We will put these recommendations in place as soon as possible as we continue to improve FDA's financial management.

Jeffrey M. Weber

Appendices



Description of FDA User Fees

FDA Acronyms

Appendix 1

Description of FDA User Fees

User Fee	Description
Prescription Drug	The Prescription Drug User Fee Act (PDUFA) was passed by Congress in 1992. It provides resources to CDER and CBER to hire additional reviewers and in return, FDA promised to meet various performance goals for reviewing human drugs. The program was a success and, in 2002, Congress re-authorized PDUFA for another five-year period. The user fees are paid by the drug industry. Salary and expenses, including additional rental expenses and certain types of information technology investments, are funded by PDUFA. The amount of PDUFA collections expended in FY 2002 was $161.8 million.
Mammography	Mammography user fees fund annual inspections of mammography facilities and the certification of those facilities. This program was established under the Mammography Quality Standards Act (MQSA) of 1992 (re-authorized by the Mammography Quality Standards Reauthorization Act of 1998). CDRH administers the program. In FY 2002, the amount of MQSA collections expended was $13.9 million.
Export Certification	The newest user fee program was established by the Export Reform and Enhancement Act (EREA) of 1996, which authorized the collection of fees from organizations for which FDA issues a certification relating to human drugs, animal drugs, medical devices, and biologic products, subject to the FD&C Act. The certificates support U.S. commerce by expediting the export of goods to foreign countries. Each of the product centers administers its own program. In FY 2002, the amount of user fees expended was $1.7 million. Export certificates issued for food products are subject to FD&C Act, but are not covered by EREA.
Certification and Other Services	The FD&C Act requires the certification of color additives and 21 CFR 80, Color Additive Certification, prescribes the fees for service. This function, which is administered by CFSAN, involves the assessment of the quality and safety of color additives used in foods, drugs, and cosmetics. Salaries and expenses of employees of the program are funded directly by FDA's Revolving Fund for Certification and Other Services. The fund's activities are financed entirely by fees paid by the affected commercial organizations. In FY 2002, the amount of fees expended was $4.7 million.

Appendix 2

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

Appendix 2 (continued)

FDA Acronyms

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

Key FDA Financial Management Officials

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Chief Financial Officer

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Director, Office of Financial Management and
Deputy Chief Financial Officer

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

This document was designed and produced by FDA's Office of Financial Management,
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